Supplemental Update Report

CR Number: **2017215004** **Implementation Date:** 10-Oct-18 Related CR: 2017215004

Change Requested	Add a New HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed HLT	*Thoracic spinal cord and nerve root disorders*	Approved After Suspension	Proposed HLT	
To HLGT	*Spinal cord and nerve root disorders*		*Thoracic spinal cord and nerve root disorders*	10082210
			To HLGT	
			Spinal cord and nerve root disorders	10041543

MSSO Comment: The proposal to add a new HLT Thoracic spinal cord and nerve root disorders to HLGT Spinal cord and nerve root disorders is approved as requested after suspension. New HLT Thoracic spinal cord and nerve root disorders complements existing HLT Cervical spinal cord and nerve root disorders and HLT Lumbar spinal cord and nerve root disorders in HLGT Spinal cord and nerve root disorders. In related changes, PT Thoracic spinal stenosis and PT Thoracic radiculopathy will be moved from HLT Spinal cord and nerve root disorders NEC to new HLT Thoracic spinal cord and nerve root disorders.

CR Number: **2018282014** **Implementation Date:** 10-Oct-18 Related CR: 2017215004

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Thoracic spinal stenosis*	Approved as Requested	Proposed PT	
From HLT	*Spinal cord and nerve root disorders NEC*		*Thoracic spinal stenosis*	10080462
To HLT	*Thoracic spinal cord and nerve root disorders*		From HLT	
			Spinal cord and nerve root disorders NEC	10041544
			To HLT	
			Thoracic spinal cord and nerve root disorders	10082210

MSSO Comment:

CR Number: **2018282015** **Implementation Date:** 10-Oct-18 Related CR: 2017215004

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Thoracic radiculopathy*	Approved as Requested	Proposed PT	
From HLT	*Spinal cord and nerve root disorders NEC*		*Thoracic radiculopathy*	10081172
To HLT	*Thoracic spinal cord and nerve root disorders*		From HLT	
			Spinal cord and nerve root disorders NEC	10041544
			To HLT	
			Thoracic spinal cord and nerve root disorders	10082210

MSSO Comment:

Supplemental Update Report

CR Number: 2017264002 **Implementation Date:** 10-Oct-18 Related CR: 2017264002

Change Requested	Link HLT to another HLGT	Final Disposition	Final Placement	MedDRA Code #
Proposed HLT	*Cardiac disorders NEC*	Approved Not as Requested After Suspension	Proposed HLGT	
From HLGT	*Cardiac disorder signs and symptoms*		*Cardiac disorders, signs and symptoms NEC*	10082206
To HLGT	*Cardiac disorders NEC*		To SOC	
			Cardiac disorders	10007541

MSSO Comment: The proposal to move the HLT Cardiac disorders NEC from HLGT Cardiac disorder signs and symptoms to another HLGT Cardiac disorders NEC is approved but not as requested after suspension. A new HLGT Cardiac disorders, signs and symptoms NEC will be added to SOC Cardiac disorders to clarify that the contents of this HLGT include miscellaneous cardiac disorders and miscellaneous signs and symptoms. Existing HLGT Cardiac disorder signs and symptoms will be merged under new HLGT Cardiac disorders, signs and symptoms NEC.

CR Number: 2018282008 **Implementation Date:** 10-Oct-18 Related CR: 2017264002

Change Requested	Merge HLGT	Final Disposition	Final Placement	MedDRA Code #
HLGT to merge	*Cardiac disorder signs and symptoms*	Approved as Requested	HLGT to merge	
To HLGT	*Cardiac disorders, signs and symptoms NEC*		*Cardiac disorder signs and symptoms*	
			To HLGT	
			Cardiac disorders, signs and symptoms NEC	10082206

MSSO Comment:

CR Number: 2017269001 **Implementation Date:** 10-Oct-18 Related CR: 2017269001

Change Requested	Rename HLGT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Vascular inflammations*	Approved Not as Requested After Suspension	Proposed HLGT	
Replacement term	*Vascular inflammations and infections*		*Vascular infections and inflammations*	10082207
			To SOC	
			Vascular disorders	10047065

MSSO Comment: The proposal to rename the HLGT Vascular inflammations to Vascular inflammations and infections is approved but not as requested after suspension. A new HLGT Vascular infections and inflammations will be added to SOC Vascular disorders to reflect the fact that the HLGT contains terms for both infections and inflammations. The naming of the new HLGT is consistent with the wording used for similar grouping terms such as HLGT Central nervous system infections and inflammations, and HLT Bladder infections and inflammations. Existing HLGT Vascular inflammations will be merged under new HLGT Vascular infections and inflammations. For similar reasons, new HLTs Aortic infections and inflammations and Arterial infections and inflammations will be added to new HLGT Vascular infections and inflammations; and underlying existing HLTs Aortic inflammatory disorders and Arterial inflammations will be merged with new HLTs Aortic infections and inflammations and Arterial infections and inflammations, respectively. HLT Phlebitis NEC and HLT Vasculitides NEC will remain as is because, in this context, these represent broad groupings covering both inflammation concepts and infective concepts, e.g., PT Phlebitis infective and PT Septic vasculitis.

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CR Number: 2018282009 **Implementation Date:** 10-Oct-18 Related CR: 2017269001

Change Requested	Merge HLGT	Final Disposition	Final Placement	MedDRA Code #
HLGT to merge	*Vascular inflammations*	Approved as Requested	HLGT to merge *Vascular inflammations*	
To HLGT	*Vascular infections and inflammations*		To HLGT *Vascular infections and inflammations*	10082207

MSSO Comment:

CR Number: 2018282010 **Implementation Date:** 10-Oct-18 Related CR: 2017269001

Change Requested	Add a New HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed HLT	*Aortic infections and inflammations*	Approved as Requested	Proposed HLT *Aortic infections and inflammations*	10082208
To HLGT	*Vascular infections and inflammations*		To HLGT *Vascular infections and inflammations*	10082207

MSSO Comment:

CR Number: 2018282011 **Implementation Date:** 10-Oct-18 Related CR: 2017269001

Change Requested	Merge HLT	Final Disposition	Final Placement	MedDRA Code #
HLT to merge	*Aortic inflammatory disorders*	Approved as Requested	HLT to merge *Aortic inflammatory disorders*	
To HLT	*Aortic infections and inflammations*		To HLT *Aortic infections and inflammations*	10082208

MSSO Comment:

Supplemental Update Report

CR Number: 2018282012 **Implementation Date:** 10-Oct-18 Related CR: 2017269001

Change Requested	Add a New HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed HLT	*Arterial infections and inflammations*	Approved as Requested	Proposed HLT	
To HLGT	*Vascular infections and inflammations*		*Arterial infections and inflammations*	10082209
			To HLGT	
			Vascular infections and inflammations	10082207

MSSO Comment:

CR Number: 2018282013 **Implementation Date:** 10-Oct-18 Related CR: 2017269001

Change Requested	Merge HLT	Final Disposition	Final Placement	MedDRA Code #
HLT to merge	*Arterial inflammations*	Approved as Requested	HLT to merge	
To HLT	*Arterial infections and inflammations*		*Arterial inflammations*	
			To HLT	
			Arterial infections and inflammations	10082209

MSSO Comment:

CR Number: 2018114006 **Implementation Date:** 10-Aug-18 Related CR: 2018114006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*IgA lambda macroglobulinemia*	Rejected After Suspension		

MSSO Comment: The proposal to add a new LLT IgA lambda macroglobulinemia is not approved after suspension. Based on feedback from the submitter this request has been withdrawn.

Supplemental Update Report

CR Number: 2018143031 **Implementation Date:** 10-Oct-18 Related CR: 2018143031

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gingival discomfort*	Approved Not as Requested After Suspension	Proposed PT	
			Gingival discomfort	10077854
From HLT	*Oral soft tissue signs and symptoms*		From HLT	
			Oral soft tissue signs and symptoms	10031021
To HLT	*Gingival disorders NEC*		To HLT	
			Gingival disorders, signs and symptoms NEC	10082211

MSSO Comment: The proposal to move the PT Gingival discomfort from HLT Oral soft tissue signs and symptoms to HLT Gingival disorders NEC is approved but not as requested after suspension. PT Gingival discomfort will be moved from HLT Oral soft tissue signs and symptoms to new HLT Gingival disorders, signs and symptoms NEC. Rather than grouping the gingival terms with oral soft tissue concepts, new HLT Gingival disorders, signs and symptoms NEC groups miscellaneous gingival disorders and signs and symptoms together to facilitate coding and retrieval. Existing HLTs - HLT Gingival disorders NEC, HLT Gingival pains, and HLT Gingival discolourations will be merged under new HLT Gingival disorders, signs and symptoms NEC. See batch 20109691, change request 2018211006. In this same change request, PT Gingival blister, PT Gingival pruritus, PT Gingival oedema, PT Gingival swelling and PT Lineal gingival erythema were also moved to new HLT Gingival disorders, signs and symptoms NEC.

CR Number: 2018144003 **Implementation Date:** 10-Oct-18 Related CR: 2018144003

Change Requested	Add a New HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed HLT	*Subacute polyneuropathies*	Rejected After Suspension		
To HLGT	*Peripheral neuropathies*			

MSSO Comment: The proposal to add a new HLT Subacute polyneuropathies to HLGT Peripheral neuropathies is not approved after suspension. The current placement of PT Subacute inflammatory demyelinating polyneuropathy under HLT Acute polyneuropathies is acceptable since subacute polyneuropathy is a sub-concept of acute polyneuropathy.

CR Number: 2018152709 **Implementation Date:** 10-Oct-18 Related CR: 2018152709

Change Requested	Add a New HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed HLT	*Severity of illness scale*	Rejected After Suspension		

MSSO Comment: The proposal to add a new HLT Severity of illness scale is not approved after suspension. Severity of illness scale terms are appropriately placed in the relevant anatomical and physiological groupings in SOC Investigations to facilitate coding and retrieval. The few more general scales such as the disability assessment scale that do not pertain to any particular anatomical location or physiological system are also appropriately grouped under HLT Investigations NEC.

Supplemental Update Report

CR Number: 2018155001 **Implementation Date:** 05-Jul-18 Related CR: 2018155001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*LABG*	Approved as Requested	Proposed LLT	
			LABG	10081801 Current
			To PT	
			Gastric banding	10060785

MSSO Comment: The proposal to add a new LLT LABG is approved as requested. Laparoscopic adjustable gastric band, also called LABG, is a restrictive type of surgery in which a silicone band is placed around the top portion of the stomach, which generates a small pouch with limited volume providing an early and prolonged feeling of satiety. The procedure is indicated in individuals with a body mass index (BMI) greater than 40 kg/m2, or in those with a BMI between 30 and 40 and who have at least one comorbidity that is associated with obesity. LABG and the spelled out term Laparoscopic adjustable gastric band will be added as sub-concept LLTs under PT Gastric banding.

CR Number: 2018186019 **Implementation Date:** 05-Jul-18 Related CR: 2018155001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Laparoscopic adjustable gastric band*	Approved as Requested	Proposed LLT	
To PT	*Gastric banding*		*Laparoscopic adjustable gastric band*	10081802 Current
			To PT	
			Gastric banding	10060785

MSSO Comment:

Supplemental Update Report

CR Number: 2018156002 **Implementation Date:** 12-Jul-18 Related CR: 2018156002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Human herpesvirus 6 encephalitis*	Approved Not as Requested	Proposed PT	
To PT	*Human herpesvirus 6 infection*		*Human herpesvirus 6 encephalitis*	10081897
			HLT primary	
			Herpes viral infections	10019972
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Encephalitis of viral origin	10057174
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new LLT Human herpesvirus 6 encephalitis to PT Human herpesvirus 6 infection is approved but not as requested. HHV-6 has been associated with neurologic disease particularly in transplant patients. Recent reports offer evidence that HHV-6 reactivation may underlie a characteristic limbic encephalitis syndrome following hematopoietic cell transplant; the cardinal features of this syndrome include memory loss, insomnia, and electroencephalographic evidence of temporal lobe seizure activity. Human herpesvirus 6 encephalitis is a well defined infectious entity which warrants placement at the PT level and will be linked primarily to HLT Herpes viral infections, with a secondary link to HLT Encephalitis of viral origin.

CR Number: 2018156003 **Implementation Date:** 12-Jul-18 Related CR: 2018156003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cerebral artery stent insertion*	Approved as Requested	Proposed PT	
HLT primary	*Arterial therapeutic procedures (excl aortic)*		*Cerebral artery stent insertion*	10081893
SOC primary	*Surgical and medical procedures*		HLT primary	
			Arterial therapeutic procedures (excl aortic)	10003167
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT Cerebral artery stent insertion to primary HLT Arterial therapeutic procedures (excl aortic) in SOC Surgical and medical procedures is approved as requested. Highly selective stenting placement for middle cerebral artery stenosis is a new therapeutic option for patients who have failed best medical therapy. Elective stenting is also an alternative therapeutic method for the prevention of secondary ischaemic stroke in stroke patients with middle cerebral artery stenosis, and seems to be a potentially effective but also hazardous therapeutic technique in patients with recurrent transient ischemic attacks.

Supplemental Update Report

CR Number: 2018156004 **Implementation Date:** 12-Jul-18 Related CR: 2018156004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Multilocular cystic nephroma*	Approved Not as Requested	Proposed PT	
To PT	*Acquired cystic kidney disease*		*Multilocular cystic nephroma*	10081895
			HLT primary	
			Renal neoplasms benign	10038487
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Renal neoplasms	10038486
			SOC secondary	
			Renal and urinary disorders	10038359

MSSO Comment: The proposal to add a new LLT Multilocular cystic nephroma to PT Acquired cystic kidney disease is approved but not as requested. Multilocular cystic nephroma is a benign mixed mesenchymal and epithelial neoplasm of the kidney, which is classically described as a benign slow-growing renal tumor. Children younger than 2 years old and adults in middle age (40–69 years old) are more commonly affected. Its most common ultrasound findings are a unilateral mass with irregular cysts and septa of variable thicknesses. Multilocular cystic nephroma warrants PT status and will be added as such to primary HLT Renal neoplasms benign; secondary HLT Renal neoplasms.

CR Number: 2018156005 **Implementation Date:** 23-Jul-18 Related CR: 2018156005

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Acquired cystic kidney disease*	Approved After Suspension	Proposed PT	
To HLT	*Renal neoplasms benign*		*Acquired cystic kidney disease*	10070869
			To HLT	
			Renal neoplasms benign	10038487

MSSO Comment: The proposal to link the PT Acquired cystic kidney disease to secondary HLT Renal neoplasms benign is approved as requested after suspension. Based upon MedDRA conventions, cystic diseases have a secondary link to the SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps). HLT Renal neoplasms benign is in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps).

Supplemental Update Report

CR Number: 2018156006 **Implementation Date:** 12-Jul-18 Related CR: 2018156006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ring chromosome*	Approved as Requested	Proposed PT	
HLT primary	*Chromosomal abnormalities NEC*		*Ring chromosome*	10081894
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Chromosomal abnormalities NEC	10008805
			SOC primary	
			Congenital, familial and genetic disorders	10010331

MSSO Comment: The proposal to add a new PT Ring chromosome to primary HLT Chromosomal abnormalities NEC in SOC Congenital, familial and genetic disorders is approved as requested. A ring chromosome is an aberrant chromosome whose ends have fused together to form a ring. They may form in cells following genetic damage by mutagens like radiation, but they may also arise spontaneously during development. Ring chromosomes can be inherited or sporadic. Mosaicism is common and affects the severity of the condition. Almost all ring chromosome associated syndromes feature marked growth delay.

CR Number: 2018156007 **Implementation Date:** 12-Jul-18 Related CR: 2018156007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cystic bronchiectasis*	Approved as Requested	Proposed LLT	
To PT	*Bronchiectasis*		*Cystic bronchiectasis*	10081907 Current
			To PT	
			Bronchiectasis	10006445

MSSO Comment: The proposal to add a new LLT Cystic bronchiectasis to PT Bronchiectasis is approved as requested. Cystic bronchiectasis is one of the less common morphological forms of bronchiectasis, which may be present on its own or may occur in combination with other forms of bronchiectasis. It is characterized by saccular dilatation of bronchi that extend to the pleural surfaces. When aggregated these may give a "bunch of grapes" like appearance.

Supplemental Update Report

CR Number: 2018156008 **Implementation Date:** 12-Jul-18 Related CR: 2018156008

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Aphakic glaucoma*	Approved Not as Requested	Proposed PT	
HLT primary	*Glaucomas (excl congenital)*		*Aphakic glaucoma*	10081898
SOC primary	*Eye disorders*		HLT primary	
			Eye and ear procedural complications	10015908
			SOC primary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new PT Aphakic glaucoma to primary HLT Glaucomas (excl congenital) in SOC Eye disorders is approved but not as requested. Aphakic glaucoma is the most common long-term complication seen following congenital cataract surgery. It has a reported incidence of between 15% and 45%. Many risk factors have been identified including microcornea, early surgery, persistent fetal vasculature, congenital rubella syndrome, Lowe syndrome, chronic inflammation and retained lens material. Surgical intervention is often required with medical treatment providing adjunctive therapy. The pathophysiological mechanism of aphakic glaucoma remains unknown. Aphakic glaucoma will be added as a PT to HLT Eye and ear procedural complications based on MedDRA convention where concepts are mainly the consequences of a procedure are primarily mapped to SOC Injury, poisoning and procedural complications.

CR Number: 2018156009 **Implementation Date:** 12-Jul-18 Related CR: 2018156009

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Urinary tract toxicity*	Approved as Requested	Proposed PT	
HLT primary	*Genital and urinary tract disorders NEC*		*Urinary tract toxicity*	10081901
SOC primary	*Renal and urinary disorders*		HLT primary	
			Genital and urinary tract disorders NEC	10027680
			SOC primary	
			Renal and urinary disorders	10038359
			HLT secondary	
			Poisoning and toxicity	10035777
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new PT Urinary tract toxicity to primary HLT Genital and urinary tract disorders NEC in SOC Renal and urinary disorders is approved as requested. Urinary tract toxicity represents a broad term indicating toxic exposure to substances of the entire urinary tract including kidney structures and urothelial layers of the urinary tract including the renal pelvis, the ureters, the bladder, and parts of the urethra. Additionally, a secondary link to HLT Poisoning and toxicity will be added.

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CR Number: 2018156010 **Implementation Date:** 12-Jul-18 Related CR: 2018156010

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hypotony maculopathy*	Approved as Requested	Proposed PT	
HLT primary	*Retinal structural change, deposit and degeneration*		*Hypotony maculopathy*	10081899
SOC primary	*Eye disorders*		HLT primary	
			Retinal structural change, deposit and degeneration	10038896
			SOC primary	
			Eye disorders	10015919
			HLT secondary	
			Eye and ear procedural complications	10015908
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new PT Hypotony maculopathy to primary HLT Retinal structural change, deposit and degeneration in SOC Eye disorders is approved as requested. Hypotony maculopathy is a condition that may result in visual deterioration from choroidal folds or optic disc edema. Optic disc edema can result from altered translaminar pressure gradients (lowered intraocular pressure, increased cerebrospinal fluid pressure, or increased orbital pressure). Additionally, a secondary link will be added to HLT Eye and ear procedural complications.

CR Number: 2018156011 **Implementation Date:** 12-Jul-18 Related CR: 2018156011

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Arterial stiffness*	Approved Not as Requested	Proposed PT	
HLT primary	*Non-site specific vascular disorders NEC*		*Arterial stiffness*	10081902
SOC primary	*Vascular disorders*		HLT primary	
			Non-site specific necrosis and vascular insufficiency NEC	10029558
			SOC primary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new PT Arterial stiffness to primary HLT Non-site specific vascular disorders NEC in SOC Vascular disorders is approved but not as requested. Arterial stiffness, also known as the loss of arterial elasticity, represents the mechanical property of artery resistant to deformation with a potential predictive value for vascular events. Arterial stiffness will be added as a PT to the more specific HLT Non-site specific necrosis and vascular insufficiency NEC.

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CR Number: 2018156012 **Implementation Date:** 12-Jul-18 Related CR: 2018156012

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Oral cavity mass*	Rejected		
HLT primary	*Oral soft tissue disorders NEC*			
SOC primary	*Gastrointestinal disorders*			

MSSO Comment: The proposal to add a new PT Oral cavity mass to primary HLT Oral soft tissue disorders NEC in SOC Gastrointestinal disorders is not approved. While there are existing localized mass terms in MedDRA, the MSSO considers 'mass' an imprecise concept and generally refrains from adding them. Existing MedDRA LLTs - Mouth bump, Oral lesion and Oral nodule within the PT Oral disorder all may sufficiently describe an oral cavity mass of unspecified histopathology.

CR Number: 2018156013 **Implementation Date:** 12-Jul-18 Related CR: 2018156013

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Donohue syndrome*	Approved Not as Requested	Proposed PT	
HLT primary	*Hyperglycaemic conditions NEC*		*Donohue syndrome*	10081896
SOC primary	*Endocrine disorders*		HLT primary	
			Endocrine disorders congenital NEC	10027671
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Hypoglycaemic conditions NEC	10021001
			SOC secondary	
			Endocrine disorders	10014698

MSSO Comment: The proposal to add a new PT Donohue syndrome to primary HLT Hyperglycaemic conditions NEC in SOC Endocrine disorders is approved but not as requested. Donohue syndrome is a rare, lethal, autosomal recessive condition caused by mutation in the INSR gene (locus: 19p13.2), which encodes the insulin receptor, characterized by slow physical and mental development, elfin facies, and endocrine abnormalities such as hyperinsulinemia and precocious puberty. Following MedDRA convention related to the placement of "congenital" concepts, Donohue syndrome will be added as a PT to primary HLT Endocrine disorders congenital NEC with secondary links to HLT Hypoglycaemic conditions NEC and HLT Musculoskeletal and connective tissue conditions NEC.

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CR Number: 2018193004 **Implementation Date:** 12-Jul-18 Related CR: 2018156013

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Donohue syndrome*	Approved as Requested	Proposed PT	
To HLT	*Musculoskeletal and connective tissue conditions NEC*		*Donohue syndrome*	10081896
			To HLT	
			Musculoskeletal and connective tissue conditions NEC	10080711

MSSO Comment:

CR Number: 2018156014 **Implementation Date:** 12-Jul-18 Related CR: 2018156014

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Leprechaunism*	Approved as Requested	Proposed LLT	
			Leprechaunism	10081903 Current
			To PT	
			Donohue syndrome	10081896

MSSO Comment: The proposal to add a new LLT Leprechaunism is approved as requested. Leprechaunism is a synonym for Donohue syndrome, which is caused by an inborn dysfunction of the insulin receptor, characterized by hyperinsulinism, pre-prandial hypoglycemia, postprandial hyperglycemia attacks, hyperandrogenism and growth retardation. LLT Leprechaunism will be added to new PT Donohue syndrome.

CR Number: 2018156015 **Implementation Date:** 12-Jul-18 Related CR: 2018156015

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Transfusion dependent thalassemia*	Approved as Requested	Proposed LLT	
To PT	*Thalassaemia*		*Transfusion dependent thalassemia*	10081904 Current
			To PT	
			Thalassaemia	10043388

MSSO Comment: The proposal to add a new LLT Transfusion dependent thalassemia to PT Thalassaemia is approved as requested. Classification of thalassemia is based on clinical and blood smear histology assessment. While it may be observed that beta thalassemia major is associated with dependence on blood transfusion and beta thalassemia minor is not associated with dependence on blood transfusion, the need for blood transfusion is not a determinant of the classification, as evidence by the fact that beta thalassemia major and beta thalassemia intermediate may both feature dependence on blood transfusion, acquired in the case of beta thalassemia intermediate. In a related change, the British English spelling counterpart LLT Transfusion dependent thalassaemia will also be added to PT Thalassaemia.

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CR Number: 2018193005 **Implementation Date:** 12-Jul-18 Related CR: 2018156015

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Transfusion dependent thalassaemia*	Approved as Requested	Proposed LLT	
To PT	*Thalassaemia*		*Transfusion dependent thalassaemia*	10081911 Current
			To PT	
			Thalassaemia	10043388

MSSO Comment:

CR Number: 2018156016 **Implementation Date:** 12-Jul-18 Related CR: 2018156016

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Subjective memory complaints*	Rejected		
HLT primary	*Cognitive and attention disorders and disturbances NEC*			
SOC primary	*Psychiatric disorders*			

MSSO Comment: The proposal to add a new PT Subjective memory complaints to primary HLT Cognitive and attention disorders and disturbances NEC in SOC Psychiatric disorders is not approved. The requested term can be represented by the most appropriate LLT under PT Amnesia or by any LLT under PT Memory impairment.

CR Number: 2018156017 **Implementation Date:** 12-Jul-18 Related CR: 2018156017

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Skin reaction to dye contained in drug*	Rejected		

MSSO Comment: The proposal to add a new LLT Skin reaction to dye contained in drug is not approved. Medication dyes are drug excipients. The requested concept can be represented by split coding with existing terms: LLT Reaction to colouring plus LLT Allergic reaction to drug excipient.

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CR Number: 2018156018 **Implementation Date:** 12-Jul-18 Related CR: 2018156018

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Application site skin flaking*	Approved as Requested	Proposed LLT	
To PT	*Application site exfoliation*		*Application site skin flaking*	10081910 Current
			To PT	
			Application site exfoliation	10064578

MSSO Comment: The proposal to add a new LLT Application site skin flaking to PT Application site exfoliation is approved as requested. "Flaking" is a commonly used colloquial synonym for "exfoliation".

CR Number: 2018156019 **Implementation Date:** 12-Jul-18 Related CR: 2018156019

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Intentional product use in unapproved combination*	Rejected		

MSSO Comment: The proposal to add a new LLT Intentional product use in unapproved combination is not approved. The concept can be represented by LLT Product use for unapproved combination and LLT Intentional product use issue.

CR Number: 2018156020 **Implementation Date:** 12-Jul-18 Related CR: 2018156020

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Goldmann perimetry*	Approved as Requested	Proposed LLT	
To PT	*Visual field tests*		*Goldmann perimetry*	10081905 Current
			To PT	
			Visual field tests	10047566

MSSO Comment: The proposal to add a new LLT Goldmann perimetry to PT Visual field tests is approved as requested. The Goldmann perimeter is a hollow white spherical bowl positioned a set distance in front of the patient. An examiner presents a test light of variable size and intensity. The light may move towards the center from the perimeter (kinetic perimetry), or it may remain in one location (static perimetry). The Goldmann perimetry method is able to test the entire range of peripheral vision, and has been used for years to follow vision changes in glaucoma patients. However, at present, automated perimetry is more commonly used.

Supplemental Update Report

CR Number: **2018156021** **Implementation Date:** 12-Jul-18 Related CR: 2018156021

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Full-field stimulus testing*	Approved as Requested	Proposed LLT	
To PT	*Visual field tests*		*Full-field stimulus testing*	10081906 Current
			To PT	
			Visual field tests	10047566

MSSO Comment: The proposal to add a new LLT Full-field stimulus testing to PT Visual field tests is approved as requested. Full-field stimulus testing is used to assess retinal degenerative diseases. The investigation may use an automated perimeter with specialized software, LED illumination of variable intensity and color, and an electroretinographic instrument to measure the retinal sensory response to the light stimuli within the visual fields.

CR Number: **2018156022** **Implementation Date:** 12-Jul-18 Related CR: 2018156022

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Humphrey visual field analyzer*	Approved Not as Requested	Proposed LLT	
To PT	*Visual field tests*		*Humphrey perimetry*	10081908 Current
			To PT	
			Visual field tests	10047566

MSSO Comment: The proposal to add a new LLT Humphrey visual field analyzer to PT Visual field tests is approved but not as requested. Humphrey visual field analyzer is a trade name and therefore will be modified to Humphrey perimetry and added as an LLT to PT Visual field tests. In current use, Humphrey perimetry is synonymous with automated perimetry. In a related change, LLT Automated perimetry will be added to PT Visual field tests.

CR Number: **2018193006** **Implementation Date:** 12-Jul-18 Related CR: 2018156022

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Automated perimetry*	Approved as Requested	Proposed LLT	
To PT	*Visual field tests*		*Automated perimetry*	10081913 Current
			To PT	
			Visual field tests	10047566

MSSO Comment:

Supplemental Update Report

CR Number: 2018156023 **Implementation Date:** 12-Jul-18 Related CR: 2018156023

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Confrontation visual field test-Donders test*	Approved Not as Requested	Proposed LLT	
To PT	*Visual field tests*		*Confrontation visual field test*	10081909 Current
			To PT	
			Visual field tests	10047566

MSSO Comment: The proposal to add a new LLT Confrontation visual field test-Donders test to PT Visual field tests is approved but not as requested. The requested term will be added as two separate synonym LLTs - LLT Confrontation visual field test and LLT Donder's test to PT Visual field tests.

CR Number: 2018193007 **Implementation Date:** 12-Jul-18 Related CR: 2018156023

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Donder's test*	Approved as Requested	Proposed LLT	
To PT	*Visual field tests*		*Donder's test*	10081912 Current
			To PT	
			Visual field tests	10047566

MSSO Comment:

Supplemental Update Report

CR Number: 2018156024 **Implementation Date:** 12-Jul-18 Related CR: 2018156024

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Re-opening of ductus arteriosus*	Approved Not as Requested	Proposed PT	
HLT primary	*Arterial disorders congenital*		*Re-opening of ductus arteriosus*	10081900
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Cardiac and vascular procedural complications	10007602
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Site specific vascular disorders NEC	10057188
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new PT Re-opening of ductus arteriosus to primary HLT Arterial disorders congenital in SOC Congenital, familial and genetic disorders is approved but not as requested. Re-opening of ductus arteriosus will be added as a PT to primary HLT Cardiac and vascular procedural complications and secondary HLT Site specific vascular disorders NEC.

CR Number: 2018156025 **Implementation Date:** 12-Jul-18 Related CR: 2018156025

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ghost image*	Rejected		
To PT	*Diplopia*			

MSSO Comment: The proposal to add a new LLT Ghost image to PT Diplopia is not approved. "Ghost image" as proposed is relatively ambiguous with many medical and non-medical connotations that do not necessarily pertain to diplopia.

Supplemental Update Report

CR Number: 2018156026 **Implementation Date:** 05-Jul-18 Related CR: 2018156026

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Bladder pacemaker insertion*	Approved as Requested	Proposed LLT	
			Bladder pacemaker insertion	10081804 Current
			To PT	
			Urinary control neurostimulator implantation	10066003

MSSO Comment: The proposal to add a new term Bladder pacemaker insertion is approved as requested. Bladder pacemaker insertion (also called sacral bladder neuromodulation or sacral bladder nerve stimulation) is a procedure which electrically stimulates the sacral nerves to modulate reflexes that improve bladder function in pathologies such as urgency urinary incontinence or non-obstructive urinary retention. This surgery is typically offered to women who have failed to adequately improve with multiple other conservative therapies. Bladder pacemaker insertion will be placed as a sub-concept LLT to PT Urinary control neurostimulator implantation.

CR Number: 2018156028 **Implementation Date:** 05-Jul-18 Related CR: 2018156028

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Rebound phenomenon*	Approved Not as Requested	Proposed LLT	
To PT	*Coordination abnormal*		*Holmes rebound phenomenon*	10081803 Current
			To PT	
			Postural reflex impairment	10067206

MSSO Comment: The proposal to add a new LLT Rebound phenomenon to PT Coordination abnormal is approved but not as requested. The Holmes rebound phenomenon is a reflex that occurs when one attempts to move a limb against resistance that is suddenly removed. When the resistance is removed, the limb will usually move a short distance in the original direction, at which point the antagonist muscles will contract, causing the muscle to yank back in the opposite direction. The proposed concept will be modified for clarification and added as LLT Holmes rebound phenomenon under PT Postural reflex impairment.

CR Number: 2018157001 **Implementation Date:** 05-Jul-18 Related CR: 2018157001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Photodermatoses*	Rejected		

MSSO Comment: The proposal to add a new LLT Photodermatoses is not approved. The requested term, LLT Photodermatoses is represented by the existing PT/LLT Photodermatosis.

Supplemental Update Report

CR Number: 2018158001 **Implementation Date:** 05-Jul-18 Related CR: 2018158001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Mid-Urethral Sling (MUS) Procedure*	Approved Not as Requested	Proposed LLT	
To PT	*Urinary bladder suspension*		*Mid-urethral sling procedure*	10081805 Current
			To PT	
			Urinary bladder suspension	10079992

MSSO Comment: The proposal to add a new LLT Mid-Urethral Sling (MUS) Procedure to PT Urinary bladder suspension is approved but not as requested. The midurethral sling is a common type of surgery used to correct stress urinary incontinence. The sling is a narrow strap made of synthetic mesh that is placed under the urethra, acting as a hammock to lift or support the urethra and the neck of the bladder. The proposed term Mid-Urethral Sling (MUS) Procedure will be modified to Mid-urethral sling procedure, without (MUS) and to conform with MedDRA capitalization and naming conventions, and added as a sub-concept LLT to PT Urinary bladder suspension.

CR Number: 2018158002 **Implementation Date:** 12-Jul-18 Related CR: 2018158002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Positive dose response relationship*	Approved as Requested	Proposed PT	
			Positive dose response relationship	10081874
			HLT primary	
			Therapeutic and nontherapeutic responses	10043409
			SOC primary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new term Positive dose response relationship is approved as requested. The shape of the dose–response curve for either drugs or therapeutic agents is important in clinical pharmacology. Positive dose response relationship will be added as a PT to HLT Therapeutic and nontherapeutic responses.

CR Number: 2018158003 **Implementation Date:** 12-Jul-18 Related CR: 2018158003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Missing dose response relationship*	Approved as Requested	Proposed PT	
			Missing dose response relationship	10081872
			HLT primary	
			Therapeutic and nontherapeutic responses	10043409
			SOC primary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new term Missing dose response relationship is approved as requested. The dose–response relationship for either drugs or therapeutic agents is important in clinical pharmacology. Missing dose response relationship will be added as a PT to HLT Therapeutic and nontherapeutic responses.

Supplemental Update Report

CR Number: 2018158004 **Implementation Date:** 12-Jul-18 Related CR: 2018158004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Atypical dose response relationship*	Approved as Requested	Proposed PT	
			Atypical dose response relationship	10081873
			HLT primary	
			Therapeutic and nontherapeutic responses	10043409
			SOC primary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new term Atypical dose response relationship is approved as requested. The characteristics of a dose–response relationship for either drugs or therapeutic agents is important in clinical pharmacology. Atypical dose response relationship will be added as a PT to HLT Therapeutic and nontherapeutic responses.

CR Number: 2018158005 **Implementation Date:** 12-Jul-18 Related CR: 2018158005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Bell shaped dose response relationship*	Approved as Requested	Proposed PT	
			Bell shaped dose response relationship	10081875
			HLT primary	
			Therapeutic and nontherapeutic responses	10043409
			SOC primary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new term Bell shaped dose response relationship is approved as requested. Some drugs may cause an inhibitory response at low concentrations, and a stimulatory response at high concentrations, or vice-versa, resulting in a bell-shaped dose-response curve. Bell shaped dose response relationship will be added as a PT to HLT Therapeutic and nontherapeutic responses.

Supplemental Update Report

CR Number: 2018159001 **Implementation Date:** 12-Jul-18 Related CR: 2018159001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Patent Ductus Arteriosus Stent placement*	Approved Not as Requested	Proposed PT	
			Patent ductus arteriosus stent placement	10081876
			HLT primary	
			Congenital cardiovascular anomaly therapeutic procedures	10010401
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT Patent Ductus Arteriosus Stent placement is approved but not as requested. As with other therapeutic procedures featuring placement of a stent to achieve and maintain structural patency, patent ductus arteriosis stent placement is an established procedure. Patent ductus arteriosus stent placement will be added, with modifications to capitalization per MedDRA convention, as a PT to HLT Congenital cardiovascular anomaly therapeutic procedures.

CR Number: 2018159002 **Implementation Date:** 12-Jul-18 Related CR: 2018159002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Varicosities*	Rejected		
To PT	*Varicose veins*			

MSSO Comment: The proposal to add a new LLT Varicosities to PT Varicose veins is not approved. The term is represented in the singular form as LLT Varicosity.

CR Number: 2018163001 **Implementation Date:** 12-Jul-18 Related CR: 2018163001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Milk leg syndrome*	Approved as Requested	Proposed LLT	
To PT	*Deep vein thrombosis*		*Milk leg syndrome*	10081877 Current
			To PT	
			Deep vein thrombosis	10051055

MSSO Comment: The proposal to add a new LLT Milk leg syndrome to PT Deep vein thrombosis is approved as requested. Milk leg syndrome is a colloquial synonym of Phlegmasia alba dolens.

Supplemental Update Report

CR Number: 2018164001 **Implementation Date:** 12-Jul-18 Related CR: 2018164001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Imerslund-grasbeck syndrome*	Approved Not as Requested	Proposed LLT	
			Imerslund-Graesbeck syndrome	10081880 Current
			To PT	
			Autosomal recessive megaloblastic anaemia	10081878

MSSO Comment: The proposal to add a new term Imerslund-grasbeck syndrome is approved but not as requested. Imerslund-Graesbeck syndrome, also known as Autosomal recessive megaloblastic anaemia, or selective vitamin B12 (cobalamin) malabsorption with proteinuria, is a rare autosomal recessive disorder characterized by vitamin B12 deficiency commonly resulting in megaloblastic anemia, which is responsive to parenteral vitamin B12 therapy and appears in childhood. Imerslund-Graesbeck syndrome will be added, with updated spelling and capitalization per MedDRA convention as an LLT to new PT Autosomal recessive megaloblastic anaemia. In a related change, new PT Autosomal recessive megaloblastic anaemia will be added to primary HLT Anaemias congenital (excl haemoglobinopathies); secondary HLTs - HLT Anaemia deficiencies, HLT Malabsorption syndromes and HLT Water soluble vitamin deficiencies. Additionally, the U.S. spelling Autosomal recessive megaloblastic anemia will be added as an LLT to new PT Autosomal recessive megaloblastic anaemia.

CR Number: 2018192005 **Implementation Date:** 12-Jul-18 Related CR: 2018164001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Autosomal recessive megaloblastic anaemia*	Approved as Requested	Proposed PT	
HLT primary	*Anaemias congenital (excl haemoglobinopathies)*		*Autosomal recessive megaloblastic anaemia*	10081878
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Anaemias congenital (excl haemoglobinopathies)	10002084
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Anaemia deficiencies	10002042
			SOC secondary	
			Blood and lymphatic system disorders	10005329

MSSO Comment:

Supplemental Update Report

CR Number: 2018192006 **Implementation Date:** 12-Jul-18 Related CR: 2018164001

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Autosomal recessive megaloblastic anaemia*	Approved as Requested	Proposed PT	
			Autosomal recessive megaloblastic anaemia	10081878
To HLT	*Malabsorption syndromes*		To HLT	
			Malabsorption syndromes	10025480

MSSO Comment:

CR Number: 2018192007 **Implementation Date:** 12-Jul-18 Related CR: 2018164001

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Autosomal recessive megaloblastic anaemia*	Approved as Requested	Proposed PT	
			Autosomal recessive megaloblastic anaemia	10081878
To HLT	*Water soluble vitamin deficiencies*		To HLT	
			Water soluble vitamin deficiencies	10047842

MSSO Comment:

CR Number: 2018192008 **Implementation Date:** 12-Jul-18 Related CR: 2018164001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Autosomal recessive megaloblastic anemia*	Approved as Requested	Proposed LLT	
			Autosomal recessive megaloblastic anemia	10081879 Current
To PT	*Autosomal recessive megaloblastic anaemia*		To PT	
			Autosomal recessive megaloblastic anaemia	10081878

MSSO Comment:

Supplemental Update Report

CR Number: 2018164002 **Implementation Date:** 12-Jul-18 Related CR: 2018164002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hysteroannsessiectomy*	Rejected		
To PT	*Hysterosalpingo-oophorectomy*			

MSSO Comment: The proposal to add a new LLT Hysteroannsessiectomy to PT Hysterosalpingo-oophorectomy is not approved. The existence of an equivalent alternate language term for an existing English term does not justify the need for inclusion of the term in both language versions of MedDRA, and supports the existence of MedDRA translations into multiple languages. Furthermore, as per MedDRA Introductory Guide Version 21.0, March 2018, page 7: “Since LLTs may accommodate colloquial or culturally unique terms, every LLT may not have a unique translation in every language.” Although the Italian translation of MedDRA contains LLT Annessiectomia bilaterale under PT Salpingo-ovariectomia bilaterale, adding the Italian alternative to the English MedDRA terminology does not serve any utility.

CR Number: 2018164003 **Implementation Date:** 12-Jul-18 Related CR: 2018164003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Bilateral Hyrtl's fissure*	Approved as Requested	Proposed LLT	
			Bilateral Hyrtl's fissure	10081916 Current
			To PT	
			Tympanomeningeal fissure	10081914

MSSO Comment: The proposal to add a new term Bilateral Hyrtl's fissure is approved as requested. Bilateral Hyrtl's fissure will be added as an LLT to new PT Tympanomeningeal fissure. In a related change, PT Tympanomeningeal fissure will be added to primary HLT Ear disorders congenital NEC; secondary HLT Congenital ear disorders (excl external ear). Additionally, synonym LLT Hyrtl's fissure will be added to PT Tympanomeningeal fissure.

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CR Number: 2018193008 **Implementation Date:** 12-Jul-18 Related CR: 2018164003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Tympanomeningeal fissure*	Approved as Requested	Proposed PT	
HLT primary	*Ear disorders congenital NEC*		*Tympanomeningeal fissure*	10081914
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Ear disorders congenital NEC	10027668
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Congenital ear disorders (excl external ear)	10010450
			SOC secondary	
			Ear and labyrinth disorders	10013993

MSSO Comment:

CR Number: 2018193009 **Implementation Date:** 12-Jul-18 Related CR: 2018164003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hyrtl's fissure*	Approved as Requested	Proposed LLT	
To PT	*Tympanomeningeal fissure*		*Hyrtl's fissure*	10081915 Current
			To PT	
			Tympanomeningeal fissure	10081914

MSSO Comment:

Supplemental Update Report

CR Number: 2018165001 **Implementation Date:** 05-Jul-18 Related CR: 2018165001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Peroral endoscopic myotomy*	Approved as Requested	Proposed LLT	
			Peroral endoscopic myotomy	10081816 Current
			To PT	
			Oesophagocardiomyotomy	10051918

MSSO Comment: The proposal to add a new term Peroral endoscopic myotomy is approved as requested. Peroral endoscopic myotomy is a low invasive endoscopic procedure, used to treat several esophageal motility disorders such as achalasia or spastic esophageal disorders (diffuse esophageal spam, nutcracker esophagus), in which an endoscope is inserted into the patient's mouth and passed into the upper esophagus. After a small incision is made in the esophageal mucosa, the endoscope dissects through the submucosal space to the lower esophageal sphincter, where the circular muscle fibers are incised. Peroral endoscopic myotomy is an endoscopic alternative to Heller's esophagomyotomy, and will be added as a sub-concept LLT to PT Oesophagocardiomyotomy.

CR Number: 2018165002 **Implementation Date:** 05-Jul-18 Related CR: 2018165002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Pericardial fenestration*	Approved as Requested	Proposed LLT	
			Pericardial fenestration	10081811 Current
			To PT	
			Pericardiotomy	10056263

MSSO Comment: The proposal to add a new term Pericardial fenestration is approved as requested. Pericardial fenestration (usually thoracoscopic) is one of the therapeutic approaches available to prevent pericardial fluid re-accumulation in cases of recurrent pericardial effusion, specially in those cases associated to recurrence of cardiac tamponade. Pericardial fenestration will be added as a sub-concept LLT of PT Pericardiotomy.

CR Number: 2018165003 **Implementation Date:** 05-Jul-18 Related CR: 2018165003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Butanol threshold test*	Approved as Requested	Proposed LLT	
			Butanol threshold test	10081813 Current
			To PT	
			Olfactory test	10062925

MSSO Comment: The proposal to add a new term Butanol threshold test is approved as requested. Odorant sniffing sticks or pens are used to assess olfactory dysfunction. After a starting concentration of the smell is found out, the dilution step is identified at which the smell can just be distinguished from non-smelling pens (blanks). The test is available in two versions, one with n-butanol and another with 2-phenylethanol. Butanol threshold test will be placed as a sub-concept LLT under PT Olfactory test.

Supplemental Update Report

CR Number: 2018165004 **Implementation Date:** 05-Jul-18 Related CR: 2018165004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Coffin-lowry syndrome*	Approved Not as Requested	Proposed PT	
			Coffin-Lowry syndrome	10081806
			HLT primary	
			Musculoskeletal disorders congenital NEC	10029513
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Musculoskeletal disorders congenital NEC	10029513
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new term Coffin-lowry syndrome is approved but not as requested. Coffin-Lowry syndrome (also called facio-digital mental retardation syndrome) is a condition that affects more severely males than females, characterized by intellectual disability, distinctive facial features, and short, tapered fingers. Coffin-Lowry syndrome will be added with corrected capitalization, as a PT with primary link to the bi-axial HLT Musculoskeletal disorders congenital NEC, primary SOC Congenital, familial and genetic disorders, and secondary SOC Musculoskeletal and connective tissue disorders; and a secondary link to the bi-axial HLT Intellectual disabilities in SOC Psychiatric disorders and SOC Nervous system disorders.

CR Number: 2018186025 **Implementation Date:** 05-Jul-18 Related CR: 2018165004

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Coffin-Lowry syndrome*	Approved as Requested	Proposed PT	
			Coffin-Lowry syndrome	10081806
To HLT	*Intellectual disabilities*		To HLT	
			Intellectual disabilities	10077548

MSSO Comment:

Supplemental Update Report

CR Number: 2018165005 **Implementation Date:** 05-Jul-18 Related CR: 2018165005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Plethoric facies*	Approved Not as Requested	Proposed PT	
			Plethoric face	10081808
			HLT primary	
			Site specific vascular disorders NEC	10057188
			SOC primary	
			Vascular disorders	10047065
			HLT secondary	
			Dermal and epidermal conditions NEC	10012424
			SOC secondary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment: The proposal to add a new term Plethoric facies is approved but not as requested. Plethoric face is a descriptive clinical term associated to dilation of superficial blood vessels causing an erythematous, reddish face. The proposed term will be modified to Plethoric face, to represent the English expression of the Latin derived proposed term, and added as a PT to primary HLT Site specific vascular disorders NEC, secondary HLT Dermal and epidermal conditions NEC and secondary HLT General signs and symptoms NEC.

CR Number: 2018186020 **Implementation Date:** 05-Jul-18 Related CR: 2018165005

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Plethoric face*	Approved as Requested	Proposed PT	
To HLT	*General signs and symptoms NEC*		*Plethoric face*	10081808
			To HLT	
			General signs and symptoms NEC	10018072

MSSO Comment:

Supplemental Update Report

CR Number: 2018165006 **Implementation Date:** 05-Jul-18 Related CR: 2018165006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Gluteal abscess*	Approved as Requested	Proposed LLT	
			Gluteal abscess	10081817 Current
			To PT	
			Abscess limb	10050473

MSSO Comment: The proposal to add a new term Gluteal abscess is approved as requested. A gluteal abscess is a pus collection in the gluteal region, caused by a wide range of etiologies, ranging from extension of glands or cysts, infections in the subcutaneous plane of the buttock area, to fat or muscle necrosis caused by repetitive trauma (for example, from frequent injections). Gluteal abscess will be added as a sub-element LLT of PT Abscess limb. In a related change, LLT Abscess on buttock will be moved from PT Subcutaneous abscess to PT Abscess limb for better alignment.

CR Number: 2018186021 **Implementation Date:** 05-Jul-18 Related CR: 2018165006

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Abscess on buttock*	Approved as Requested	Proposed LLT	
From PT	*Subcutaneous abscess*		*Abscess on buttock*	10000309 Current
To PT	*Abscess limb*		From PT	
			Subcutaneous abscess	10042343
			To PT	
			Abscess limb	10050473

MSSO Comment:

CR Number: 2018165007 **Implementation Date:** 05-Jul-18 Related CR: 2018165007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Sonozaki syndrome*	Approved as Requested	Proposed LLT	
			Sonozaki syndrome	10081814 Current
			To PT	
			Pustulotic arthro-osteitis	10081810

MSSO Comment: The proposal to add a new term Sonozaki syndrome is approved as requested. Pustulotic arthro-osteitis, also known as Sonozaki syndrome, is a relatively rare, chronic member of the seronegative spondyloarthritis group of diseases (which includes ankylosing spondylitis, Reiter's syndrome, and psoriatic arthritis) and is characterized by symmetrically localised sterile pustulae on the feet and hands, and painful, inflamed joints. The most commonly affected peripheral joints are the metacarpophalangeal joints, the proximal interphalangeal joints of fingers, and the elbow and knee joints. Other joints such as the hip, the ankle, and the wrist joints have also been involved rarely. Sonozaki syndrome will be added as a synonym LLT to PT Pustulotic arthro-osteitis. In a related change, PT Pustulotic arthro-osteitis will be added to primary HLT Psoriatic arthropathies, to secondary HLT Psoriatic conditions, and to secondary HLT Immune and associated conditions NEC.

Supplemental Update Report

CR Number: 2018186022 **Implementation Date:** 05-Jul-18 Related CR: 2018165007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pustulotic arthro-osteitis*	Approved as Requested	Proposed PT	
HLT primary	*Psoriatic arthropathies*		*Pustulotic arthro-osteitis*	10081810
SOC primary	*Musculoskeletal and connective tissue disorders*		HLT primary	
			Psoriatic arthropathies	10037163
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395
			HLT secondary	
			Psoriatic conditions	10065874
			SOC secondary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment:

CR Number: 2018186023 **Implementation Date:** 05-Jul-18 Related CR: 2018165007

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pustulotic arthro-osteitis*	Approved as Requested	Proposed PT	
To HLT	*Immune and associated conditions NEC*		*Pustulotic arthro-osteitis*	10081810
			To HLT	
			Immune and associated conditions NEC	10027682

MSSO Comment:

Supplemental Update Report

CR Number: 2018165008 **Implementation Date:** 05-Jul-18 Related CR: 2018165008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Myopic foveoschisis*	Approved as Requested	Proposed LLT	
			Myopic foveoschisis	10081815 Current
			To PT	
			Myopic traction maculopathy	10080534

MSSO Comment: The proposal to add a new term Myopic foveoschisis is approved as requested. Due to excessive axial elongation of the globe, patients with high myopia can develop posterior bulging or ectasia of the globe, causing posterior staphyloma. The abnormal contour of the posterior staphyloma results in anatomic changes in the vitreomacular interface, resulting in the development of macular pathologies such as myopic foveoschisis. Myopic foveoschisis is the splitting of the retinal layers in the macula, causing accumulation of intraretinal and subretinal fluid at the macula in the absence of a full-thickness macular hole. Abnormal traction caused by posterior hyaloid surface in eyes with posterior staphyloma is the current pathogenesis of myopic foveoschisis. Myopic foveoschisis will be added as an LLT to PT Myopic traction maculopathy. In a related change, Myopic traction maculopathy will be promoted from PT Myopic chorioretinal degeneration to a PT under HLT Retinal structural change, deposit and degeneration.

CR Number: 2018186024 **Implementation Date:** 05-Jul-18 Related CR: 2018165008

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Myopic traction maculopathy*	Approved as Requested	Proposed LLT	
			Myopic traction maculopathy	10080534
From PT	*Myopic chorioretinal degeneration*		From PT	
			Myopic chorioretinal degeneration	10079959
HLT primary	*Retinal structural change, deposit and degeneration*		HLT primary	
			Retinal structural change, deposit and degeneration	10038896
			SOC primary	
			Eye disorders	10015919

MSSO Comment:

Supplemental Update Report

CR Number: 2018165009 **Implementation Date:** 05-Jul-18 Related CR: 2018165009

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Sitting disability*	Approved as Requested	Proposed PT	
		Sitting disability	10081807
		HLT primary	
		Disability issues	10057171
		SOC primary	
		Social circumstances	10041244

MSSO Comment: The proposal to add a new term Sitting disability is approved as requested. A sitting disability is a condition in which a person has difficulties sitting or is unable to do so at all, usually due to pain. Pain while sitting is a well known symptom associated with ischial tuberosity pain, myofascial pain syndrome, coccyx pain (coccydynia), failed back surgery, arachnoiditis, and back pain in general. Sitting disability will be added as a PT to HLT Disability issues.

CR Number: 2018165010 **Implementation Date:** 05-Jul-18 Related CR: 2018165010

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Kegel exercises*	Approved as Requested	Proposed LLT	
		Kegel exercises	10081818 Current
		To PT	
		Pelvic floor muscle training	10077309

MSSO Comment: The proposal to add a new term Kegel exercises is approved as requested. Kegel exercises, also known as pelvic floor exercises, consists of repeatedly contracting and relaxing the muscles that form part of the pelvic floor. These exercises are usually done to reduce urinary stress incontinence (especially after childbirth), and to reduce premature ejaculation in men. Kegel exercises will be added as a synonym LLT to PT Pelvic floor muscle training.

CR Number: 2018165011 **Implementation Date:** 05-Jul-18 Related CR: 2018165011

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Gilmore's groin*	Approved as Requested	Proposed LLT	
		Gilmore's groin	10081812 Current
		To PT	
		Muscle strain	10050031

MSSO Comment: The proposal to add a new term Gilmore's groin is approved as requested. Sportsmen’s groin, also called sports hernia and Gilmore's groin, is one of the most frequent sports injuries and represents a severe clinical problem, especially in athletes. Currently, there is little consensus regarding pathophysiology, diagnostic criteria, or treatment. Among the existing theories, one suggests that the entrapment of the genital branch of the genitofemoral nerve or the ilioinguinal, lateral femoral cutaneous, and obturator nerves may be responsible for the pain. Gilmore's groin will be added as a sub-concept LLT to PT Muscle strain.

Supplemental Update Report

CR Number: 2018165012 **Implementation Date:** 05-Jul-18 Related CR: 2018165012

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Ophidiophobia*	Approved as Requested	Proposed LLT	
			Ophidiophobia	10081819 Current
			To PT	
			Herpetophobia	10081809

MSSO Comment: The proposal to add a new term Ophidiophobia is approved as requested. Ophidiophobia or ophiophobia is a particular type of specific phobia, the abnormal fear of snakes. It is sometimes called by a more general term, herpetophobia, fear of reptiles or amphibians. Ophidiophobia will be added as a sub-concept LLT to PT Herpetophobia added in change request 2018165013.

CR Number: 2018165013 **Implementation Date:** 05-Jul-18 Related CR: 2018165013

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Herpetophobia*	Approved as Requested	Proposed PT	
			Herpetophobia	10081809
			HLT primary	
			Fear symptoms and phobic disorders (incl social phobia)	10068299
			SOC primary	
			Psychiatric disorders	10037175

MSSO Comment: The proposal to add a new term Herpetophobia is approved as requested. Herpetophobia is a specific phobia, which consists of fear or aversion to reptiles, commonly lizards and snakes. Herpetophobia will be added as a PT to HLT Fear symptoms and phobic disorders (incl social phobia).

CR Number: 2018165014 **Implementation Date:** 12-Jul-18 Related CR: 2018165014

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Fear of death*	Rejected		
To PT	*Thanatophobia*			

MSSO Comment: The proposal to demote the PT Fear of death under PT Thanatophobia is not approved. Fear and phobia are two distinct concepts described in the psychiatric literature and therefore they should be kept as separate PTs.

Supplemental Update Report

CR Number: **2018165015** **Implementation Date:** 12-Jul-18 Related CR: 2018165015

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Angor mortis*	Rejected		
From PT	*Fear of death*			
To PT	*Thanatophobia*			

MSSO Comment: The proposal to move the LLT Angor mortis from PT Fear of death to PT Thanatophobia is not approved. Angor mortis, a feeling of imminent death, represents an intense feeling of fear which is better represented under PT Fear of death. Angor mortis does not fulfill the criteria of a phobic disorder.

CR Number: **2018165016** **Implementation Date:** 06-Jul-18 Related CR: 2018165016

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Generalised allergic skin reaction*	Rejected		

MSSO Comment: The proposal to add a new term Generalised allergic skin reaction is not approved. The existing LLT Allergic skin reaction can be coded to convey the allergic nature of the event. Furthermore, if the coder wishes to code additional information on the distribution of the reaction, split coding can be done with LLT Allergic skin reaction and LLTs such as LLT Generalized rash, or LLT Generalized macular rash.

CR Number: **2018166001** **Implementation Date:** 06-Jul-18 Related CR: 2018166001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Chronic lymphocytic leukemia of B-cell type not having achieved remission*	Approved Not as Requested	Proposed LLT		
			B-cell chronic lymphocytic leukemia refractory	10081842	Current
			To PT		
			Chronic lymphocytic leukaemia refractory	10008962	

MSSO Comment: The proposal to add a new LLT Chronic lymphocytic leukemia of B-cell type not having achieved remission is approved but not as requested. Chronic lymphocytic leukemia of B-cell type not having achieved remission will be modified for clarification and added as LLT B-cell chronic lymphocytic leukemia refractory to PT Chronic lymphocytic leukaemia refractory. In a related change the British spelled counterpart LLT B-cell chronic lymphocytic leukaemia refractory will also be added to PT Chronic lymphocytic leukaemia refractory.

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CR Number: 2018187002 **Implementation Date:** 06-Jul-18 Related CR: 2018166001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*B-cell chronic lymphocytic leukaemia refractory*	Approved as Requested	Proposed LLT	
To PT	*Chronic lymphocytic leukaemia refractory*		*B-cell chronic lymphocytic leukaemia refractory*	10081843 Current
			To PT	
			Chronic lymphocytic leukaemia refractory	10008962

MSSO Comment:

CR Number: 2018166002 **Implementation Date:** 06-Jul-18 Related CR: 2018166002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Spindle cell carcinoma of the skin*	Approved as Requested	Proposed LLT	
			Spindle cell carcinoma of the skin	10081844 Current
			To PT	
			Squamous cell carcinoma of skin	10041834

MSSO Comment: The proposal to add a new LLT Spindle cell carcinoma of the skin is approved as requested. Spindle cell squamous cell carcinoma is a rare variant of squamous cell carcinoma, therefore Spindle cell carcinoma of the skin will be added as an LLT to PT Squamous cell carcinoma of skin.

CR Number: 2018169001 **Implementation Date:** 05-Jul-18 Related CR: 2018169001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Asymptomatic ARIA-E*	Approved Not as Requested	Proposed LLT	
			Asymptomatic ARIA-E	10081821 Current
			To PT	
			Amyloid related imaging abnormality-oedema/effusion	10072260

MSSO Comment: The proposal to add a new PT Asymptomatic ARIA-E is approved but not as requested. Though MedDRA does not usually differentiate between symptomatic or asymptomatic states of conditions, the clinical relevance of the presence or absence of symptoms associated to amyloid related imaging abnormalities images of cerebral amyloid angiopathy warrants the addition of Asymptomatic ARIA-E as a sub-concept LLT to PT Amyloid related imaging abnormality-oedema/effusion.

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CR Number: 2018169002 **Implementation Date:** 05-Jul-18 Related CR: 2018169002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Symptomatic ARIA-E*	Approved Not as Requested	Proposed LLT	
			Symptomatic ARIA-E	10081823 Current
			To PT	
			Amyloid related imaging abnormality-oedema/effusion	10072260

MSSO Comment: The proposal to add a new PT Symptomatic ARIA-E is approved but not as requested. Though MedDRA does not usually differentiate between symptomatic or asymptomatic states of conditions, the clinical relevance of the presence or absence of symptoms associated to amyloid related imaging abnormalities images of cerebral amyloid angiopathy warrants the addition of Symptomatic ARIA-E as a sub-element LLT of PT Amyloid related imaging abnormality-oedema/effusion.

CR Number: 2018169003 **Implementation Date:** 05-Jul-18 Related CR: 2018169003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Asymptomatic ARIA-H*	Approved Not as Requested	Proposed LLT	
			Asymptomatic ARIA-H	10081820 Current
			To PT	
			Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits	10072601

MSSO Comment: The proposal to add a new PT Asymptomatic ARIA-H is approved but not as requested. Though MedDRA does not usually differentiate between symptomatic or asymptomatic states of conditions, the clinical relevance of the presence or absence of symptoms associated to amyloid related imaging abnormalities images of cerebral amyloid angiopathy warrants the addition of Asymptomatic ARIA-H as a sub-concept LLT to PT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits.

CR Number: 2018169004 **Implementation Date:** 05-Jul-18 Related CR: 2018169004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Symptomatic ARIA-H*	Approved Not as Requested	Proposed LLT	
			Symptomatic ARIA-H	10081822 Current
			To PT	
			Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits	10072601

MSSO Comment: The proposal to add a new PT Symptomatic ARIA-H is approved but not as requested. Though MedDRA does not usually differentiate between symptomatic or asymptomatic states of conditions, the clinical relevance of the presence or absence of symptoms associated to amyloid related imaging abnormalities images of cerebral amyloid angiopathy warrants the addition of Symptomatic ARIA-H as a sub-concept LLT to PT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits.

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CR Number: **2018170001** **Implementation Date:** 06-Jul-18 Related CR: 2018170001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Surfer;s eye*	Approved Not as Requested	Proposed LLT	
To PT	*Pterygium*		*Surfer's eye*	10081845 Current
			To PT	
			Pterygium	10037263

MSSO Comment: The proposal to add a new LLT Surfer;s eye to PT Pterygium is approved but not as requested. The requested concept will be added with corrected punctuation as Surfer's eye as an LLT to PT Pterygium.

CR Number: **2018170002** **Implementation Date:** 06-Jul-18 Related CR: 2018170002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Eye web*	Rejected		
To PT	*Pterygium*			

MSSO Comment: The proposal to add a new LLT Eye web to PT Pterygium is not approved. The requested term represents a colloquial expression which does not necessarily relate to a Pterygium.

CR Number: **2018170003** **Implementation Date:** 06-Jul-18 Related CR: 2018170003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Getting your tubes tied*	Rejected		
To PT	*tubal ligation*			

MSSO Comment: The proposal to add a new LLT Getting your tubes tied to PT tubal ligation is not approved. The requested term represents a colloquial expression which may not have a universally-accepted international interpretation. The requester can add this colloquial expression to their organization's synonym list for tubal ligation. The concept is appropriately represented by LLT Tubal ligation in MedDRA.

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CR Number: 2018170004 **Implementation Date:** 06-Jul-18 Related CR: 2018170004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Thornwaldt bursitis*	Approved Not as Requested	Proposed PT	
To PT	*Thornwaldt disease*		*Tornwaldt bursitis*	10081846
			HLT primary	
			Upper respiratory tract infections	10046309
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Upper respiratory tract infections NEC	10045573
			SOC secondary	
			Respiratory, thoracic and mediastinal disorders	10038738

MSSO Comment: The proposal to add a new LLT Thornwaldt bursitis to PT Thornwaldt disease is approved but not as requested. The requested term will be added with corrected spelling as Tornwaldt bursitis as a PT to primary HLT Upper respiratory tract infections and secondary HLT Upper respiratory tract infections NEC. In a related change, existing PT Thornwaldt disease will be merged under new PT Tornwaldt bursitis because this spelling is also commonly used in literature but not really the correct eponym.

CR Number: 2018187003 **Implementation Date:** 06-Jul-18 Related CR: 2018170004

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Thornwaldt disease*	Approved as Requested	PT to merge	
To PT	*Tornwaldt bursitis*		*Thornwaldt disease*	10070524 Current
			To PT	
			Tornwaldt bursitis	10081846

MSSO Comment:

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CR Number: 2018172001 **Implementation Date:** 05-Jul-18 Related CR: 2018172001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ureaplasma urealyticum infection*	Approved as Requested	Proposed LLT	
To PT	*Ureaplasma infection*		*Ureaplasma urealyticum infection*	10081825 Current
			To PT	
			Ureaplasma infection	10059640

MSSO Comment: The proposal to add a new LLT Ureaplasma urealyticum infection to PT Ureaplasma infection is approved as requested. Ureaplasma urealyticum is the most frequent species of Ureaplasma infections and is associated with a variety of genitourinary tract disorders and neonatal infections.

CR Number: 2018172002 **Implementation Date:** 05-Jul-18 Related CR: 2018172002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Herpes zoster immunisation*	Approved as Requested	Proposed PT	
			Herpes zoster immunisation	10081824
			HLT primary	
			Immunisations	10021431
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Herpes zoster immunisation is approved as requested. Herpes zoster immunization is principally based on a new recombinant vaccine which has proved to be more than 90% effective in preventing shingles and post-herpetic neuralgia in adults 50 and older. Herpes zoster immunisation will be added as a PT to HLT Immunisations. In an associated change, the American spelled counterpart Herpes zoster immunization will be added as an LLT to PT Herpes zoster immunisation.

CR Number: 2018186026 **Implementation Date:** 05-Jul-18 Related CR: 2018172002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Herpes zoster immunization*	Approved as Requested	Proposed LLT	
To PT	*Herpes zoster immunisation*		*Herpes zoster immunization*	10081826 Current
			To PT	
			Herpes zoster immunisation	10081824

MSSO Comment:

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CR Number: 2018173001 **Implementation Date:** 05-Jul-18 Related CR: 2018173001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Gaming disorder*	Approved as Requested	Proposed PT	
			Gaming disorder	10081827
			HLT primary	
			Substance related and addictive disorders	10079102
			SOC primary	
			Psychiatric disorders	10037175

MSSO Comment: The proposal to add a new term Gaming disorder is approved as requested. Gaming disorder is a pattern of persistent or recurrent gaming, to the point of not being able to control one's urge to play video games. It is considered a mental health condition, in which playing video games takes priority over other interests and activities, without regard to negative consequences. Although there are differing opinions as to whether addictive gaming behaviors should be classified as a disorder, the World Health Organization included gaming disorder alongside gambling disorder under "Disorders Due to Addictive Behaviors" in its diagnostic International Classification of Diseases. Because Gaming disorder is a recognized concept, it will be added as a PT to HLT Substance related and addictive disorders. In a related change, Internet gaming disorder, as listed in the Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM-5), Section III, will be added as an LLT to PT Gaming disorder.

CR Number: 2018186028 **Implementation Date:** 05-Jul-18 Related CR: 2018173001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Internet gaming disorder*	Approved as Requested	Proposed LLT	
To PT	*Gaming disorder*		*Internet gaming disorder*	10081829 Current
			To PT	
			Gaming disorder	10081827

MSSO Comment:

CR Number: 2018173002 **Implementation Date:** 05-Jul-18 Related CR: 2018173002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Tumor Infection*	Approved Not as Requested	Proposed LLT	
To PT	*Infected neoplasm*		*Tumor infection*	10081828 Current
			To PT	
			Infected neoplasm	10058014

MSSO Comment: The proposal to add a new LLT Tumor Infection to PT Infected neoplasm is approved but not as requested. Recognizing that a tumour is a form of neoplasm, LLT Tumor infection, modified according to MedDRA capitalization conventions, will be added as a sub-concept LLT to PT Infected neoplasm. In a related change, the British English counterpart spelling, LLT Tumour infection will also be added to PT Infected neoplasm.

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CR Number: 2018186027 **Implementation Date:** 05-Jul-18 Related CR: 2018173002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Tumour infection*	Approved as Requested	Proposed LLT	
To PT	*Infected neoplasm*		*Tumour infection*	10081830 Current
			To PT	
			Infected neoplasm	10058014

MSSO Comment:

CR Number: 2018173003 **Implementation Date:** 05-Jul-18 Related CR: 2018173003

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*High response to ovarian stimulation*	Approved as Requested	Proposed PT	
To HLT	*Female gonadal function disorders*		*High response to ovarian stimulation*	10081734
			To HLT	
			Female gonadal function disorders	10013307

MSSO Comment: The proposal to link the PT High response to ovarian stimulation to the HLT Female gonadal function disorders is approved as requested. High response to ovarian stimulation is also correlated with Female gonadal function disorders and etiologically is similar to the existing PT Ovarian hyperstimulation syndrome.

CR Number: 2018173004 **Implementation Date:** 10-Jul-18 Related CR: 2018173004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Chronic pneumonitis*	Approved as Requested	Proposed LLT	
			Chronic pneumonitis	10081849 Current
			To PT	
			Pneumonitis	10035742

MSSO Comment: The proposal to add a new LLT Chronic pneumonitis is approved as requested. Pneumonitis is an acute or chronic inflammation of the lungs that is characterized especially by cough, shortness of breath, fatigue, and fever, and may result in the development of fibrotic scar tissue when chronic or untreated. Therefore, Chronic pneumonitis will be added as a sub-concept LLT to PT Pneumonitis.

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CR Number: 2018173005 **Implementation Date:** 10-Jul-18 Related CR: 2018173005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Portal Vein Tumor Thrombus*	Rejected		

MSSO Comment: The proposal to add a new LLT Portal Vein Tumor Thrombus is not approved. It is not practical for MedDRA to contain a term for every type of malignancy related thrombotic event. Please consider using the existing LLT Thrombosis portal vein and LLT Paraneoplastic thrombosis.

CR Number: 2018176001 **Implementation Date:** 11-Jul-18 Related CR: 2018176001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ovarian gonadoblastoma*	Approved Not as Requested	Proposed LLT	
			Ovarian gonadoblastoma	10081854 Current
			To PT	
			Ovarian germ cell tumour	10075812

MSSO Comment: The proposal to add a new PT Ovarian gonadoblastoma is approved but not as requested. Gonadoblastoma is a complex neoplasm composed of a mixture of gonadal elements, such as large primordial germ cells, immature Sertoli cells or granulosa cells of the sex cord, and gonadal stromal cells, which frequently affects a subset of patients with an intersex disorder or disorder of sex development. Therefore, Ovarian gonadoblastoma will be added as a sub-concept LLT to PT Ovarian germ cell tumour. In a related change, LLT Gonadoblastoma will be moved from PT Testicular germ cell cancer to PT Germ cell neoplasm for better placement.

CR Number: 2018191001 **Implementation Date:** 11-Jul-18 Related CR: 2018176001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Gonadoblastoma*	Approved as Requested	Proposed LLT	
From PT	*Testicular germ cell cancer*		*Gonadoblastoma*	10018506 Current
To PT	*Germ cell neoplasm*		From PT	
			Testicular germ cell cancer	10061378
			To PT	
			Germ cell neoplasm	10075292

MSSO Comment:

Supplemental Update Report

CR Number: 2018176002 **Implementation Date:** 11-Jul-18 Related CR: 2018176002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Lacrimal gland insufficiency*	Approved Not as Requested	Proposed LLT	
			Lacrimal gland insufficiency	10081852 Current
			To PT	
			Dry eye	10013774

MSSO Comment: The proposal to add a new PT Lacrimal gland insufficiency is approved but not as requested. The proposed term relates to the inadequate function of the lacrimal gland usually producing the symptom of dry eye, and therefore will be added as an LLT to PT Dry eye.

CR Number: 2018176003 **Implementation Date:** 11-Jul-18 Related CR: 2018176003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*CORNEAL GRAFT FAILURE*	Approved Not as Requested	Proposed PT	
			Corneal graft failure	10081851
			HLT primary	
			Transplantation complications	10074474
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Corneal disorders NEC	10011004
			SOC secondary	
			Eye disorders	10015919

MSSO Comment: The proposal to add a new PT CORNEAL GRAFT FAILURE is approved but not as requested. While the term graft rejection refers to a specific immunologic response of the host to the donor corneal tissue, the term corneal graft failure represents other non-immune mediated graft failures, such as primary donor failure, or “high-risk” recipients complications, as those derived from vascularization of the cornea. Corneal graft failure will be added, in accordance with MedDRA capitalization conventions, as a PT with a primary link to HLT Transplantation complications and a secondary link to Corneal disorders NEC.

Supplemental Update Report

CR Number: 2018176004 **Implementation Date:** 11-Jul-18 Related CR: 2018176004

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*raised TG*	Approved Not as Requested	LLT to change	
Status	*non-current*		*Raised TG*	10037828 Non-Current
			Status	
			Non-current	

MSSO Comment: The proposal to change status of LLT raised TG to non-current is approved but not as requested. The capitalized LLT Raised TG will be made non-current for its ambiguity as a stand alone term, provided the many medical concepts it may represent, such as: triglyceride; tendon graft; testosterone glucuronide; tocogram; total gastrectomy; toxic goiter; transmissible gastroenteritis; treated group; tricuspid gradient; trigeminal ganglion; tumor growth, etc.

CR Number: 2018176005 **Implementation Date:** 11-Jul-18 Related CR: 2018176005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Jugular vein embolism*	Approved as Requested	Proposed PT	
			Jugular vein embolism	10081850
			HLT primary	
			Peripheral embolism and thrombosis	10034572
			SOC primary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new term Jugular vein embolism is approved as requested. Jugular vein embolism represents the origin of a migrating embolus in the internal or external jugular vein. Jugular vein embolism will be added as a PT to HLT Peripheral embolism and thrombosis.

CR Number: 2018176006 **Implementation Date:** 11-Jul-18 Related CR: 2018176006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Presacral abscess*	Approved Not as Requested	Proposed LLT	
			Presacral abscess	10081853 Current
			To PT	
			Pelvic abscess	10034236

MSSO Comment: The proposal to add a new PT Presacral abscess is approved but not as requested. Presacral abscess will be added as a anatomical sub-concept LLT to existing PT Pelvic abscess.

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CR Number: 2018176007 **Implementation Date:** 11-Jul-18 Related CR: 2018176007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Littoral cell angioma*	Approved Not as Requested	Proposed LLT	
To PT	*Hemangioma of spleen*		*Littoral cell angioma*	10081855 Current
			To PT	
			Haemangioma of spleen	10068123

MSSO Comment: The proposal to add a new LLT Littoral cell angioma to PT Hemangioma of spleen is approved but not as requested. Littoral cell angioma will be added as an LLT under PT Haemangioma of spleen, the British English counterpart at the PT level. Littoral-cell angioma is a type of primary splenic hemangioma clinically and is mostly found in the normal spleen red sinus shore cells. It is essentially a benign splenic hemangioma with malignant potential. A typical feature of littoral-cell angioma is that the associated antigens of endothelial cells and tissue cells can be expressed strongly at the same time, thereby representing the characteristic of double differentiation; a characteristic different to normal spleen red sinus shore cells which are only positive for endothelial cell markers.

CR Number: 2018176008 **Implementation Date:** 11-Jul-18 Related CR: 2018176008

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Cancer pain*	Rejected		
To PT	*Tumor pain*			

MSSO Comment: The proposal to demote the PT Cancer pain under PT Tumor pain is not approved. While the MSSO recognizes there is an overlap in the use of cancer pain and tumor pain, cancer pain is not necessarily limited to the tumor site. In addition, tumor pain can be related to either a malignant or benign mass.

CR Number: 2018176009 **Implementation Date:** 11-Jul-18 Related CR: 2018176009

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Transient hypogammaglobulinemia*	Approved Not as Requested	LLT to change	
From PT	*Transient hypogammaglobulinaemia of infancy*		*Transient hypogammaglobulinemia*	10044389 Non-Current
To PT	*Hypogammaglobulinaemia*		Status	
			Non-current	

MSSO Comment: The proposal to move the LLT Transient hypogammaglobulinemia from PT Transient hypogammaglobulinaemia of infancy to PT Hypogammaglobulinaemia is approved but not as requested. "Transient" can refer to unspecified transient hypogammaglobulinemia in adults or to Transient hypogammaglobulinemia of infancy. Therefore, due to the ambiguity of the term, the status of LLT Transient hypogammaglobulinemia will be changed to Non-current. In a related change, the British English counterpart LLT Transient hypogammaglobulinaemia will also be made Non-current.

Supplemental Update Report

CR Number: 2018191002 **Implementation Date:** 11-Jul-18 Related CR: 2018176009

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Change Status of LLT				
LLT to change	*Transient hypogammaglobulinaemia*	Approved as Requested	LLT to change	
Status	*Non-current*		*Transient hypogammaglobulinaemia*	10060426 Non-Current
			Status	
			Non-current	

MSSO Comment:

CR Number: 2018176056 **Implementation Date:** 06-Jul-18 Related CR: 2018176056

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Plasma cell myeloma refractory*	Approved Not as Requested	Proposed PT	
			Plasma cell myeloma refractory	10081847
			HLT primary	
			Plasma cell myelomas	10074470
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Plasma cell myelomas	10074470
			SOC secondary	
			Blood and lymphatic system disorders	10005329

MSSO Comment: The proposal to add a new LLT Plasma cell myeloma refractory is approved but not as requested. Relapsed/progressive multiple myeloma acquires additional mutation or genetic alterations that render the disease more resistant, leading to progressively shorter durations of remission or response to each salvage therapy, and the ultimate development of relapsed/refractory multiple myeloma. Plasma cell myeloma refractory will be added as a PT to HLT Plasma cell myelomas which is subordinate to bi-axial HLGT Plasma cell neoplasms, under primary SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps), and secondary SOC Blood and lymphatic system disorders.

Supplemental Update Report

CR Number: 2018176057 **Implementation Date:** 06-Jul-18 Related CR: 2018176057

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Allogenic stem cell transplantation*	Approved Not as Requested	Proposed LLT	
From PT	*Stem cell transplant*		*Allogenic stem cell transplantation*	10067859
To PT	*Allogenic stem cell transplantation*		From PT	
			Stem cell transplant	10063581
			HLT primary	
			Blood and blood product treatment	10019028
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to move the LLT Allogenic stem cell transplantation from PT Stem cell transplant to PT Allogenic stem cell transplantation is approved but not as requested. Allogeneic stem cell transplantation is a procedure in which a person receives blood-forming stem cells from a genetically similar, but not identical, donor to suppress the disease and restore the patient's immune system. In general, allogeneic transplants have been used predominantly in the treatment of leukemias and myelodysplastic syndromes. Because of its specificity in technique and indications, Allogenic stem cell transplantation warrants representation at the PT level, and will be promoted from PT Stem cell transplant to a PT under HLT Blood and blood product treatment. In a related change, the following LLTs will be moved from PT Stem cell transplant to the newly promoted PT Allogenic stem cell transplantation: LLT Allogeneic peripheral haematopoietic stem cell transplant, LLT Allogeneic peripheral hematopoietic stem cell transplant, and LLT Allogeneic stem cell transplantation.

CR Number: 2018187007 **Implementation Date:** 06-Jul-18 Related CR: 2018176057

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Allogeneic peripheral haematopoietic stem cell transplant*	Approved as Requested	Proposed LLT	
From PT	*Stem cell transplant*		*Allogeneic peripheral haematopoietic stem cell transplant*	10059041 Current
To PT	*Allogenic stem cell transplantation*		From PT	
			Stem cell transplant	10063581
			To PT	
			Allogenic stem cell transplantation	10067859

MSSO Comment:

Supplemental Update Report

CR Number: 2018187008 **Implementation Date:** 06-Jul-18 Related CR: 2018176057

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Allogeneic peripheral hematopoietic stem cell transplant*	Approved as Requested	Proposed LLT		
			Allogeneic peripheral hematopoietic stem cell transplant	10059044	Current
From PT	*Stem cell transplant*		From PT		
			Stem cell transplant	10063581	
To PT	*Allogenic stem cell transplantation*		To PT		
			Allogenic stem cell transplantation	10067859	

MSSO Comment:

CR Number: 2018187009 **Implementation Date:** 06-Jul-18 Related CR: 2018176057

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Allogeneic stem cell transplantation*	Approved as Requested	Proposed LLT		
			Allogeneic stem cell transplantation	10067862	Current
From PT	*Stem cell transplant*		From PT		
			Stem cell transplant	10063581	
To PT	*Allogenic stem cell transplantation*		To PT		
			Allogenic stem cell transplantation	10067859	

MSSO Comment:

Supplemental Update Report

CR Number: 2018176058 **Implementation Date:** 06-Jul-18 Related CR: 2018176058

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Autologous peripheral hematopoietic stem cell transplant*	Approved Not as Requested	Proposed LLT	
			Autologous haematopoietic stem cell transplant	10081347
From PT	*Stem cell transplant*		From PT	
			Stem cell transplant	10063581
To PT	*Autologous peripheral haematopoietic stem cell transplant*		HLT primary	
			Blood and blood product treatment	10019028
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to move the LLT Autologous peripheral hematopoietic stem cell transplant from PT Stem cell transplant to PT Autologous peripheral haematopoietic stem cell transplant is approved but not as requested. Peripheral blood stem cell transplantation is a procedure in which a patient receives healthy blood-forming cells to replace their own stem cells that have been destroyed by disease, radiation, or high doses of anticancer drugs. A blood stem cell transplant may be autologous, using a patient's own stem cells that were collected and saved before treatment. Autologous haematopoietic stem cell transplant will be promoted from PT Stem cell transplant to a PT under HLT Blood and blood product treatment. In a related change, the following LLTs will be moved from PT Stem cell transplant to the newly promoted PT Autologous haematopoietic stem cell transplant: LLT Autologous hematopoietic stem cell transplant, LLT Autologous peripheral haematopoietic stem cell transplant and LLT Autologous peripheral hematopoietic stem cell transplant.

CR Number: 2018187004 **Implementation Date:** 06-Jul-18 Related CR: 2018176058

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Autologous hematopoietic stem cell transplant*	Approved as Requested	Proposed LLT	
			Autologous hematopoietic stem cell transplant	10081344 Current
From PT	*Stem cell transplant*		From PT	
			Stem cell transplant	10063581
To PT	*Autologous haematopoietic stem cell transplant*		To PT	
			Autologous haematopoietic stem cell transplant	10081347

MSSO Comment:

Supplemental Update Report

CR Number: 2018187005 **Implementation Date:** 06-Jul-18 Related CR: 2018176058

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Autologous peripheral haematopoietic stem cell transplant*	Approved as Requested	Proposed LLT *Autologous peripheral haematopoietic stem cell transplant*	10059040 Current
From PT	*Stem cell transplant*		From PT *Stem cell transplant*	10063581
To PT	*Autologous haematopoietic stem cell transplant*		To PT *Autologous haematopoietic stem cell transplant*	10081347

MSSO Comment:

CR Number: 2018187006 **Implementation Date:** 06-Jul-18 Related CR: 2018176058

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Autologous peripheral hematopoietic stem cell transplant*	Approved as Requested	Proposed LLT *Autologous peripheral hematopoietic stem cell transplant*	10059043 Current
From PT	*Stem cell transplant*		From PT *Stem cell transplant*	10063581
To PT	*Autologous haematopoietic stem cell transplant*		To PT *Autologous haematopoietic stem cell transplant*	10081347

MSSO Comment:

Supplemental Update Report

CR Number: 2018176059 **Implementation Date:** 06-Jul-18 Related CR: 2018176059

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Tonsillar hyperplasia*	Approved as Requested	Proposed LLT	
			Tonsillar hyperplasia	10081848 Current
			To PT	
			Tonsillar hypertrophy	10044003

MSSO Comment: The proposal to add a new LLT Tonsillar hyperplasia is approved as requested. Tonsillar hyperplasia will be added as an LLT under the PT Tonsillar hypertrophy. Hyperplasia results when the component cells of a tissue are stimulated to undergo mitotic division, thereby increasing the number of cells. Hypertrophy results from increased amounts of cytoplasm and cytoplasmic organelles in cells. Strictly speaking, hyperplasia and hypertrophy are not synonymous, but in practice the terms are used in such a manner. Consequently, in MedDRA hyperplasia concepts are often placed as sub-concept LLTs to hypertrophy terms.

CR Number: 2018177001 **Implementation Date:** 11-Jul-18 Related CR: 2018177001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New Term				
Proposed Term	*Macroorchidism*	Approved as Requested	Proposed PT	
			Macroorchidism	10081860
			HLT primary	
			Testicular and epididymal disorders NEC	10043296
			SOC primary	
			Reproductive system and breast disorders	10038604

MSSO Comment: The proposal to add a new term Macroorchidism is approved as requested. Macroorchidism is defined as an increase of testicular volume at least twice the normal for age. A variety of potential etiologies may be associated with Macroorchidism, including: genetic, endocrine, idiopathic and secondary to neoplasm or testicular torsions. Macroorchidism will be added as a PT to HLT Testicular and epididymal disorders NEC.

CR Number: 2018177002 **Implementation Date:** 11-Jul-18 Related CR: 2018177002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New Term				
Proposed Term	*Dysdiadochokinesia*	Rejected		

MSSO Comment: The proposal to add a new term Dysdiadochokinesia is not approved. The concept LLT Dysdiadochokinesis already exists in MedDRA.

Supplemental Update Report

CR Number: 2018177003 **Implementation Date:** 03-Aug-18 Related CR: 2018177003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*Laparoscopic implantation of neuroprothesis or LION procedure*	Approved Not as Requested After Suspension	Proposed LLT *Laparoscopic implantation of neuroprosthesis*	10081970	Current
			To PT *Neuroprosthesis implantation*	10081968	

MSSO Comment: The proposal to add a new term Laparoscopic implantation of neuroprothesis or LION procedure is approved but not as requested after suspension. A neuroprosthesis is a device used to improve the function of an impaired nervous system, often in the form of a neurostimulator. Laparoscopic implantation of neuroprosthesis (with corrected spelling and without the acronym LION procedure) will be added as a sub-concept LLT to a broader new PT Neuroprosthesis implantation. In a related change, PT Neuroprosthesis implantation will be added to HLT Nervous system therapeutic procedures NEC. Furthermore, the frequently used synonym LION procedure will be added as an LLT to PT Neuroprosthesis implantation. Additionally, PT Neurostimulator implantation will be demoted as a sub-concept LLT to new PT Neuroprosthesis implantation.

CR Number: 2018214935 **Implementation Date:** 03-Aug-18 Related CR: 2018177003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neuroprosthesis implantation*	Approved as Requested	Proposed PT *Neuroprosthesis implantation*	10081968
HLT primary	*Nervous system therapeutic procedures NEC*		HLT primary *Nervous system therapeutic procedures NEC*	10052731
SOC primary	*Surgical and medical procedures*		SOC primary *Surgical and medical procedures*	10042613

MSSO Comment:

CR Number: 2018214936 **Implementation Date:** 03-Aug-18 Related CR: 2018177003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*LION procedure*	Approved as Requested	Proposed LLT *LION procedure*	10081969	Current
To PT	*Neuroprosthesis implantation*		To PT *Neuroprosthesis implantation*	10081968	

MSSO Comment:

Supplemental Update Report

CR Number: **2018214937** **Implementation Date:** 03-Aug-18 Related CR: 2018177003

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Neurostimulator implantation*	Approved as Requested	PT to merge	
To PT	*Neuroprosthesis implantation*		*Neurostimulator implantation*	10069205 Current
			To PT	
			Neuroprosthesis implantation	10081968

MSSO Comment:

CR Number: **2018177004** **Implementation Date:** 11-Jul-18 Related CR: 2018177004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Neocerebellar syndrome*	Approved as Requested	Proposed LLT	
			Neocerebellar syndrome	10081867 Current
			To PT	
			Cerebellar syndrome	10008072

MSSO Comment: The proposal to add a new term Neocerebellar syndrome is approved as requested. Neocerebellar (or lateral cerebellar) disorder results in diminished muscle tone, disturbances of muscular coordination, and tremor. In a unilateral lesion, the motor disorders are expressed on the same side as the lesion. Neocerebellar syndrome will be added as a sub-concept LLT to PT Cerebellar syndrome.

CR Number: **2018177005** **Implementation Date:** 11-Jul-18 Related CR: 2018177005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Medication induced nausea*	Rejected		

MSSO Comment: The proposal to add a new term Medication induced nausea is not approved. MedDRA cannot accommodate a separate MedDRA term for the combination of all possible diseases and medical conditions with an associated drug product or etiology. For the same reason, the terminology generally does not include "due to concepts" unless the closely associated disorder and etiology are an internationally recognized term concept, such as diabetic retinopathy, hypertensive cardiomegaly, etc. The requested term can be represented by LLT Nausea.

Supplemental Update Report

CR Number: 2018177006 **Implementation Date:** 11-Jul-18 Related CR: 2018177006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Catheter ablation*	Approved Not as Requested	Proposed LLT	
			Cardiac catheter ablation	10081865 Current
			To PT	
			Cardiac ablation	10059864

MSSO Comment: The proposal to add a new term Catheter ablation is approved but not as requested. Catheter ablation is usually used in the context of a treatment that uses radiofrequency energy to remove small areas of heart tissue that cause tachyarrhythmias. For clarification, Catheter ablation will be added as a synonym LLT Cardiac catheter ablation to PT Cardiac ablation.

CR Number: 2018177007 **Implementation Date:** 11-Jul-18 Related CR: 2018177007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Paroxysmal extreme pain disorder or familial rectal pain syndrome*	Approved Not as Requested	Proposed PT	
			Paroxysmal extreme pain disorder	10081856
			HLT primary	
			Peripheral nervous system disorders congenital NEC	10052632
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Anal and rectal pains	10002115
			SOC secondary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new term Paroxysmal extreme pain disorder or familial rectal pain syndrome is approved but not as requested. Paroxysmal extreme pain disorder is a rare autosomal dominant inherited condition characterized by skin flushing and attacks of severe pain in various parts of the body, especially in the anorectal area. The area of flushing typically corresponds to the site of the pain. The pain attacks usually last seconds to minutes, but can last hours. Paroxysmal extreme pain disorder is considered a form of peripheral neuropathy because it affects the peripheral nervous system. Paroxysmal extreme pain disorder will be added as a PT to primary HLT Peripheral nervous system disorders congenital NEC and secondary HLTs - HLT Anal and rectal pains and HLT Peripheral neuropathies NEC. Additionally, synonym LLT Familial rectal pain syndrome will be added to new PT Paroxysmal extreme pain disorder.

Supplemental Update Report

CR Number: 2018191003 **Implementation Date:** 11-Jul-18 Related CR: 2018177007

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Paroxysmal extreme pain disorder*	Approved as Requested	Proposed PT	
To HLT	*Peripheral neuropathies NEC*		*Paroxysmal extreme pain disorder*	10081856
			To HLT	
			Peripheral neuropathies NEC	10034607

MSSO Comment:

CR Number: 2018191004 **Implementation Date:** 11-Jul-18 Related CR: 2018177007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Familial rectal pain syndrome*	Approved as Requested	Proposed LLT	
To PT	*Paroxysmal extreme pain disorder*		*Familial rectal pain syndrome*	10081871 Current
			To PT	
			Paroxysmal extreme pain disorder	10081856

MSSO Comment:

CR Number: 2018177008 **Implementation Date:** 11-Jul-18 Related CR: 2018177008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Ocular lesion or retinal lesion*	Rejected		

MSSO Comment: The proposal to add a new term Ocular lesion or retinal lesion is not approved. Although "ocular lesion" or "retinal lesion" are sometimes used to describe a tumor, the definition of lesion is considerably broader in nature, as it may represent a region in an organ or tissue that has suffered damage through injury or disease, such as a wound, ulcer, abscess, tumor, etc. The MSSO refrains from including additional "lesion" terms in MedDRA, except when the word “lesion” is part of the wording of a medical concept e.g., PT Glomerulonephritis minimal lesion, or is itself a well documented medical concept (e.g., LLT Bankart lesion). Generally, a broad “lesion” term only adds an additional imprecise term to existing “disorder” concepts. Please consider the existing terms such as LLT Retinal disorder, and LLT Eye disorder for your coding needs.

Supplemental Update Report

CR Number: 2018177009 **Implementation Date:** 11-Jul-18 Related CR: 2018177009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Sensory defensiveness*	Approved as Requested	Proposed LLT	
			Sensory defensiveness	10081863 Current
			To PT	
			Sensory processing disorder	10077516

MSSO Comment: The proposal to add a new term Sensory defensiveness is approved as requested. Sensory defensiveness is an intense reaction to a stimulus that most people would not perceive as negative. Individuals with sensory defensiveness over-respond to sensory input and react by displaying negative emotions or behaviors processing sensory information from the auditory, olfactory, visual, vestibular, and tactile systems. Oral defensiveness, gravitational insecurity, and postural insecurity have also been described. Sensory defensiveness indicates a low neurological threshold for the brain to respond to sensory information, as it is a sensory processing disorder frequently thought to be linked to poor limbic or reticular system processing. Sensory defensiveness will be added as a sub-concept LLT to PT Sensory processing disorder.

CR Number: 2018177010 **Implementation Date:** 11-Jul-18 Related CR: 2018177010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Scleral reinforcement*	Approved as Requested	Proposed PT	
			Scleral reinforcement	10081858
			HLT primary	
			Corneal and scleral therapeutic procedures	10010988
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Scleral reinforcement is approved as requested. Scleral reinforcement is a surgical procedure used to reduce or stop further macular damage caused by high degenerative myopia. The surgery aims to cover the thinning posterior pole with a supportive material to withstand intraocular pressure and prevent further progression of the posterior staphyloma. Scleral reinforcement will be added as a PT under HLT Corneal and scleral therapeutic procedures.

CR Number: 2018177011 **Implementation Date:** 11-Jul-18 Related CR: 2018177011

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Procedure site bruising*	Approved as Requested	Proposed LLT	
			Procedure site bruising	10081866 Current
			To PT	
			Post procedural contusion	10073353

MSSO Comment: The proposal to add a new term Procedure site bruising is approved as requested. Nearly any procedure can potentially result in bruising, which is a normal part of the healing process. Procedure site bruising will be added as an LLT under PT Post procedural contusion in line with the closely related existing LLT Postoperative bruise.

Supplemental Update Report

CR Number: 2018177012 **Implementation Date:** 11-Jul-18 Related CR: 2018177012

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Anonychia*	Approved as Requested	Proposed PT	
			Anonychia	10081861
			HLT primary	
			Nail and nail bed conditions (excl infections and infestations)	10028685
			SOC primary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment: The proposal to add a new term Anonychia is approved as requested. Anonychia is the absence of nails, an anomaly, which may be the result of a congenital ectodermal defect, ichthyosis, severe infection, severe allergic contact dermatitis, self-inflicted trauma, Raynaud's phenomenon, lichen planus, etc. Anonychia will be added as a PT to HLT Nail and nail bed conditions (excl infections and infestations). In a related change, new LLT Congenital anonychia will be added to PT Nail aplasia to represent the congenital etiology of anonychia.

CR Number: 2018191005 **Implementation Date:** 11-Jul-18 Related CR: 2018177012

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Congenital anonychia*	Approved as Requested	Proposed LLT	
To PT	*Nail aplasia*		*Congenital anonychia*	10081869 Current
			To PT	
			Nail aplasia	10079732

MSSO Comment:

Supplemental Update Report

CR Number: 2018177013 **Implementation Date:** 11-Jul-18 Related CR: 2018177013

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Zimmerman-laband syndrome or Laband syndrome*	Approved Not as Requested	Proposed PT *Laband syndrome*	10081859
			HLT primary *Musculoskeletal disorders congenital NEC*	10029513
			SOC primary *Congenital, familial and genetic disorders*	10010331
			HLT secondary *Musculoskeletal disorders congenital NEC*	10029513
			SOC secondary *Musculoskeletal and connective tissue disorders*	10028395

MSSO Comment: The proposal to add a new term Zimmerman-laband syndrome or Laband syndrome is approved but not as requested. Laband syndrome is an extremely rare genetic disorder characterized by abnormalities of the head and face (craniofacial) area and the fingers and toes, particularly the thumbs and great toes. The requested term will be added as PT Laband syndrome to multi-axial HLT Musculoskeletal disorders congenital NEC primary to SOC Congenital, familial and genetic disorders; secondary to SOC Musculoskeletal and connective tissue disorders, with an additional secondary link to HLT Gingival disorders NEC.

CR Number: 2018191006 **Implementation Date:** 11-Jul-18 Related CR: 2018177013

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Laband syndrome*	Approved as Requested	Proposed PT *Laband syndrome*	10081859
To HLT	*Gingival disorders NEC*		To HLT *Gingival disorders NEC*	

MSSO Comment:

Supplemental Update Report

CR Number: 2018177014 **Implementation Date:** 11-Jul-18 Related CR: 2018177014

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*LINX system*	Approved Not as Requested	Proposed PT	
			Lower oesophageal sphincter magnetic augmentation	10081862
			HLT primary	
			Gastric therapeutic procedures	10017813
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term LINX system is approved but not as requested. Lower esophageal sphincter magnetic augmentation is a procedure meant to reduce gastro-esophageal reflux consisting in the laparoscopic implantation of a device constituted by a small expandable ring of linked magnetic beads. The magnetic attractive forces between the beads augment the pressure of the LES, impeding or reducing gastro-esophageal reflux. At higher pressures, the magnetic forces are overcome and the ring expands to allow esophageal distention and the passage of a swallowed bolus or other physiologic functions, such as belching or vomiting. MedDRA avoids adding terms based on trademark names; therefore, the proposed term will be substituted by its medical neutral denomination Lower oesophageal sphincter magnetic augmentation, which will be added as a PT under HLT Gastric therapeutic procedures. In a related change, American spelling LLT Lower esophageal sphincter magnetic augmentation will be added to new PT Lower oesophageal sphincter magnetic augmentation.

CR Number: 2018191007 **Implementation Date:** 11-Jul-18 Related CR: 2018177014

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Lower esophageal sphincter magnetic augmentation*	Approved as Requested	Proposed LLT	
			Lower esophageal sphincter magnetic augmentation	10081870 Current
To PT	*Lower oesophageal sphincter magnetic augmentation*		To PT	
			Lower oesophageal sphincter magnetic augmentation	10081862

MSSO Comment:

Supplemental Update Report

CR Number: 2018177015 **Implementation Date:** 11-Jul-18 Related CR: 2018177015

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*AGAT deficiency*	Approved Not as Requested	Proposed PT	
			L-arginine-glycine amidinotransferase deficiency	10081857
			HLT primary	
			Inborn errors of amino acid metabolism	10021602
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Inborn errors of amino acid metabolism	10021602
			SOC secondary	
			Metabolism and nutrition disorders	10027433

MSSO Comment: The proposal to add a new term AGAT deficiency is approved but not as requested. L-arginine-glycine amidinotransferase deficiency is an autosomal recessive inborn error affecting the first step of creatine synthesis, resulting in reduced production of guanidinoacetate, the immediate precursor of creatine. It is a rare condition that primarily affects the brain. People with AGAT deficiency generally have mild to moderate intellectual disability. Other signs and symptoms may include seizures, delayed language development, muscle weakness, failure to thrive, autistic behaviors, and delayed motor milestones (i.e., walking, sitting). The term in its spelled out version - L-arginine-glycine amidinotransferase deficiency will be added as a PT to the bi-axial HLT Inborn errors of amino acid metabolism, under primary SOC Congenital, familial and genetic disorders and secondary SOC Metabolism and nutrition disorders. Also, a secondary link to the bi-axial HLT Intellectual disabilities in SOC Psychiatric disorders and SOC Nervous system disorders. In a related change, the acronym AGAT deficiency will be added to new PT L-arginine-glycine amidinotransferase deficiency.

CR Number: 2018191008 **Implementation Date:** 11-Jul-18 Related CR: 2018177015

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*L-arginine-glycine amidinotransferase deficiency*	Approved as Requested	Proposed PT	
To HLT	*Intellectual disabilities*		*L-arginine-glycine amidinotransferase deficiency*	10081857
			To HLT	
			Intellectual disabilities	10077548

MSSO Comment:

Supplemental Update Report

CR Number: 2018191009 **Implementation Date:** 11-Jul-18 Related CR: 2018177015

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*AGAT deficiency*	Approved as Requested	Proposed LLT	
To PT	*L-arginine-glycine amidinotransferase deficiency*		*AGAT deficiency*	10081868 Current
			To PT	
			L-arginine-glycine amidinotransferase deficiency	10081857

MSSO Comment:

CR Number: 2018177016 **Implementation Date:** 11-Jul-18 Related CR: 2018177016

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Stucco keratosis*	Approved as Requested	Proposed LLT	
			Stucco keratosis	10081864 Current
			To PT	
			Seborrhoeic keratosis	10039796

MSSO Comment: The proposal to add a new term Stucco keratosis is approved as requested. Stucco keratoses are also described as verrucous, serrated, hyperkeratotic, and digitate. These lesions are commonly 1- to 3-mm, flat-topped, white to tan papules that adhere tightly to the skin on the lower legs. It is a common benign skin condition characterized by a lesion with a dull or lackluster surface, and projections of epidermal cells around collagen seen histologically. Stucco keratosis is a variant of seborrheic keratosis, and thus will be added as a sub-element LLT to PT Seborrhoeic keratosis.

CR Number: 2018177017 **Implementation Date:** 11-Jul-18 Related CR: 2018177017

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Ulcer prevention or Ulcer prophylaxis*	Rejected		

MSSO Comment: The proposal to add a new term Ulcer prevention or Ulcer prophylaxis is not approved. The proposed term is ambiguous, since it may refer to ulcers of very different pathological states, such as gastric ulcers or diabetic foot ulcers. Moreover, the MSSO usually refrains from adding new terms related to “prophylaxis”. Such concepts can be represented by the existing unqualified PT Prophylaxis, in combination with the PT/LLT representing the disease condition.

Supplemental Update Report

CR Number: 2018178001 **Implementation Date:** 12-Jul-18 Related CR: 2018178001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Urine strip test*	Approved as Requested	Proposed LLT	
			Urine strip test	10081881 Current
			To PT	
			Urine analysis	10046614

MSSO Comment: The proposal to add a new term Urine strip test is approved as requested. A urine test strip or dipstick test is a basic diagnostic tool used to determine abnormal characteristics in a patient's urine in standard urinalysis. Urine strip test will be added as an LLT to PT Urine analysis.

CR Number: 2018178002 **Implementation Date:** 05-Jul-18 Related CR: 2018178002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Autosomal dominant brachyolmia*	Approved as Requested	Proposed LLT	
			Autosomal dominant brachyolmia	10081840 Current
			To PT	
			Brachyolmia	10081832

MSSO Comment: The proposal to add a new LLT Autosomal dominant brachyolmia is approved as requested. Autosomal dominant brachyolmia is a relatively severe form of brachyolmia, a group of rare genetic skeletal disorders, characterized by short-trunked short stature, platyspondyly and kyphoscoliosis. Degenerative joint disease (osteoarthropathy) in the spine, large joints and interphalangeal joints becomes manifest in adulthood. Autosomal dominant brachyolmia will be added as a sub-concept LLT to PT Brachyolmia added in change request 2018178006.

Supplemental Update Report

CR Number: 2018178003 **Implementation Date:** 05-Jul-18 Related CR: 2018178003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*TRPV4 gene mutation*	Approved as Requested	Proposed PT	
			TRPV4 gene mutation	10081831
			HLT primary	
			Chromosomal abnormalities NEC	10008805
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Musculoskeletal and connective tissue conditions NEC	10080711
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new term TRPV4 gene mutation is approved as requested. Calcium channelopathy mutations in the TRPV4 gene lead to skeletal dysplasias, premature osteoarthritis, and neurological motor function disorders and are associated with a broad range of disorders. TRPV4 gene mutation will be added as a PT to primary HLT Chromosomal abnormalities NEC, and to secondary HLT Musculoskeletal and connective tissue conditions NEC.

CR Number: 2018178004 **Implementation Date:** 05-Jul-18 Related CR: 2018178004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Autosomal recessive brachyolmia*	Approved as Requested	Proposed LLT	
			Autosomal recessive brachyolmia	10081837 Current
			To PT	
			Brachyolmia	10081832

MSSO Comment: The proposal to add a new LLT Autosomal recessive brachyolmia is approved as requested. Brachyolmia is a rare, clinically and genetically heterogeneous group of congenital bone disorders characterized by short trunk, mild short stature, scoliosis and generalized platyspondyly (widening of the vertebral body), without significant abnormalities in the long bones. Patients with autosomal recessive brachyolmia, a type of brachyolmia, generally have a normal birth weight and length. Platyspondyly is present in early childhood but patients usually come to medical attention in late childhood or early puberty as a result of stunted growth and a short trunk. Sub-types include: Hobaek and Toledo types, brachyolmia-amelogenesis imperfecta syndrome, and Maroteaux type. Autosomal recessive brachyolmia will be placed as an LLT to PT Brachyolmia added in change request 2018178006.

Supplemental Update Report

CR Number: 2018178005 **Implementation Date:** 05-Jul-18 Related CR: 2018178005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*PAPSS2 gene mutation*	Approved Not as Requested	Proposed PT	
			PAPSS2 gene mutation	10081833
			HLT primary	
			Chromosomal abnormalities NEC	10008805
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Musculoskeletal and connective tissue conditions NEC	10080711
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new LLT PAPSS2 gene mutation is approved but not as requested. This gene encodes one of the two PAPS synthetases. Defects in this gene cause the Pakistani type of spondyloepimetaphyseal dysplasia. Two alternatively spliced transcript variants that encode different isoforms have been described for this gene. PAPSS2 is a protein coding gene, also known as the ATPSK2 gene. Diseases associated with PAPSS2 mutations include Brachyolmia type 4 with mild epiphyseal and metaphyseal changes. PAPSS2 gene mutation will be added as a PT to primary HLT Chromosomal abnormalities NEC, and to secondary HLT Musculoskeletal and connective tissue conditions NEC.

Supplemental Update Report

CR Number: 2018178006 **Implementation Date:** 05-Jul-18 Related CR: 2018178006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Brachyolmia*	Approved Not as Requested	Proposed PT	
			Brachyolmia	10081832
			HLT primary	
			Musculoskeletal and connective tissue disorders of spine congenital	10028383
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Musculoskeletal and connective tissue disorders of spine congenital	10028383
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new LLT Brachyolmia is approved but not as requested. Brachyolmia is a rare, clinically and genetically heterogeneous group of congenital bone disorders that may be autosomal recessive or autosomal dominant in nature. Brachyolmia is characterized by a short trunk, mild short stature, scoliosis and generalized platyspondyly (widening of the vertebral body), without significant abnormalities in the long bones. Brachyolmia will be added as a new PT to HLT Musculoskeletal and connective tissue disorders of spine congenital, under HLGT Musculoskeletal and connective tissue disorders congenital which is biaxial to primary SOC Congenital, familial and genetic disorders and to secondary SOC Musculoskeletal and connective tissue disorders.

CR Number: 2018178007 **Implementation Date:** 05-Jul-18 Related CR: 2018178007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Brachyolmia type 1, Hobaek type*	Approved as Requested	Proposed LLT	
			Brachyolmia type 1, Hobaek type	10081835 Current
			To PT	
			Brachyolmia	10081832

MSSO Comment: The proposal to add a new term Brachyolmia type 1, Hobaek type is approved as requested. Brachyolmia type 1, Hobaek type is an autosomal recessive type of brachyolmia with universal platyspondyly, irregular and reduced intervertebral spaces, and marked extension of the lateral margins of the vertebrae. Rectangular and elongated vertebral bodies are seen on lateral views of the spine, which become more pronounced with age. Brachyolmia type 1, Hobaek type will be added as a sub-concept LLT of PT Brachyolmia added in change request 2018178006.

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CR Number: 2018178008 **Implementation Date:** 05-Jul-18 Related CR: 2018178008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Brachyolmia type 1, Toledo type*	Approved as Requested	Proposed LLT *Brachyolmia type 1, Toledo type* To PT *Brachyolmia*	 10081836 Current 10081832

MSSO Comment: The proposal to add a new term Brachyolmia type 1, Toledo type is approved as requested. Toledo type — radiographically similar to Hobaek type but also associated with corneal opacities and precocious ossification of costal cartilage. Brachyolmia type 1, Toledo type will be added as a sub-concept LLT of PT Brachyolmia added in change request 2018178006.

CR Number: 2018178009 **Implementation Date:** 05-Jul-18 Related CR: 2018178009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Brachyolmia, Maroteaux type*	Approved as Requested	Proposed LLT *Brachyolmia, Maroteaux type* To PT *Brachyolmia*	 10081834 Current 10081832

MSSO Comment: The proposal to add a new LLT Brachyolmia, Maroteaux type is approved as requested. Brachyolmia, Maroteaux type is an autosomal recessive brachyolmia that is distinguished from Hobaek type by rounding of the anterior and posterior vertebral borders with less elongation on lateral view and less lateral extension on anterior-posterior view. This type may be associated with precocious calcification of the falx cerebri, and minor facial anomalies. Brachyolmia, Maroteaux type will be added as a sub-concept LLT to PT Brachyolmia added in change request 2018178006.

CR Number: 2018178010 **Implementation Date:** 05-Jul-18 Related CR: 2018178010

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Brachyolmia-amelogenesis imperfecta syndrome*	Approved as Requested	Proposed LLT *Brachyolmia-amelogenesis imperfecta syndrome* To PT *Brachyolmia*	 10081838 Current 10081832

MSSO Comment: The proposal to add a new LLT Brachyolmia-amelogenesis imperfecta syndrome is approved as requested. Brachyolmia-amelogenesis imperfecta syndrome is an exceedingly rare form of brachyolmia, characterized by mild platyspondyly, broad ilia, elongated femoral necks with coxa valga, scoliosis, and short trunked short stature associated with amelogenesis imperfecta of both primary and permanent dentition. Brachyolmia-amelogenesis imperfecta syndrome will be added as a sub-concept LLT to PT Brachyolmia added in change request 2018178006.

Supplemental Update Report

CR Number: **2018178011** **Implementation Date:** 05-Jul-18 Related CR: 2018178011

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Brachyrachia*	Approved as Requested	Proposed LLT	
			Brachyrachia	10081839 Current
			To PT	
			Brachyolmia	10081832

MSSO Comment: The proposal to add a new term Brachyrachia is approved as requested. Brachyolmia is a rare, clinically and genetically heterogeneous group of bone disorders characterized by short trunk, mild short stature, scoliosis and generalized platyspondyly without significant abnormalities in the long bones. Brachyrachia is a synonym of autosomal dominant brachyolmia, and brachyolmia type 3. Brachyrachia will be added as a sub-concept LLT to PT Brachyolmia added in change request 2018178006.

CR Number: **2018179096** **Implementation Date:** 12-Jul-18 Related CR: 2018179096

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ischemic vasculitis*	Approved Not as Requested	Proposed LLT	
			Ischemic vasculitis	10081884 Current
			To PT	
			Vasculitis	10047115

MSSO Comment: The proposal to add a new PT Ischemic vasculitis is approved but not as requested. Ischemic vasculitis is an inflammation of blood vessels often associated with vascular occlusion and subsequent hypoperfusion. Ischemic vasculitis will be added as a sub-concept LLT under PT Vasculitis. In a related change, British spelling Ischaemic vasculitis will be added as an LLT to PT Vasculitis.

CR Number: **2018192012** **Implementation Date:** 12-Jul-18 Related CR: 2018179096

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ischaemic vasculitis*	Approved as Requested	Proposed LLT	
To PT	*Vasculitis*		*Ischaemic vasculitis*	10081883 Current
			To PT	
			Vasculitis	10047115

MSSO Comment:

Supplemental Update Report

CR Number: 2018179097 **Implementation Date:** 12-Jul-18 Related CR: 2018179097

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Listeria food poisoning*	Approved as Requested	Proposed LLT *Listeria food poisoning* To PT *Gastroenteritis listeria*	 10081885 Current 10081882

MSSO Comment: The proposal to add a new term Listeria food poisoning is approved as requested. Food poisoning in humans by Listeria monocytogenes is commonly reported and is often associated with life-threatening outbreaks. In accordance with other "food poisoning" terms in MedDRA caused by bacteria, Listeria food poisoning will be added as an LLT to a new PT Gastroenteritis listeria. In a related change, Gastroenteritis listeria will be added as a PT to primary HLT Listeria infections; secondary HLT Gastric and gastroenteric infections.

CR Number: 2018192013 **Implementation Date:** 12-Jul-18 Related CR: 2018179097

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gastroenteritis listeria*	Approved as Requested	Proposed PT *Gastroenteritis listeria*	 10081882
HLT primary	*Listeria infections*		HLT primary *Listeria infections*	 10024639
SOC primary	*Infections and infestations*		SOC primary *Infections and infestations*	 10021881
			HLT secondary *Gastric and gastroenteric infections*	 10017887
			SOC secondary *Gastrointestinal disorders*	 10017947

MSSO Comment:

CR Number: 2018183001 **Implementation Date:** 12-Jul-18 Related CR: 2018183001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Meniscus Pain*	Rejected		

MSSO Comment: The proposal to add a new LLT Meniscus Pain is not approved. Meniscus pain is a causative term which can be represented by the combination of the involved meniscus lesion (e.g., Meniscus tear or Meniscal degeneration) with the most adequate of the several LLTs available to represent knee pain (e.g., Anterior knee pain syndrome, Pain in knee, Painful knee, etc.).

Supplemental Update Report

CR Number: 2018183363 **Implementation Date:** 12-Jul-18 Related CR: 2018183363

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Bladder and bowel dysfunction*	Rejected		

MSSO Comment: The proposal to add a new PT Bladder and bowel dysfunction is not approved. The requested term is a combination of the two existing LLTs Bowel dysfunction and Bladder dysfunction. The fact that they may often occur simultaneously or have a common physio-pathology, does not support the creation of a combined term in MedDRA.

CR Number: 2018183364 **Implementation Date:** 12-Jul-18 Related CR: 2018183364

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Biventricular pacemaker reprogramming*	Approved as Requested	Proposed LLT	
To PT	*Cardiac device reprogramming*		*Biventricular pacemaker reprogramming*	10081888 Current
			To PT	
			Cardiac device reprogramming	10081886

MSSO Comment: The proposal to add a new LLT Biventricular pacemaker reprogramming to PT Cardiac device reprogramming is approved as requested. Programming of biventricular pacemaker devices has to be carefully evaluated and followed up to ensure continual biventricular capture at rest and during exercise. See addition of PT Cardiac device reprogramming in change request 2018183368.

CR Number: 2018183365 **Implementation Date:** 12-Jul-18 Related CR: 2018183365

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Implantable defibrillator reprogramming*	Approved as Requested	Proposed LLT	
To PT	*Cardiac device reprogramming*		*Implantable defibrillator reprogramming*	10081889 Current
			To PT	
			Cardiac device reprogramming	10081886

MSSO Comment: The proposal to add a new LLT Implantable defibrillator reprogramming to PT Cardiac device reprogramming is approved as requested. Electrophysiological testing of a chronically implanted ICD is recommended if any of the following events occur: cardiac surgery, acute myocardial infarction, change in heart failure status of more than one New York Heart Association functional class, or a 25% increase in the dose of antiarrhythmic drugs other than ß-blockers, digoxin, or calcium antagonists. See the addition of PT Cardiac device reprogramming in change request 2018183368.

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CR Number: 2018183366 **Implementation Date:** 12-Jul-18 Related CR: 2018183366

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cardiac pacemaker reprogramming*	Approved as Requested	Proposed LLT	
To PT	*Cardiac device reprogramming*		*Cardiac pacemaker reprogramming*	10081887 Current
			To PT	
			Cardiac device reprogramming	10081886

MSSO Comment: The proposal to add a new LLT Cardiac pacemaker reprogramming to PT Cardiac device reprogramming is approved as requested. Remote follow-up enables physicians to cope with the expanding number of pacemaker follow-ups. Although remote follow-up offers comparable monitoring options to that of in-office, some reprogramming of device settings is not available, therefore both patient arrhythmic changes and pacemaker characteristics may require in-office visits for adequate reprogramming. See the addition of PT Cardiac device reprogramming in change request 2018183368.

CR Number: 2018183367 **Implementation Date:** 12-Jul-18 Related CR: 2018183367

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Antiarrhythmic drug therapy*	Rejected		
HLT primary	*Cardiac therapeutic procedures NEC*			
SOC primary	*Surgical and medical procedures*			

MSSO Comment: The proposal to add a new PT Antiarrhythmic drug therapy to primary HLT Cardiac therapeutic procedures NEC in SOC Surgical and medical procedures is not approved. Since MedDRA is not a drug dictionary, the MSSO generally refrains from adding new terms related to drug classes and "anti-name of disease/disorder" therapies. Such concepts can be represented by the existing underlying diseases, in this case e.g., LLT Arrhythmia.

CR Number: 2018183368 **Implementation Date:** 12-Jul-18 Related CR: 2018183368

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cardiac device reprogramming*	Approved as Requested	Proposed PT	
HLT primary	*Cardiac device therapeutic procedures*		*Cardiac device reprogramming*	10081886
SOC primary	*Surgical and medical procedures*		HLT primary	
			Cardiac device therapeutic procedures	10007600
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT Cardiac device reprogramming to primary HLT Cardiac device therapeutic procedures in SOC Surgical and medical procedures is approved as requested. Adjusting of parameters of cardiac devices like implantable defibrillators, pacemakers, biventricular pacemakers, is frequently needed due to both patient arrhythmic changes and life habits and device characteristics.

Supplemental Update Report

CR Number: 2018183369 **Implementation Date:** 05-Jul-18 Related CR: 2018183369

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Desmoplastic fibroblastoma*	Approved Not as Requested	Proposed PT	
HLT primary	*Neoplasms benign site unspecified NEC*		*Desmoplastic fibroblastoma*	10081841
SOC primary	*Neoplasms benign, malignant and unspecified (incl cysts and polyps)*		HLT primary	
			Soft tissue neoplasms benign NEC	10041295
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Benign musculoskeletal and connective tissue neoplasms	10004297
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new PT Desmoplastic fibroblastoma to primary HLT Neoplasms benign site unspecified NEC in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is approved but not as requested. Desmoplastic fibroblastomas (also known as collagenous fibromas) are benign tumours that present as slow growing masses in subcutaneous soft tissues or intramuscular tissues, and range in size from 1 - 20 cm. They are characterized by a paucicellular lesion with spindle- and stellate-shaped fibroblastic cells embedded in a hypovascular, densely fibrous stroma. Desmoplastic fibroblastomas mainly occur in middle age, and have been described as involving a wide range of anatomic sites, commonly arising in the shoulder, thigh, back, and neck. Desmoplastic fibroblastoma will be added as a PT to the more specific primary HLT Soft tissue neoplasms benign NEC, and to secondary HLT Benign musculoskeletal and connective tissue neoplasms.

CR Number: 2018184001 **Implementation Date:** 03-Aug-18 Related CR: 2018184001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Loose stools*	Rejected After Suspension		
From PT	*Diarrhoea*			
To PT	*Frequent bowel movements*			

MSSO Comment: The proposal to move the LLT Loose stools from PT Diarrhoea to PT Frequent bowel movements is not approved after suspension. Loose stool is an issue of stool quality (e.g., watery or loose) and does not infer anything about the frequency of stool production.

Supplemental Update Report

CR Number: 2018184002 **Implementation Date:** 13-Jul-18 Related CR: 2018184002

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hypoplasia enamel*	Approved Not as Requested	PT to merge	
From PT	*Tooth hypoplasia*		*Amelogenesis imperfecta*	10081678 Current
To PT	*Amelogenesis imperfecta*		To PT	
			Tooth hypoplasia	10044041

MSSO Comment: The proposal to move the LLT Hypoplasia enamel from PT Tooth hypoplasia to PT Amelogenesis imperfecta is approved but not as requested. Instead of moving LLT Hypoplasia enamel, the MSSO will demote PT Amelogenesis imperfecta under the broader PT Tooth hypoplasia. In a related change, new PT Acquired enamel hypoplasia will be added to HLT Dental developmental disorders and anomalies to provide a concept for forms usually acquired later in life and secondary to multiple causes, such as nutritional factors, hypocalcemia, infections, trauma, drugs, etc. Furthermore, PT Dentinogenesis imperfecta will be demoted to the broader PT Tooth hypoplasia.

CR Number: 2018194010 **Implementation Date:** 13-Jul-18 Related CR: 2018184002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Acquired enamel hypoplasia*	Approved as Requested	Proposed PT	
HLT primary	*Dental developmental disorders and anomalies*		*Acquired enamel hypoplasia*	10081918
SOC primary	*Gastrointestinal disorders*		HLT primary	
			Dental developmental disorders and anomalies	10012321
			SOC primary	
			Gastrointestinal disorders	10017947

MSSO Comment:

CR Number: 2018194011 **Implementation Date:** 13-Jul-18 Related CR: 2018184002

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Dentinogenesis imperfecta*	Approved as Requested	PT to merge	
To PT	*Tooth hypoplasia*		*Dentinogenesis imperfecta*	10054013 Current
			To PT	
			Tooth hypoplasia	10044041

MSSO Comment:

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CR Number: 2018184003 **Implementation Date:** 13-Jul-18 Related CR: 2018184003

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Enamel hypoplasia*	Rejected		
From PT	*Tooth hypoplasia*			
To PT	*Amelogenesis imperfecta*			

MSSO Comment: The proposal to move the LLT Enamel hypoplasia from PT Tooth hypoplasia to PT Amelogenesis imperfecta is not approved. Based on the changes made in previous change request 2018184002, LLT Enamel hypoplasia will be kept under PT Tooth hypoplasia.

CR Number: 2018184267 **Implementation Date:** 13-Jul-18 Related CR: 2018184267

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ileus adhesive*	Approved as Requested	Proposed LLT	
From PT	*Ileus*		*Ileus adhesive*	10056322 Current
To PT	*Mechanical ileus*		From PT	
			Ileus	10021328
			To PT	
			Mechanical ileus	10051399

MSSO Comment: The proposal to move the LLT Ileus adhesive from PT Ileus to PT Mechanical ileus is approved as requested. Postoperative adhesions form after trauma to the peritoneal cavity and are a result of the biochemical and cellular response that occurs in an attempt to repair the peritoneum. Adhesions are the leading cause of small intestinal obstruction after abdominal surgery and can be the source of significant morbidity, in some cases leading to mortality. A mechanical ileus is an obstruction of the bowel arising from a mechanical cause, such as volvulus, a gallstone, or adhesions. Therefore, LLT Ileus adhesive is better represented under PT Mechanical ileus.

CR Number: 2018185001 **Implementation Date:** 13-Jul-18 Related CR: 2018185001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vaccination site lividity*	Approved as Requested	Proposed LLT	
			Vaccination site lividity	10081919 Current
			To PT	
			Vaccination site discolouration	10069474

MSSO Comment: The proposal to add a new LLT Vaccination site lividity is approved as requested. Lividity is defined as having a discolored, bluish appearance caused by a bruise, congestion of blood vessels, strangulation, etc. Vaccination site lividity will be added as an LLT to PT Vaccination site discolouration.

Supplemental Update Report

CR Number: 2018186001 **Implementation Date:** 13-Jul-18 Related CR: 2018186001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hydrocephalus shunt or ventriculoperitoneal shunt*	Rejected		

MSSO Comment: The proposal to add a new LLT Hydrocephalus shunt or ventriculoperitoneal shunt is not approved. Ventriculoperitoneal shunting is a surgical procedure primarily for the treatment of hydrocephalus and is represented in MedDRA by LLT Ventriculo-peritoneal shunt.

CR Number: 2018186002 **Implementation Date:** 03-Aug-18 Related CR: 2018186002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Delayed multiple injection site reaction*	Approved Not as Requested After Suspension	Proposed LLT	
			Delayed injection site reaction following multiple administrations	10081971 Current
			To PT	
			Injection site reaction	10022095

MSSO Comment: The proposal to add a new term Delayed multiple injection site reaction is approved but not as requested after suspension. Delayed multiple injection site reaction, a local reaction after multiple drug dose injections, will be modified for clarification of the concept to Delayed injection site reaction following multiple administrations and placed as a sub-concept LLT to PT Injection site reaction.

CR Number: 2018186003 **Implementation Date:** 12-Jul-18 Related CR: 2018186003

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Redness corner of mouth*	Rejected		
From PT	*Angular cheilitis*			
To PT	*Oral mucosal erythema*			

MSSO Comment: The proposal to move the LLT Redness corner of mouth from PT Angular cheilitis to PT Oral mucosal erythema is not approved. As cheilitis, redness in the corner of the mouth may also include the perioral skin and the vermilion border, and not only the labial mucosa. Moreover, the qualifier angular is a synonym of corner of the mouth, conferring a high anatomical correspondence to current alignment of the terms. Therefore, current placement is considered adequate. However, since angular cheilitis only indicates inflammation of the corner of the mouth, the primary SOC of PT Angular cheilitis will be changed from SOC Infections and infestations to SOC Gastrointestinal disorders. Additionally the link to SOC Infections and infestations (i.e., HLT Dental and oral soft tissue infections) will be removed.

Supplemental Update Report

CR Number: 2018192009 **Implementation Date:** 12-Jul-18 Related CR: 2018186003

Change Requested	Reassign Primary SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Angular cheilitis*	Approved as Requested	Proposed PT	
Old Primary SOC	*Infections and infestations*		*Angular cheilitis*	10002509
New Primary SOC	*Gastrointestinal disorders*		Old Primary SOC	
			Infections and infestations	10021881
			New Primary SOC	
			Gastrointestinal disorders	10017947

MSSO Comment:

CR Number: 2018192010 **Implementation Date:** 12-Jul-18 Related CR: 2018186003

Change Requested	Unlink a PT from a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Angular cheilitis*	Approved as Requested	Proposed PT	
From HLT	*Dental and oral soft tissue infections*		*Angular cheilitis*	10002509
			From HLT	
			Dental and oral soft tissue infections	10012326

MSSO Comment:

CR Number: 2018186004 **Implementation Date:** 12-Jul-18 Related CR: 2018186004

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Soreness corner mouth*	Rejected		
Status	*non-current*			

MSSO Comment: The proposal to change status of LLT Soreness corner mouth to non-current is not approved. The LLT Soreness corner mouth is a common manifestation of angular cheilitis. Reports of soreness of the mouth corners may be coded to one of the LLTs under PT Oral pain. Given the potential impact on legacy data, the LLT Soreness corner mouth will remain current.

Supplemental Update Report

CR Number: 2018186005 **Implementation Date:** 12-Jul-18 Related CR: 2018186005

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hyperaesthesia skin*	Rejected		
From PT	*Hyperaesthesia*			
HLT primary	*Dermal and epidermal conditions NEC*			

MSSO Comment: The proposal to promote the LLT Hyperaesthesia skin from PT Hyperaesthesia to primary HLT Dermal and epidermal conditions NEC in SOC Skin and subcutaneous tissue disorders and secondary HLT Paraesthesias and dysaesthesias in SOC Nervous system disorders is not approved. The current term placement in MedDRA is appropriate. Skin hyperaesthesia is a subconcept under the more general concept of hyperaesthesia and hyperaesthesia is related to abnormal neural activity caused by various stimuli and not abnormality in the skin structure. However, in a related change, the MSSO will add a secondary link for PT Hyperaesthesia to HLT Dermal and epidermal conditions NEC in SOC Skin and subcutaneous tissue disorders to reflect the site of manifestation.

CR Number: 2018192011 **Implementation Date:** 12-Jul-18 Related CR: 2018186005

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hyperaesthesia*	Approved as Requested	Proposed PT	
To HLT	*Dermal and epidermal conditions NEC*		*Hyperaesthesia*	10020568
			To HLT	
			Dermal and epidermal conditions NEC	10012424

MSSO Comment:

CR Number: 2018186006 **Implementation Date:** 12-Jul-18 Related CR: 2018186006

Change Requested	Swap a PT with an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hypoaesthesia*	Rejected		
With LLT	*Skin hypoaesthesia*			

MSSO Comment: The proposal to swap the PT Hypoaesthesia with the LLT Skin hypoaesthesia is not approved. The concepts of hypo-, hyper-, dys-, and paraesthesia are essentially sensory nerve abnormalities but by default refer to skin as the site of manifestation. If other sites are reported for those sensory nerve abnormalities, a qualifier is indicated in MedDRA, e.g., PT Hypoaesthesia oral. However, a secondary link to SOC Skin and subcutaneous tissue disorders has been added for PT Hypoaesthesia to HLT Dermal and epidermal conditions NEC in change request 2018186005.

Supplemental Update Report

CR Number: 2018186007 **Implementation Date:** 12-Jul-18 Related CR: 2018186007

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Paraesthesia skin*	Rejected		
From PT	*Paraesthesia*			
HLT primary	*Dermal and epidermal conditions NEC*			

MSSO Comment: The proposal to promote the LLT Paraesthesia skin from PT Paraesthesia to primary HLT Dermal and epidermal conditions NEC in SOC Skin and subcutaneous tissue disorders and secondary HLT Paraesthesias and dysaesthesias in SOC Nervous system disorders is not approved. The concepts of hypo-, hyper-, dys-, and paraesthesia are essentially sensory nerve abnormalities but by default refer to skin as the site of manifestation. If other sites are reported for those sensory nerve abnormalities, a qualifier is indicated in MedDRA, e.g., PT Hypoaesthesia oral. However, in a related change, a secondary link to SOC Skin and subcutaneous tissue disorders will be added for PT Paraesthesia to HLT Dermal and epidermal conditions NEC.

CR Number: 2018192014 **Implementation Date:** 12-Jul-18 Related CR: 2018186007

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Paraesthesia*	Approved as Requested	Proposed PT	
To HLT	*Dermal and epidermal conditions NEC*		*Paraesthesia*	10033775
			To HLT	
			Dermal and epidermal conditions NEC	10012424

MSSO Comment:

CR Number: 2018186008 **Implementation Date:** 12-Jul-18 Related CR: 2018186008

Change Requested	Swap a PT with an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Dysaesthesia*	Rejected		
With LLT	*Skin dysaesthesia*			

MSSO Comment: The proposal to swap the PT Dysaesthesia with the LLT Skin dysaesthesia is not approved. The concepts of hypo-, hyper-, dys-, and paraesthesia are essentially sensory nerve abnormalities but by default refer to skin as the site of manifestation. If other sites are reported for those sensory nerve abnormalities, a qualifier is indicated in MedDRA, e.g., PT Hypoaesthesia oral. However, in a related change, a secondary link to SOC Skin and subcutaneous tissue disorders will be added for PT Dysaesthesia to HLT Dermal and epidermal conditions NEC.

Supplemental Update Report

CR Number: 2018192015 **Implementation Date:** 12-Jul-18 Related CR: 2018186008

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Dysaesthesia*	Approved as Requested	Proposed PT	
To HLT	*Dermal and epidermal conditions NEC*		*Dysaesthesia*	10013886
			To HLT	
			Dermal and epidermal conditions NEC	10012424

MSSO Comment:

CR Number: 2018186009 **Implementation Date:** 12-Jul-18 Related CR: 2018186009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Abnormal skin sensation*	Rejected		
To PT	*Dysaesthesia*			

MSSO Comment: The proposal to add a new LLT Abnormal skin sensation to PT Dysaesthesia is not approved. The colloquial expression of "Abnormal skin sensation" can refer to other types of local discomfort that either do not involve the nervous system or involve sensory perceptions other than dysaesthesia such as paraesthesia.

CR Number: 2018186010 **Implementation Date:** 12-Jul-18 Related CR: 2018186010

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Flaking scalp*	Approved as Requested	Proposed LLT	
To PT	*Skin exfoliation*		*Flaking scalp*	10081891 Current
			To PT	
			Skin exfoliation	10040844

MSSO Comment: The proposal to add a new LLT Flaking scalp to PT Skin exfoliation is approved as requested. Flaking scalp is essentially synonymous with LLT Flaking skin.

Supplemental Update Report

CR Number: **2018186011** **Implementation Date:** 12-Jul-18 Related CR: 2018186011

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Palmar erythema*	Rejected		
To PT	*Erythema*			

MSSO Comment: The proposal to demote the PT Palmar erythema under PT Erythema is not approved. Even though, palmar erythema is located on skin, it is not a pure skin site of manifestation and it is preferable to keep as a single PT for differential diagnostic reasons and PV aspects. Erythema of palms and soles are of high clinical relevance in dermatology, sometimes being the hallmark in a differential diagnosis.

CR Number: **2018186012** **Implementation Date:** 12-Jul-18 Related CR: 2018186012

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Plantar erythema*	Rejected		
To PT	*Erythema*			

MSSO Comment: The proposal to demote the PT Plantar erythema under PT Erythema is not approved. Even though plantar erythema is located on skin, it is not a pure skin site of manifestation and it is preferable to keep as a single PT for differential diagnostic reasons and PV aspects. Erythema of palms and soles are of high clinical relevance in dermatology, sometimes being the hallmark in a differential diagnosis.

CR Number: **2018186013** **Implementation Date:** 12-Jul-18 Related CR: 2018186013

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pharynx strange sensation of*	Rejected		
From PT	*Oropharyngeal discomfort*			
To PT	*Dysaesthesia pharynx*			

MSSO Comment: The proposal to move the LLT Pharynx strange sensation of from PT Oropharyngeal discomfort to PT Dysaesthesia pharynx is not approved. There are unusual sensations in the pharynx such as pharyngeal "globus", or a throat sensation of a non-passing phlegm, which could not be classified as dysesthesias.

Supplemental Update Report

CR Number: 2018186014 **Implementation Date:** 12-Jul-18 Related CR: 2018186014

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Periorbital pain*	Approved as Requested	Proposed LLT	
From PT	*Eye pain*		*Periorbital pain*	10034546
			From PT	
			Eye pain	10015958
			HLT primary	
			Ocular disorders NEC	10030032
			SOC primary	
			Eye disorders	10015919

MSSO Comment: The proposal to promote the LLT Periorbital pain from PT Eye pain is approved as requested. Periorbital pain can be considered a separate concept from eye pain and will be promoted to a PT to HLT Ocular disorders NEC.

CR Number: 2018186015 **Implementation Date:** 12-Jul-18 Related CR: 2018186015

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Stool discolouration*	Approved as Requested	Proposed LLT	
To PT	*Faeces discoloured*		*Stool discolouration*	10081890 Current
			To PT	
			Faeces discoloured	10016100

MSSO Comment: The proposal to add a new LLT Stool discolouration to PT Faeces discoloured is approved as requested. American spelling LLT Stool discoloration already exists in MedDRA.

CR Number: 2018186016 **Implementation Date:** 12-Jul-18 Related CR: 2018186016

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Stool discoloured*	Approved as Requested	Proposed LLT	
To PT	*Faeces discoloured*		*Stool discoloured*	10081892 Current
			To PT	
			Faeces discoloured	10016100

MSSO Comment: The proposal to add a new LLT Stool discoloured to PT Faeces discoloured is approved as requested. American spelling LLT Stool discolored already exists in MedDRA.

Supplemental Update Report

CR Number: 2018186017 **Implementation Date:** 12-Jul-18 Related CR: 2018186017

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Sour stomach*	Approved as Requested	Proposed LLT	
From PT	*Hyperchlorhydria*		*Sour stomach*	10041373 Current
To PT	*Dyspepsia*		From PT	
			Hyperchlorhydria	10020601
			To PT	
			Dyspepsia	10013946

MSSO Comment: The proposal to move the LLT Sour stomach from PT Hyperchlorhydria to PT Dyspepsia is approved as requested. A sour stomach — or an upset stomach — describes a wide range of common symptoms, which can include, but are not limited to: regurgitation, nausea, heartburn, bloating, indigestion and gassiness. Such symptoms can be related to a variety of upper gastrointestinal disorders and conditions. Accordingly, because the etiology of sour stomach symptoms is not limited to Hyperchlorhydria, sour stomach and dyspepsia are essentially synonyms. LLT Sour stomach will be moved from PT Hyperchlorhydria to PT Dyspepsia.

CR Number: 2018186018 **Implementation Date:** 13-Jul-18 Related CR: 2018186018

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Alveobronchiolitis*	Approved Not as Requested	Proposed LLT	
HLT primary	*Lower respiratory tract inflammatory and immunologic conditions*		*Alveobronchiolitis*	10081920 Current
SOC primary	*Respiratory, thoracic and mediastinal disorders*		To PT	
			Alveolitis	10001889

MSSO Comment: The proposal to add a new PT Alveobronchiolitis to primary HLT Lower respiratory tract inflammatory and immunologic conditions in SOC Respiratory, thoracic and mediastinal disorders is approved but not as requested. Alveobronchiolitis, inflammation of the bronchioles and alveoli of the lungs, will be placed as a sub-concept LLT to existing PT Alveolitis.

CR Number: 2018187001 **Implementation Date:** 12-Jul-18 Related CR: 2018187001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hairline fracture*	Approved as Requested	Proposed LLT	
To PT	*Stress fracture*		*Hairline fracture*	10081917 Current
			To PT	
			Stress fracture	10042212

MSSO Comment: The proposal to add a new LLT Hairline fracture to PT Stress fracture is approved as requested. Hairline fractures are often caused by overuse or repetitive actions when microscopic damage is done to the bone over time and synonymously used to refer to stress fractures.

Supplemental Update Report

CR Number: 2018192001 **Implementation Date:** 13-Jul-18 Related CR: 2018192001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cuboid syndrome*	Approved Not as Requested	Proposed PT	
To PT	*Joint dislocation*		*Cuboid syndrome*	10081921
			HLT primary	
			Fractures and dislocations NEC	10027677
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Musculoskeletal and connective tissue pain and discomfort	10068757
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new LLT Cuboid syndrome to PT Joint dislocation is approved but not as requested. Cuboid syndrome is defined as a minor disruption or subluxation of the structural congruity of the calcaneocuboid portion of the midtarsal joint. The disruption of the cuboid's position irritates the surrounding joint capsule, ligaments, and peroneus longus tendon. Cuboid syndrome causes pain on the lateral side of the foot which is the side of the little toe. Cuboid syndrome will be placed as a PT to primary HLT Fractures and dislocations NEC; secondary HLT Musculoskeletal and connective tissue pain and discomfort.

CR Number: 2018192002 **Implementation Date:** 13-Jul-18 Related CR: 2018192002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Dyscholia*	Approved Not as Requested	Proposed LLT	
			Dyscholia	10081922 Current
			To PT	
			Deficiency of bile secretion	10071634

MSSO Comment: The proposal to add a new PT Dyscholia is approved but not as requested. Dyscholia is a general term for an abnormal condition of the bile, related to either the quantity secreted or to the condition of bile constituents. Dyscholia will be added as a sub-concept LLT to PT Deficiency of bile secretion.

Supplemental Update Report

CR Number: 2018192003 **Implementation Date:** 12-Sep-18 Related CR: 2018192003

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Antiphospholipid syndrome*	Approved Not as Requested	Proposed PT	
To SMQ	*Embolic and thrombotic events (SMQ)*		*Antiphospholipid syndrome*	10002817
Term scope	*Narrow*		To SMQ	
			Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (SMQ)	20000083
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Antiphospholipid syndrome to Embolic and thrombotic events (SMQ) as a narrow term is approved but not as requested. Antiphospholipid syndrome (APS) is characterized by venous or arterial thrombosis and/or an adverse pregnancy outcome in the presence of persistent laboratory evidence of antiphospholipid antibodies (aPL). Antiphospholipid syndrome will be added as a narrow scope term to sub-search SMQ Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous.

CR Number: 2018192004 **Implementation Date:** 13-Jul-18 Related CR: 2018192004

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Congenital hydrocele*	Rejected		
From PT	*Hydrocele*			

MSSO Comment: The proposal to promote the LLT Congenital hydrocele from PT Hydrocele is not approved. In accordance with the “General Word Usage” section (5.1) of the MedDRA Introductory Guide, for conditions or diseases existing in both congenital and acquired forms, the more common form of the condition/disease is represented at the PT level without adding a qualifier of either “congenital” or “acquired”. Both congenital hydrocele and hydrocele in the adult (acquired) forms are frequent conditions. However, the high prevalence of spontaneously resolving hydroceles in neonates and infants favors the classification of non-qualified term Hydrocele as a congenital form, with the subsequent subordination of Congenital hydrocele to this non-qualified term. Please, consider redirecting acquired auto-encoded cases from the non-qualified congenital term to the alternate PT/LLT Acquired hydrocele.

Supplemental Update Report

CR Number: 2018193001 **Implementation Date:** 20-Jul-18 Related CR: 2018193001

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Macular telangiectasia*	Approved as Requested	Proposed LLT	
From PT	*Retinal telangiectasia*		*Macular telangiectasia*	10081199
			From PT	
			Retinal telangiectasia	10038899
			HLT primary	
			Retinal bleeding and vascular disorders (excl retinopathy)	10038837
			SOC primary	
			Eye disorders	10015919
			HLT secondary	
			Vascular malformations and acquired anomalies	10047091
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to promote the LLT Macular telangiectasia from PT Retinal telangiectasia is approved as requested. PT Macular telangiectasia will be linked to primary HLT Retinal bleeding and vascular disorders (excl retinopathy) and secondary HLT Vascular malformations and acquired anomalies.

CR Number: 2018193002 **Implementation Date:** 20-Jul-18 Related CR: 2018193002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Cranioencephalic Trauma*	Approved Not as Requested	Proposed LLT	
			Cranioencephalic trauma	10081923 Current
			To PT	
			Craniocerebral injury	10070976

MSSO Comment: The proposal to add a new term Cranioencephalic Trauma is approved but not as requested. Cranioencephalic trauma defines any trauma to the skull and brain and will be added in accordance to MedDRA capitalisation conventions as an synonym LLT to PT Craniocerebral injury.

Supplemental Update Report

CR Number: 2018193003 **Implementation Date:** 20-Jul-18 Related CR: 2018193003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Cranioencephalic Trauma*	Rejected		

MSSO Comment: The proposal to add a new term Cranioencephalic Trauma is not approved. The requested term is a duplicate of change request 2018193002.

CR Number: 2018194008 **Implementation Date:** 20-Jul-18 Related CR: 2018194008

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Spermatic cord cyst*	Approved as Requested	Proposed PT	
HLT primary	*Testicular and epididymal neoplasms*		*Spermatic cord cyst*	10081924
SOC primary	*Reproductive system and breast disorders*		HLT primary	
			Testicular and epididymal neoplasms	10029108
			SOC primary	
			Reproductive system and breast disorders	10038604
			HLT secondary	
			Reproductive neoplasms male benign NEC	10038598
			SOC secondary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104

MSSO Comment: The proposal to add a new PT Spermatic cord cyst to primary HLT Testicular and epididymal neoplasms in SOC Reproductive system and breast disorders is approved as requested. Cysts of the epididymis are common, frequently asymptomatic cystic lesions, which are usually not palpable at clinical examination due to their small size and softness. They may be originated by different cells and structural elements, such as epithelium cells containing a clear serous liquid, cystic formations of the lymphatic ducts, tubules dilatation in response to inflammatory or congenital obstruction of the seminiferous tubules, etc. PT Spermatic cord cyst will also be secondarily linked to HLT Reproductive neoplasms male benign NEC.

Supplemental Update Report

CR Number: 2018194009 **Implementation Date:** 20-Jul-18 Related CR: 2018194009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Os odontoideum*	Approved as Requested	Proposed PT	
			Os odontoideum	10081925
			HLT primary	
			Bone disorders NEC	10027658
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new term Os odontoideum is approved as requested. This anomaly describes separation of the odontoid process from the body of the axis of the second cervical vertebrae. Evidence suggests that most cases represent an acquired lesion, perhaps traumatic in nature. Os odontoideum will be added as a PT under HLT Bone disorders NEC.

CR Number: 2018197001 **Implementation Date:** 25-Jul-18 Related CR: 2018197001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Tethered cord release*	Approved as Requested	Proposed LLT	
			Tethered cord release	10081931 Current
			To PT	
			Spinal cord operation	10053348

MSSO Comment: The proposal to add a new LLT Tethered cord release is approved as requested. Tethered spinal cord release is a fairly routine surgical procedure used to treat a tethered spine. Treatment is aimed at the restoration of cord mobility by means of microsurgical release of the conus, the cauda equina and the filum terminale with the aid of cauda equina neuromonitoring. Tethered cord release will be added as a sub-concept LLT to PT Spinal cord operation.

CR Number: 2018197002 **Implementation Date:** 25-Jul-18 Related CR: 2018197002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Bascom procedure*	Approved as Requested	Proposed LLT	
To PT	*Pilonidal sinus repair*		*Bascom procedure*	10081932 Current
			To PT	
			Pilonidal sinus repair	10035047

MSSO Comment: The proposal to add a new LLT Bascom procedure to PT Pilonidal sinus repair is approved as requested. Bascom (cleft closure flap) procedure is a technique pioneered by Dr. John Bascom intended to treat pilonidal sinus.

Supplemental Update Report

CR Number: 2018197003 **Implementation Date:** 20-Jul-18 Related CR: 2018197003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Eyelid Gold-weight Insertion*	Approved Not as Requested	Proposed PT	
			Eyelid gold weight insertion	10081926 Current
			HLT primary	
			Eyelid therapeutic procedures	10015994
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Eyelid Gold-weight Insertion is approved but not as requested. An upper eyelid gold-weight insertion allows an improperly working eyelid to close with gravity. Several medical disorders, notably facial paralysis, create a condition of lagophthalmos, in which the upper eyelid does not close because the orbicularis oculi muscle fails to function. The levator palpebrae muscle, which raises the eyelid usually retains function, so without the added weight, the eyelid might otherwise remain unclosed. As a result, the cornea, often with decreased sensation, can become dry, inflamed, or ulcerated. Eyelid Gold-weight Insertion will be added as PT Eyelid gold weight insertion, to conform with MedDRA capitalization and punctuation conventions to HLT Eyelid therapeutic procedures.

CR Number: 2018198001 **Implementation Date:** 20-Jul-18 Related CR: 2018198001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Checkpoint kinase 2 gene mutation*	Approved as Requested	Proposed PT	
HLT primary	*Acquired gene mutations and other alterations*		*Checkpoint kinase 2 gene mutation*	10081927
SOC primary	*General disorders and administration site conditions*		HLT primary	
			Acquired gene mutations and other alterations	10071951
			SOC primary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Checkpoint kinase 2 gene mutation to primary HLT Acquired gene mutations and other alterations in SOC General disorders and administration site conditions is approved as requested. The Checkpoint kinase 2 gene acts as a tumor suppressor, which means that it regulates cell division by keeping cells from growing and dividing too rapidly or in an uncontrolled way. Mutations to the CHEK2 gene have been linked to a wide range of cancers.

Supplemental Update Report

CR Number: 2018198002 **Implementation Date:** 20-Jul-18 Related CR: 2018198002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*CHEK2 gene mutation*	Approved as Requested	Proposed LLT	
			CHEK2 gene mutation	10081928 Current
			To PT	
			Checkpoint kinase 2 gene mutation	10081927

MSSO Comment: The proposal to add a new LLT CHEK2 gene mutation is approved as requested. CHEK2 gene mutation is an abbreviated name for Checkpoint kinase 2 gene mutation. CHEK2 gene mutation will be added as LLT to PT Checkpoint kinase 2 gene mutation, which was added in change request 2018198001.

CR Number: 2018198003 **Implementation Date:** 24-Jul-18 Related CR: 2018198003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vaccine bacteria shedding*	Approved Not as Requested	Proposed PT	
			Vaccine bacteria shedding	10081929
			HLT primary	
			Infectious transmissions	10027684
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Vaccination related complications	10068755
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new LLT Vaccine bacteria shedding is approved but not as requested. Vaccine bacteria shedding represents the transmission and potential infection of the live attenuated bacteria used in the development of immunity from a vaccinated individual to a non-vaccinated one, specially in the latter suffers some form of immunosuppression. Vaccine bacteria shedding will be placed as a PT to primary HLT Infectious transmissions and secondary HLT Vaccination related complications.

Supplemental Update Report

CR Number: 2018199001 **Implementation Date:** 25-Jul-18 Related CR: 2018199001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Trisomy 16*	Approved as Requested	Proposed PT	
			Trisomy 16	10081933
			HLT primary	
			Autosomal chromosomal abnormalities	10003842
			SOC primary	
			Congenital, familial and genetic disorders	10010331

MSSO Comment: The proposal to add a new term Trisomy 16 is approved as requested. Trisomy 16 is a chromosomal deformity in which there are three copies of chromosome 16 instead of the normal two. Trisomies are the most common chromosome-related cause found in post-miscarriage testing. Of all trisomies, trisomy 16 seems to be the most common in humans, occurring in 1% of all pregnancies. Trisomy 16 will be added as PT to HLT Autosomal chromosomal abnormalities.

CR Number: 2018199002 **Implementation Date:** 25-Jul-18 Related CR: 2018199002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Full trisomy 16*	Approved as Requested	Proposed LLT	
			Full trisomy 16	10081936 Current
			To PT	
			Trisomy 16	10081933

MSSO Comment: The proposal to add a new LLT Full trisomy 16 is approved as requested. Trisomies are the most common chromosome-related cause found in post-miscarriage testing. Of all trisomies, trisomy 16 seems to be the most common in humans, occurring in 1% of all pregnancies. Full trisomy 16 will be added as synonym LLT to new PT Trisomy 16 added in change request 2018199001.

Supplemental Update Report

CR Number: 2018199003 **Implementation Date:** 25-Jul-18 Related CR: 2018199003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Confined placental mosaicism*	Approved Not as Requested	Proposed PT	
			Confined placental mosaicism	10081934
			HLT primary	
			Chromosomal abnormalities NEC	10008805
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Placental abnormalities (excl neoplasms)	10035130
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new LLT Confined placental mosaicism is approved but not as requested. Confined placental mosaicism represents a discrepancy between the chromosomal makeup of the cells in the placenta and the cells in the fetus. Since Confined placental mosaicism is not limited to abnormality of chromosome 16, it will be placed as a PT to primary HLT Chromosomal abnormalities NEC and secondary HLT Placental abnormalities (excl neoplasms).

CR Number: 2018199004 **Implementation Date:** 25-Jul-18 Related CR: 2018199004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Trisomy 16 Mosaicism*	Approved Not as Requested	Proposed LLT	
			Trisomy 16 mosaicism	10081935 Current
			To PT	
			Trisomy 16	10081933

MSSO Comment: The proposal to add a new LLT Trisomy 16 Mosaicism is approved but not as requested. Mosaic trisomy 16 (MT16) is less severe than full trisomy 16 and occurs when only some of the body's cells have an extra copy of chromosome 16. Trisomy 16 mosaicism, with corrected spelling, will be added as sub-concept LLT to newly added PT Trisomy 16 in change request 2018199001.

Supplemental Update Report

CR Number: 2018199005 **Implementation Date:** 20-Jul-18 Related CR: 2018199005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pulsed-Dye-Laser Treatment*	Approved Not as Requested	Proposed LLT	
			Pulsed dye laser therapy	10081930 Current
			To PT	
			Laser therapy	10062035

MSSO Comment: The proposal to add a new LLT Pulsed-Dye-Laser Treatment is approved but not as requested. The pulsed-dye laser has been the first laser to utilize the concept of selective photothermolysis to treat several dermatologic conditions, such as rosacea, scars, red striae, some lower-extremity spider veins, photodamage, cherry hemangioma, and verrucae. During photothermolysis, selective heating with a laser that is selectively absorbed by the target tissue, lasts sufficiently enough to cause damage to the target tissue, but not so long for the heat to spread to the surrounding tissue. The proposed term will be renamed to comply with capitalization and hyphenation MedDRA rules, using therapy instead of treatment to be consistent with other similar laser terms in the terminology. Pulsed dye laser therapy will be added as a sub-concept LLT of PT Laser therapy.

CR Number: 2018199006 **Implementation Date:** 26-Jul-18 Related CR: 2018199006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cardio-ankle vascular index increased*	Approved as Requested	Proposed PT	
HLT primary	*Vascular tests NEC (incl blood pressure)*		*Cardio-ankle vascular index increased*	10081948
SOC primary	*Investigations*		HLT primary	
			Vascular tests NEC (incl blood pressure)	10047110
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Cardio-ankle vascular index increased to primary HLT Vascular tests NEC (incl blood pressure) in SOC Investigations is approved as requested. Cardio-ankle vascular index is a medical test which is an indicator of arterial stiffness which has been used to assess an individual's potential risks of developing cardiovascular disease, and to quantitatively evaluate the progression of disease and the effectiveness of treatment. The addition of PT Cardio-ankle vascular index increased complements the existing unqualified PT Cardio-ankle vascular index. In a related change, the synonym acronym LLT CAVI increased will be added to the new PT Cardio-ankle vascular index increased.

CR Number: 2018206012 **Implementation Date:** 26-Jul-18 Related CR: 2018199006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*CAVI increased*	Approved as Requested	Proposed LLT	
To PT	*Cardio-ankle vascular index increased*		*CAVI increased*	10081951 Current
			To PT	
			Cardio-ankle vascular index increased	10081948

MSSO Comment:

Supplemental Update Report

CR Number: 2018199007 **Implementation Date:** 26-Jul-18 Related CR: 2018199007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*PSTPIP1-associated myeloid-related proteinemia inflammatory syndrome*	Approved Not as Requested	Proposed LLT	
			PSTPIP1-associated myeloid-related proteinemia inflammatory syndrome	10081949 Current
HLT primary	*Autoinflammatory diseases*			
SOC primary	*Immune system disorders*		To PT	
			PSTPIP1-associated myeloid-related proteinaemia inflammatory syndrome	10081947

MSSO Comment: The proposal to add a new PT PSTPIP1-associated myeloid-related proteinemia inflammatory syndrome to primary HLT Autoinflammatory diseases in SOC Immune system disorders is approved but not as requested. PSTPIP1-associated myeloid-related proteinemia inflammatory syndrome, a PSTPIP1-gene associated disorder, manifests mainly with haematologic abnormalities and autoinflammation with or without purulent features. PSTPIP1-associated myeloid-related proteinemia inflammatory syndrome will be added as an LLT to the British English spelled PT PSTPIP1-associated myeloid-related proteinaemia inflammatory syndrome. In a related change, PSTPIP1-associated myeloid-related proteinaemia inflammatory syndrome will be added as a PT to primary HLT Immune system abnormalities congenital, secondary HLT Autoinflammatory diseases, and secondary HLT Haematological disorders.

CR Number: 2018206013 **Implementation Date:** 26-Jul-18 Related CR: 2018199007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*PSTPIP1-associated myeloid-related proteinaemia inflammatory syndrome*	Approved as Requested	Proposed PT	
			PSTPIP1-associated myeloid-related proteinaemia inflammatory syndrome	10081947
HLT primary	*Immune system abnormalities congenital*		HLT primary	
SOC primary	*Congenital, familial and genetic disorders*		*Immune system abnormalities congenital*	10021424
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Autoinflammatory diseases	10073080
			SOC secondary	
			Immune system disorders	10021428

MSSO Comment:

Supplemental Update Report

CR Number: 2018206014 **Implementation Date:** 26-Jul-18 Related CR: 2018199007

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*PSTPIP1-associated myeloid-related proteinaemia inflammatory syndrome*	Approved as Requested	Proposed PT	
			PSTPIP1-associated myeloid-related proteinaemia inflammatory syndrome	10081947
To HLT	*Haematological disorders*		To HLT	
			Haematological disorders	10018847

MSSO Comment:

CR Number: 2018199008 **Implementation Date:** 26-Jul-18 Related CR: 2018199008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*PAMI syndrome*	Approved Not as Requested	Proposed LLT	
			PAMI syndrome	10081950 Current
To PT	*PSTPIP1-associated myeloid-related proteinemia inflammatory syndrome*		To PT	
			PSTPIP1-associated myeloid-related proteinaemia inflammatory syndrome	10081947

MSSO Comment: The proposal to add a new LLT PAMI syndrome to PT PSTPIP1-associated myeloid-related proteinemia inflammatory syndrome is approved not as requested. The commonly used acronym, PAMI syndrome, will be added as a synonym LLT to PT PSTPIP1-associated myeloid-related proteinaemia inflammatory syndrome, with British English spelling, which was added in CR 2018199007.

CR Number: 2018199009 **Implementation Date:** 26-Jul-18 Related CR: 2018199009

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Surgical shock*	Approved as Requested	Proposed LLT	
			Surgical shock	10049519 Current
From PT	*Shock*		From PT	
			Shock	10040560
To PT	*Procedural shock*		To PT	
			Procedural shock	10080894

MSSO Comment: The proposal to move the LLT Surgical shock from PT Shock to PT Procedural shock is approved as requested. Surgical shock, is shock that occurs during or after a surgical procedure, usually related to a loss of blood which results in insufficient blood volume. Because surgical shock is related to a surgical procedure, LLT Surgical shock is better aligned with PT Procedural shock.

Supplemental Update Report

CR Number: 2018199010 **Implementation Date:** 14-Aug-18 Related CR: 2018199010

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Cardialgia*	Approved After Suspension	LLT to change	
Status	*non-current*		*Cardialgia*	10007616 Non-Current
			Status	
			non-current	

MSSO Comment: The proposal to change status of LLT Cardialgia to non-current is approved as requested after suspension. Cardialgia is an ambiguous term as it is defined as pain in and around the heart and has been used to represent heartburn in addition to heart pain.

CR Number: 2018201001 **Implementation Date:** 25-Jul-18 Related CR: 2018201001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Arteriovenous fistula site extravasation*	Approved as Requested	Proposed LLT	
To PT	*Arteriovenous fistula site complication*		*Arteriovenous fistula site extravasation*	10081937 Current
			To PT	
			Arteriovenous fistula site complication	10055122

MSSO Comment: The proposal to add a new LLT Arteriovenous fistula site extravasation to PT Arteriovenous fistula site complication is approved as requested. Arteriovenous fistula site extravasation is a discharge or escape of blood or other fluid from an arteriovenous fistula site, into the surrounding tissues.

CR Number: 2018201002 **Implementation Date:** 26-Jul-18 Related CR: 2018201002

Change Requested	Link HLT to another HLGT	Final Disposition	Final Placement	MedDRA Code #
Proposed HLT	*Phototherapies*	Rejected		
From HLGT	*Therapeutic procedures and supportive care NEC*			
To HLGT	*Skin and subcutaneous tissue therapeutic procedures*			

MSSO Comment: The proposal to move the HLT Phototherapies from HLGT Therapeutic procedures and supportive care NEC to another HLGT Skin and subcutaneous tissue therapeutic procedures is not approved. Phototherapy is not limited to dermatologic treatment - it is also used to treat intraocular disorders, seasonal affective disorder, etc.

Supplemental Update Report

CR Number: 2018201658 **Implementation Date:** 26-Jul-18 Related CR: 2018201658

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Eczema Coxsackium*	Approved as Requested	Proposed PT	
HLT primary	*Coxsackie viral infections*		*Eczema Coxsackium*	10081940
SOC primary	*Infections and infestations*		HLT primary	
			Coxsackie viral infections	10011262
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Dermatitis and eczema	10012435
			SOC secondary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment: The proposal to add a new PT Eczema Coxsackium to primary HLT Coxsackie viral infections in SOC Infections and infestations and secondary HLT Dermatitis and eczema in SOC Skin and subcutaneous tissue disorders is approved as requested. Eczema Coxsackium, named for the city the condition was found in Coxsackie, NY describes as an unusual cutaneous manifestation of hand foot and mouth disease characterized by vesicles and erosions in areas affected by atopic dermatitis, similar to eczema herpeticum caused by herpes simplex virus. The exanthem is more widespread, severe, and varied than classic hand foot and mouth disease that could be confused with bullous impetigo, eczema herpeticum, vasculitis, and primary immunobullous disease.

CR Number: 2018201659 **Implementation Date:** 26-Jul-18 Related CR: 2018201659

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Behavioral induced insufficient sleep syndrome*	Approved Not as Requested	Proposed LLT	
			Behavioral induced insufficient sleep syndrome	10081941 Current
			To PT	
			Behavioural induced insufficient sleep syndrome	10081938

MSSO Comment: The proposal to add a new PT Behavioral induced insufficient sleep syndrome is approved but not as requested. Behavioral induced insufficient sleep syndrome is characterized by excessive daytime sleepiness, short habitual sleep duration and sleeping considerably longer than usual during weekend/vacations. Behavioral induced insufficient sleep syndrome is listed in the International Classification of Sleep Disorders third edition under the category of Central Disorders of Hypersomnolence along with other sleep disorders such as narcolepsy, idiopathic hypersomnia, and Kleine-Levin Syndrome. Behavioral induced insufficient sleep syndrome will be added as LLT to the British English spelled PT Behavioural induced insufficient sleep syndrome. In a related change, Behavioural induced insufficient sleep syndrome will be added as a PT to primary HLT Sleep disturbances NEC and to secondary HLT Dyssomnias. Based upon MedDRA spelling conventions, the British English spelled PT Behavioural addiction will be added to primary HLT Substance related and addictive disorders and the American English spelled PT Behavioral addiction will be merged under the new PT Behavioural addiction.

Supplemental Update Report

CR Number: 2018206005 **Implementation Date:** 26-Jul-18 Related CR: 2018201659

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Behavioural induced insufficient sleep syndrome*	Approved as Requested	Proposed PT	
HLT primary	*Sleep disturbances NEC*		*Behavioural induced insufficient sleep syndrome*	10081938
SOC primary	*Nervous system disorders*		HLT primary	
			Sleep disturbances NEC	10040996
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Dyssomnias	10013980
			SOC secondary	
			Psychiatric disorders	10037175

MSSO Comment:

CR Number: 2018206006 **Implementation Date:** 26-Jul-18 Related CR: 2018201659

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Behavioural addiction*	Approved as Requested	Proposed PT	
HLT primary	*Substance related and addictive disorders*		*Behavioural addiction*	10081939
SOC primary	*Psychiatric disorders*		HLT primary	
			Substance related and addictive disorders	10079102
			SOC primary	
			Psychiatric disorders	10037175

MSSO Comment:

Supplemental Update Report

CR Number: **2018206007** **Implementation Date:** 26-Jul-18 Related CR: 2018201659

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Behavioral addiction*	Approved as Requested	PT to merge	
To PT	*Behavioural addiction*		*Behavioral addiction*	10078602 Current
			To PT	
			Behavioural addiction	10081939

MSSO Comment:

CR Number: **2018204001** **Implementation Date:** 26-Jul-18 Related CR: 2018204001

Change Requested	Reassign Primary SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Rhinitis*	Rejected		
Old Primary SOC	*Infections and infestations*			
New Primary SOC	*Respiratory, thoracic and mediastinal disorders*			

MSSO Comment: The proposal to reassign the primary SOC of PT Rhinitis from current SOC Infections and infestations to SOC Respiratory, thoracic and mediastinal disorders is not approved. Based on the statement in the Introductory Guide MedDRA Version 21.0, section 6.11.2 Conventions and Exceptions for placement of terms ending with -itis , i.e. " Terms ending with “-itis” are linked to SOC Infections and infestations only if they most frequently represent infectious conditions (PT Tonsillitis). Those terms that most frequently represent inflammatory conditions (e.g., PT Arteritis) are linked to their corresponding site of manifestation SOCs without a primary link to SOC Infections and infestations, the primary link to SOC Infections and infestations for PT Rhinitis is appropriate as most often infectious of origin. For reports of non-infective causes, MedDRA offers specific coding options where Rhinitis is having qualifiers such as atopic, allergic, eosinophilic, ulcerative, etc. However, to provide a coding option for noninfective types of rhinitis a new PT Noninfective Rhinitis will be added to HLT Nasal congestion and inflammations.

CR Number: **2018206008** **Implementation Date:** 26-Jul-18 Related CR: 2018204001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Noninfective Rhinitis*	Approved as Requested	Proposed PT	
HLT primary	*Nasal congestion and inflammations*		*Noninfective Rhinitis*	10081942
SOC primary	*Respiratory, thoracic and mediastinal disorders*		HLT primary	
			Nasal congestion and inflammations	10028736
			SOC primary	
			Respiratory, thoracic and mediastinal disorders	10038738

MSSO Comment:

Supplemental Update Report

CR Number: 2018204002 **Implementation Date:** 26-Jul-18 Related CR: 2018204002

Change Requested	Reassign Primary SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Conjunctivitis*	Rejected		
Old Primary SOC	*Infections and infestations*			
New Primary SOC	*Eye disorders*			

MSSO Comment: The proposal to reassign the primary SOC of PT Conjunctivitis from current SOC Infections and infestations to SOC Eye disorders is not approved. Based on the statement in the Introductory Guide MedDRA Version 21.0, section 6.11.2 Conventions and Exceptions for placement of -itis terms, i.e. " Terms ending with “-itis” are linked to SOC Infections and infestations only if they most frequently represent infectious conditions (PT Tonsillitis). Those terms that most frequently represent inflammatory conditions (e.g., PT Arteritis) are linked to their corresponding site of manifestation SOCs without a primary link to SOC Infections and infestations", the primary link to SOC Infections and infestations for PT conjunctivitis is appropriate as most often infectious of origin. For noninfective reports of conjunctivitis, MedDRA offers a broad LLT Noninfective conjunctivitis or more specific LLTs such as LLT Atopic conjunctivitis, LLT Alergic conjunctivitis, etc.

CR Number: 2018204006 **Implementation Date:** 25-Jul-18 Related CR: 2018204006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Focal myositis*	Approved Not as Requested	Proposed PT	
To PT	*Myositis*		*Focal myositis*	10081943
			HLT primary	
			Muscle infections and inflammations	10021992
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395
			HLT secondary	
			Inflammations	10021950
			SOC secondary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new LLT Focal myositis to PT Myositis is approved but not as requested. Focal myositis is a rare inflammatory myopathy characterized by a localized swelling of skeletal muscle that is usually located in the lower extremities. Electromyography shows spontaneous activity associated with a myopathic pattern. Focal myositis warrants PT status and will be linked to primary HLT Muscle infections and inflammations and secondary HLT Inflammations.

Supplemental Update Report

CR Number: 2018204007 **Implementation Date:** 26-Jul-18 Related CR: 2018204007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Prolonged shedding*	Approved Not as Requested	Proposed LLT	
			Prolonged bacterial vaccine shedding	10081944 Current
			To PT	
			Vaccine bacteria shedding	10081929

MSSO Comment: The proposal to add a new LLT Prolonged shedding is approved but not as requested. Vaccine bacteria shedding represents the transmission and potential infection of the live attenuated bacteria used in the development of immunity from a vaccinated individual to a non-vaccinated one, specially in the latter suffers some form of immunosuppression. Prolongation of bacterial vaccine shedding usually is described to occur beyond 3 - 4 weeks following vaccination. To represent the concept more specifically, the proposed term, Prolonged shedding, will be rephrased to Prolonged bacterial vaccine shedding, and will be added as a sub-concept LLT to new PT Vaccine bacteria shedding, added in CR 2018198003 for Version 22.0.

CR Number: 2018205001 **Implementation Date:** 26-Jul-18 Related CR: 2018205001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Growth disorder NOS*	Approved Not as Requested	Proposed PT	
HLT primary	*Musculoskeletal and connective tissue conditions NEC*		*Growth disorder*	10081945
			HLT primary	
SOC primary	*Musculoskeletal and connective tissue disorders*		*Musculoskeletal and connective tissue conditions NEC*	10080711
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395
			HLT secondary	
			General nutritional disorders NEC	10018067
			SOC secondary	
			Metabolism and nutrition disorders	10027433

MSSO Comment: The proposal to add a new PT Growth disorder NOS to primary HLT Musculoskeletal and connective tissue conditions NEC in SOC Musculoskeletal and connective tissue disorders is approved but not as requested. Growth disorder can refer to any type of problem that prevents kids from meeting realistic expectations of growth, from failure to gain height and weight in young children to short stature or delayed sexual development in teens. Diseases of the kidneys, heart, gastrointestinal tract, lungs, bones, endocrine diseases, or other body systems might affect growth. Since the MSSO in general does not add any further concepts with "NOS", Growth disorder, without the qualifier "NOS" will be added as PT to primary HLT Musculoskeletal and connective tissue conditions NEC, secondary HLT General nutritional disorders NEC, and secondary HLT Hypothalamic and pituitary disorders NEC.

Supplemental Update Report

CR Number: 2018206009 **Implementation Date:** 26-Jul-18 Related CR: 2018205001

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Growth disorder*	Approved as Requested	Proposed PT	
To HLT	*Hypothalamic and pituitary disorders NEC*		*Growth disorder*	10081945
			To HLT	
			Hypothalamic and pituitary disorders NEC	10021109

MSSO Comment:

CR Number: 2018205002 **Implementation Date:** 26-Jul-18 Related CR: 2018205002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Laryngeal stroboscopy*	Approved as Requested	Proposed PT	
HLT primary	*Respiratory tract and thoracic imaging procedures*		*Laryngeal stroboscopy*	10081946
SOC primary	*Investigations*		HLT primary	
			Respiratory tract and thoracic imaging procedures	10006476
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Laryngeal stroboscopy to primary HLT Respiratory tract and thoracic imaging procedures in SOC Investigations is approved as requested. Laryngeal stroboscopy is a special method used to visualize vocal fold vibration. It uses a synchronized, flashing light passed through a flexible or rigid telescope. The flashes of light from the stroboscope are synchronized to the vocal fold vibration at a slightly slower speed, allowing the examiner to observe vocal fold vibration during sound production in what appears to be slow motion, for the purpose of investigating vocal pathology.

CR Number: 2018206001 **Implementation Date:** 01-Aug-18 Related CR: 2018206001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Stercoral peritonitis*	Approved Not as Requested	Proposed LLT	
To PT	*Fecal peritonitis*		*Stercoral peritonitis*	10081954 Current
			To PT	
			Peritonitis	10034674

MSSO Comment: The proposal to add a new LLT Stercoral peritonitis to PT Fecal peritonitis is approved but not as requested. Stercoral peritonitis is fecal contamination of the peritoneal cavity due to various causes, most commonly diverticular disease and colorectal tumor. Stercoral peritonitis will be added as LLT to PT Peritonitis aligned with synonym LLT Fecal peritonitis.

Supplemental Update Report

CR Number: **2018206002** **Implementation Date:** 01-Aug-18 Related CR: 2018206002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Adult onset scoliosis*	Approved as Requested	Proposed LLT	
To PT	*Scoliosis*		*Adult onset scoliosis*	10081955 Current
			To PT	
			Scoliosis	10039722

MSSO Comment: The proposal to add a new LLT Adult onset scoliosis to PT Scoliosis is approved as requested. There are people who have no history of scoliosis who develop spinal deformity of a progressive nature as adults. Adult onset scoliosis may be a continuation of adolescent idiopathic scoliosis that was not previously apparent, or may result from degeneration of the discs, arthritis of the facet joints and collapse and wedging of the disc spaces.

CR Number: **2018206003** **Implementation Date:** 01-Aug-18 Related CR: 2018206003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Battered woman syndrome*	Approved Not as Requested	Proposed LLT	
			Battered woman syndrome	10081953 Current
			To PT	
			Post-traumatic stress disorder	10036316

MSSO Comment: The proposal to add a new PT Battered woman syndrome is approved but not as requested. Gender violence is often fostered by the old-school social standard that men should be more powerful than women; therefore, some men feel the need to exercise their power and control women with violence. In some women victims, battered woman syndrome psychological symptoms, called battered woman syndrome can develop, making it difficult for them to leave the abusive situation to regain control of their lives. Battered woman syndrome is considered to fulfill the criteria of Post traumatic stress disorder in DSM-V, and therefore will be placed as a sub-concept LLT to PT Post-traumatic stress disorder, rather than a PT as proposed.

CR Number: **2018206004** **Implementation Date:** 01-Aug-18 Related CR: 2018206004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Nuclear magnetic resonance imaging pancreas*	Approved as Requested	Proposed PT	
			Nuclear magnetic resonance imaging pancreas	10081952
			HLT primary	
			Gastrointestinal and abdominal imaging procedures	10017963
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Nuclear magnetic resonance imaging pancreas is approved as requested. Nuclear magnetic resonance imaging of the pancreas enables diagnostic imaging of the parenchyma, ducts, and vessels of the pancreas for the purpose of evaluating pancreatic diseases and disorders. Nuclear magnetic resonance imaging pancreas will be added as PT to HLT Gastrointestinal and abdominal imaging procedures.

Supplemental Update Report

CR Number: 2018207001 **Implementation Date:** 02-Aug-18 Related CR: 2018207001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Tracheal abscess*	Approved as Requested	Proposed PT	
HLT primary	*Upper respiratory tract infections*		*Tracheal abscess*	10081956
SOC primary	*Infections and infestations*		HLT primary	
			Upper respiratory tract infections	10046309
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Upper respiratory tract infections NEC	10045573
			SOC secondary	
			Respiratory, thoracic and mediastinal disorders	10038738

MSSO Comment: The proposal to add a new PT Tracheal abscess to primary HLT Upper respiratory tract infections in SOC Infections and infestations is approved as requested. A tracheal abscess is a localized collection of pus within the tissue of the trachea, and has been observed to occur as a complication of bacterial and viral infections such as sinus infection, tonsillitis, pharyngitis, otitis media, etc. Tracheal abscess will be added as a PT to primary HLT Upper respiratory tract infections, and to secondary HLT Upper respiratory tract infections NEC.

CR Number: 2018207002 **Implementation Date:** 02-Aug-18 Related CR: 2018207002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Puncture site haematoma*	Approved as Requested	Proposed PT	
HLT primary	*Administration site reactions NEC*		*Puncture site haematoma*	10081957
SOC primary	*General disorders and administration site conditions*		HLT primary	
			Administration site reactions NEC	10057196
			SOC primary	
			General disorders and administration site conditions	10018065
			HLT secondary	
			Haemorrhages NEC	10018987
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new PT Puncture site haematoma to primary HLT Administration site reactions NEC in SOC General disorders and administration site conditions is approved as requested. A puncture site haematoma is a concept that usually represents a haematoma which occurs in the location of a puncture of a body surface, or blood vessel. Puncture site haematoma will also be secondarily linked to HLT Haemorrhages NEC. In a related change, the American English counterpart spelling, LLT Puncture site hematoma will be added to the new PT Puncture site haematoma.

Supplemental Update Report

CR Number: 2018214001 **Implementation Date:** 02-Aug-18 Related CR: 2018207002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Puncture site hematoma*	Approved as Requested	Proposed LLT	
To PT	*Puncture site haematoma*		*Puncture site hematoma*	10081958 Current
			To PT	
			Puncture site haematoma	10081957

MSSO Comment:

CR Number: 2018208001 **Implementation Date:** 02-Aug-18 Related CR: 2018208001

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Eczema Coxsackium*	Rejected		
Replacement term	*Eczema coxsackium*			

MSSO Comment: The proposal to rename PT/LLT Eczema Coxsackium to Eczema coxsackium is not approved. Coxsackie is the proper name of the virus - Coxsackium is the genitive form of it - found in literature in both variations and there is no need to change the capital spelling.

CR Number: 2018208002 **Implementation Date:** 02-Aug-18 Related CR: 2018208002

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Noninfective Rhinitis*	Approved as Requested	Term to modify	
Replacement term	*Noninfective rhinitis*		*Noninfective Rhinitis*	10081942
			Replacement term	
			Noninfective rhinitis	10081942

MSSO Comment: The proposal to rename PT/LLT Noninfective Rhinitis to Noninfective rhinitis is approved as requested. PT Noninfective Rhinitis, in change request 2018204001 rhinitis was inadvertently capitalized.

Supplemental Update Report

CR Number: 2018208003 **Implementation Date:** 02-Aug-18 Related CR: 2018208003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Large intestine infection*	Approved Not as Requested	Proposed PT	
To PT	*Infectious colitis*		*Large intestine infection*	10081959
			HLT primary	
			Abdominal and gastrointestinal infections	10017967
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Intestinal infections	10022678
			SOC secondary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new LLT Large intestine infection to PT Infectious colitis is approved but not as requested. Because the large intestine includes the colon, cecum and rectum, Large intestine infection will be added as a PT to primary HLT Abdominal and gastrointestinal infections and secondary HLT Intestinal infections. In a related change, PT Infectious colitis and PT Proctitis infectious will be merged as a sub-concept LLTs to the new PT Large intestine infection.

CR Number: 2018214931 **Implementation Date:** 02-Aug-18 Related CR: 2018208003

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Infectious colitis*	Approved as Requested	PT to merge	
To PT	*Large intestine infection*		*Infectious colitis*	10021905 Current
			To PT	
			Large intestine infection	10081959

MSSO Comment:

CR Number: 2018214932 **Implementation Date:** 02-Aug-18 Related CR: 2018208003

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Proctitis infectious*	Approved as Requested	PT to merge	
To PT	*Large intestine infection*		*Proctitis infectious*	10070540 Current
			To PT	
			Large intestine infection	10081959

MSSO Comment:

Supplemental Update Report

CR Number: 2018208004 **Implementation Date:** 02-Aug-18 Related CR: 2018208004

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Intestinal strangulation*	Approved as Requested	Proposed PT	
To HLT	*Gastrointestinal necrosis and vascular insufficiency*		*Intestinal strangulation*	10063658
			To HLT	
			Gastrointestinal necrosis and vascular insufficiency	10017984

MSSO Comment: The proposal to link the PT Intestinal strangulation to the HLT Gastrointestinal necrosis and vascular insufficiency is approved as requested. Intestinal strangulation is associated with interference of blood supply of an intestinal segment leading to congestion, ischemia and gangrene and, therefore, a secondary link to HLT Gastrointestinal necrosis and vascular insufficiency is appropriate.

CR Number: 2018208005 **Implementation Date:** 02-Aug-18 Related CR: 2018208005

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Angina pectoris CCS class IV*	Rejected		
From PT	*Angina pectoris*			
To PT	*Angina unstable*			

MSSO Comment: The proposal to move the LLT Angina pectoris CCS class IV from PT Angina pectoris to PT Angina unstable is not approved. The Canadian Cardiovascular Society Grading System for angina pectoris is a grading scale used to assess severity of stable angina. It would not be appropriate to move a single class of the scale (i.e., Class 4) under a different medical concept within MedDRA. The Class 4 state is reflective of the clinical worsening of angina to a point where it occurs without exertion but this overlap of the stable/unstable concepts is intended feature of this grading system.

Supplemental Update Report

CR Number: 2018208006 **Implementation Date:** 02-Aug-18 Related CR: 2018208006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Palatal polyp*	Approved as Requested	Proposed PT	
HLT primary	*Benign oral cavity neoplasms*		*Palatal polyp*	10081960
SOC primary	*Gastrointestinal disorders*		HLT primary	
			Benign oral cavity neoplasms	10030968
			SOC primary	
			Gastrointestinal disorders	10017947
			HLT secondary	
			Lip and oral cavity neoplasms benign	10024531
			SOC secondary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104

MSSO Comment: The proposal to add a new PT Palatal polyp to primary HLT Benign oral cavity neoplasms in SOC Gastrointestinal disorders and secondary HLT Lip and oral cavity neoplasms benign in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is approved as requested. A polyp is an abnormal protruding growth from a mucous membrane; accordingly, a palatal polyp originates from the mucous membrane of the palate. The existing unqualified polyp terms in MedDRA (e.g., PT Gastric polyps) currently default to a benign classification within SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps). Newly accepted polyp terms do not include a qualifier of “benign.”

CR Number: 2018208007 **Implementation Date:** 02-Aug-18 Related CR: 2018208007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Eustachian valve hypertrophy*	Approved Not as Requested	Proposed PT	
To PT	*Endocardial disease*		*Eustachian valve hypertrophy*	10081961
			HLT primary	
			Endocardial disorders NEC	10014660
			SOC primary	
			Cardiac disorders	10007541

MSSO Comment: The proposal to add a new LLT Eustachian valve hypertrophy to PT Endocardial disease is approved but not as requested. Eustachian valve hypertrophy often produces no clinical consequences and therefore will be placed as a PT under HLT Endocardial disorders NEC.

Supplemental Update Report

CR Number: 2018208008 **Implementation Date:** 14-Aug-18 Related CR: 2018208008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Challenge strain shedding*	Approved Not as Requested After Suspension	Proposed PT	
			Post vaccination challenge strain shedding	10081989
			HLT primary	
			Therapeutic and nontherapeutic responses	10043409
			SOC primary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new LLT Challenge strain shedding is approved but not as requested after suspension. Testing with challenge strain is a standard protocol in vaccine studies. The requested term will be rephrased for clarification of the concept and added as PT Post vaccination challenge strain shedding to HLT Therapeutic and nontherapeutic responses.

CR Number: 2018211001 **Implementation Date:** 02-Aug-18 Related CR: 2018211001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Beltectomy*	Rejected		
To PT	*Abdominoplasty*			

MSSO Comment: The proposal to add a new LLT Beltectomy to PT Abdominoplasty is not approved. Beltectomy is very colloquial and may not be recognized globally. Beltectomy or extended tummy tuck is the operation used to remove large amounts of skin and fat from the lower backside of the torso and the hips. In a related change, the more recognizable medical term Extended tummy tuck will be added as a sub-concept LLT to PT Abdominoplasty.

CR Number: 2018214933 **Implementation Date:** 02-Aug-18 Related CR: 2018211001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Extended tummy tuck*	Approved as Requested	Proposed LLT	
To PT	*Abdominoplasty*		*Extended tummy tuck*	10081962 Current
			To PT	
			Abdominoplasty	10053774

MSSO Comment:

Supplemental Update Report

CR Number: 2018211002 **Implementation Date:** 02-Aug-18 Related CR: 2018211002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Endoscopic clipping*	Approved as Requested	Proposed LLT	
			Endoscopic clipping	10081965 Current
			To PT	
			Haemostasis	10067439

MSSO Comment: The proposal to add a new term Endoscopic clipping is approved as requested. Endoscopic clipping, a haemostatic surgical intervention for haemorrhages (e.g. in the gastrointestinal tract), will be added as LLT to PT Haemostasis.

CR Number: 2018211003 **Implementation Date:** 02-Aug-18 Related CR: 2018211003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*CHILD syndrome*	Approved as Requested	Proposed PT	
			CHILD syndrome	10081963
			HLT primary	
			Musculoskeletal and connective tissue disorders of limbs congenital	10028381
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Ichthyoses	10021197
			SOC secondary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment: The proposal to add a new term CHILD syndrome is approved as requested. CHILD syndrome (an acronym for congenital hemidysplasia with ichthyosiform erythroderma and limb defects) is an inherited disorder, affecting primarily women, that is characterized by ichthyosis-like skin abnormalities and limb defects on one side of the body. Other abnormalities may be present, as well. CHILD Syndrome will be added as PT to primary HLT Musculoskeletal and connective tissue disorders of limbs congenital and secondary HLT Ichthyoses. In a related change, the fully spelled out name of this concepts will be added as LLT Congenital hemidysplasia with ichthyosiform erythroderma and limb defects to the new PT CHILD syndrome.

Supplemental Update Report

CR Number: 2018214934 **Implementation Date:** 02-Aug-18 Related CR: 2018211003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Congenital hemidysplasia with ichthyosiform erythroderma and limb defects*	Approved as Requested	Proposed LLT *Congenital hemidysplasia with ichthyosiform erythroderma and limb defects*	10081966	Current
To PT	*CHILD syndrome*		To PT *CHILD syndrome*	10081963	

MSSO Comment:

CR Number: 2018211004 **Implementation Date:** 02-Aug-18 Related CR: 2018211004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*NSDHL gene mutation*	Approved as Requested	Proposed LLT *NSDHL gene mutation*	10081964	Current
			To PT *CHILD syndrome*	10081963	

MSSO Comment: The proposal to add a new LLT NSDHL gene mutation is approved as requested. The NSDHL gene provides instructions for making an enzyme that is involved in the synthesis of cholesterol. Mutations in this gene are associated with CHILD syndrome, which is a X-linked dominant disorder of lipid metabolism with disturbed cholesterol biosynthesis. NSDHL gene mutation will be added as sub-concept LLT to new PT CHILD syndrome, added in change request 2018211003.

CR Number: 2018211005 **Implementation Date:** 02-Aug-18 Related CR: 2018211005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Inguinal lymph nodes enlarged*	Approved as Requested	Proposed LLT *Inguinal lymph nodes enlarged*	10081967	Current
To PT	*Lymphadenopathy*		To PT *Lymphadenopathy*	10025197	

MSSO Comment: The proposal to add a new LLT Inguinal lymph nodes enlarged to PT Lymphadenopathy is approved as requested. Inguinal lymph nodes are more commonly known as groin nodes. The most common cause of swollen or enlarged lymph glands is infection. There are some other uncommon causes of swollen lymph nodes, such as sarcoidosis, systemic lupus erythematosus, HIV and AIDS, leukemia, lymphomas, etc. Inguinal lymph nodes enlarged can be considered synonym of LLT Groin nodes.

Supplemental Update Report

CR Number: 2018211006 **Implementation Date:** 10-Oct-18 Related CR: 2018211006

Change Requested	Merge HLT	Final Disposition	Final Placement	MedDRA Code #
HLT to merge	*Gingival pains*	Approved Not as Requested After Suspension	HLT to merge *Gingival pains*	
To HLT	*Oral soft tissue pain and paraesthesia*		To HLT *Gingival disorders, signs and symptoms NEC*	10082211

MSSO Comment: The proposal to merge HLT Gingival pains to HLT Oral soft tissue pain and paraesthesia is approved but not as requested after suspension. Based on feedback, the MSSO will add a new HLT Gingival disorders, signs and symptoms NEC to HLGT Dental and gingival conditions and merge existing HLTs - HLT Gingival pains, HLT Gingival disorders NEC, and HLT Gingival discolourations under the new HLT Gingival disorders, signs and symptoms NEC. Rather than grouping the gingival terms with oral soft tissue concepts, new HLT Gingival disorders, signs and symptoms NEC groups miscellaneous gingival disorders and signs and symptoms together to facilitate coding and retrieval. In related changes, the following PTs will be moved to new HLT Gingival disorders, signs and symptoms NEC: PT Gingival blister, PT Gingival pruritus, PT Gingival oedema, PT Gingival swelling and PT Lineal gingival erythema. Note, PT Gingival discomfort will be moved to HLT Gingival disorders, signs and symptoms NEC in change request 2018143031.

CR Number: 2018283001 **Implementation Date:** 10-Oct-18 Related CR: 2018211006

Change Requested	Add a New HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed HLT	*Gingival disorders, signs and symptoms NEC*	Approved as Requested	Proposed HLT *Gingival disorders, signs and symptoms NEC*	10082211
To HLGT	*Dental and gingival conditions*		To HLGT *Dental and gingival conditions*	10044018

MSSO Comment:

CR Number: 2018283002 **Implementation Date:** 10-Oct-18 Related CR: 2018211006

Change Requested	Merge HLT	Final Disposition	Final Placement	MedDRA Code #
HLT to merge	*Gingival disorders NEC*	Approved as Requested	HLT to merge *Gingival disorders NEC*	
To HLT	*Gingival disorders, signs and symptoms NEC*		To HLT *Gingival disorders, signs and symptoms NEC*	10082211

MSSO Comment:

Supplemental Update Report

CR Number: 2018283003 **Implementation Date:** 10-Oct-18 Related CR: 2018211006

Change Requested	Merge HLT	Final Disposition	Final Placement	MedDRA Code #
HLT to merge	*Gingival discolourations*	Approved as Requested	HLT to merge	
			Gingival discolourations	
To HLT	*Gingival disorders, signs and symptoms NEC*		To HLT	
			Gingival disorders, signs and symptoms NEC	10082211

MSSO Comment:

CR Number: 2018283004 **Implementation Date:** 10-Oct-18 Related CR: 2018211006

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gingival blister*	Approved as Requested	Proposed PT	
			Gingival blister	10049304
From HLT	*Oral soft tissue signs and symptoms*		From HLT	
			Oral soft tissue signs and symptoms	10031021
To HLT	*Gingival disorders, signs and symptoms NEC*		To HLT	
			Gingival disorders, signs and symptoms NEC	10082211

MSSO Comment:

CR Number: 2018283005 **Implementation Date:** 10-Oct-18 Related CR: 2018211006

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gingival pruritus*	Approved as Requested	Proposed PT	
			Gingival pruritus	10049306
From HLT	*Oral soft tissue signs and symptoms*		From HLT	
			Oral soft tissue signs and symptoms	10031021
To HLT	*Gingival disorders, signs and symptoms NEC*		To HLT	
			Gingival disorders, signs and symptoms NEC	10082211

MSSO Comment:

Supplemental Update Report

CR Number: 2018283006 **Implementation Date:** 10-Oct-18 Related CR: 2018211006

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gingival oedema*	Approved as Requested	Proposed PT	
From HLT	*Oral soft tissue swelling and oedema*		*Gingival oedema*	10049305
To HLT	*Gingival disorders, signs and symptoms NEC*		From HLT	
			Oral soft tissue swelling and oedema	10031020
			To HLT	
			Gingival disorders, signs and symptoms NEC	10082211

MSSO Comment:

CR Number: 2018283007 **Implementation Date:** 10-Oct-18 Related CR: 2018211006

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gingival swelling*	Approved as Requested	Proposed PT	
From HLT	*Oral soft tissue swelling and oedema*		*Gingival swelling*	10018291
To HLT	*Gingival disorders, signs and symptoms NEC*		From HLT	
			Oral soft tissue swelling and oedema	10031020
			To HLT	
			Gingival disorders, signs and symptoms NEC	10082211

MSSO Comment:

CR Number: 2018283008 **Implementation Date:** 10-Oct-18 Related CR: 2018211006

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Lineal gingival erythema*	Approved as Requested	Proposed PT	
From HLT	*Oral soft tissue infections*		*Lineal gingival erythema*	10067199
To HLT	*Gingival disorders, signs and symptoms NEC*		From HLT	
			Oral soft tissue infections	10031017
			To HLT	
			Gingival disorders, signs and symptoms NEC	10082211

MSSO Comment:

Supplemental Update Report

CR Number: 2018211007 **Implementation Date:** 14-Aug-18 Related CR: 2018211007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Creatinine clearance increased*	Approved Not as Requested After Suspension	Proposed LLT	
To PT	*Creatinine renal clearance increased*		*Increased creatinine clearance*	10081990 Current
			To PT	
			Creatinine renal clearance increased	10011364

MSSO Comment: The proposal to add a new LLT Creatinine clearance increased to PT Creatinine renal clearance increased is approved but not as requested after suspension. The term could not be added in the requested word order because “Creatinine clearance increased” was originally an LLT in MedDRA Version 2.1 (code # 10011364) and was subsequently renamed to “Creatinine renal clearance increased” and promoted to a PT in Version 3.1. Adding the requested term would create two identical terms with different MedDRA codes which violates the MedDRA data integrity rules. For this reason, renaming terms in this manner is no longer practiced to avoid complications with up versioning and data analysis. To accommodate this request, a new LLT Increased creatinine clearance with a new MedDRA code will be added to PT Creatinine renal clearance increased. Furthermore, to facilitate coding, the counterpart term LLT Decreased creatinine clearance will be added to PT Creatinine renal clearance decreased.

CR Number: 2018226006 **Implementation Date:** 14-Aug-18 Related CR: 2018211007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Decreased creatinine clearance*	Approved as Requested	Proposed LLT	
To PT	*Creatinine renal clearance decreased*		*Decreased creatinine clearance*	10081991 Current
			To PT	
			Creatinine renal clearance decreased	10011372

MSSO Comment:

CR Number: 2018212001 **Implementation Date:** 07-Aug-18 Related CR: 2018212001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Transtracheal aspiration*	Approved as Requested	Proposed LLT	
From PT	*Aspiration*		*Transtracheal aspiration*	10050803 Current
To PT	*Tracheal aspiration procedure*		From PT	
			Aspiration	10003504
			To PT	
			Tracheal aspiration procedure	10081462

MSSO Comment: The proposal to move the LLT Transtracheal aspiration from PT Aspiration to PT Tracheal aspiration procedure is approved as requested. This is a finding during review of the unqualified term list movements for version 21.1. The PT Aspiration tracheal has been merged under PT Aspiration which is linked to SOC Respiratory, thoracic and mediastinal disorders in version 21.1. However, the LLT Transtracheal aspiration is not a disease but a procedure and better aligned under newly added PT Tracheal aspiration procedure- Transtracheal aspiration is a technique for the collection of bronchial secretions for laboratory evaluation and culture. This technique is useful when standard sputum collection has not provided adequate material or determination of the infective agent(s). Specimens collected by this technique are free of contamination from nasal, oral, and pharyngeal secretions.

Supplemental Update Report

CR Number: 2018212002 **Implementation Date:** 07-Aug-18 Related CR: 2018212002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Fragility fracture*	Approved Not as Requested	Proposed LLT	
To PT	*Osteoporotic fracture*		*Fragility fracture*	10081976 Current
			To PT	
			Pathological fracture	10034156

MSSO Comment: The proposal to add a new LLT Fragility fracture to PT Osteoporotic fracture is approved but not as requested. Fragility fracture is a type of pathologic fracture that occurs as result of an injury that would be insufficient to cause fracture in a normal bone. This definition arises because a normal human being ought to be able to fall from standing height without breaking any bones, and a fracture therefore suggests weakness of the skeleton. Osteoporosis is a major risk factor for fragility fractures; however, other causes include other conditions affecting bone strength, such as acromegaly or osteogenesis imperfecta. Therefore, Fragility fracture will be added as LLT to PT Pathological fracture.

CR Number: 2018212003 **Implementation Date:** 07-Aug-18 Related CR: 2018212003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Thalassaemia carrier*	Approved as Requested	Proposed LLT	
			Thalassaemia carrier	10081978 Current
			To PT	
			Thalassaemia minor	10043393

MSSO Comment: The proposal to add a new term Thalassaemia carrier is approved as requested. Thalassemia minor: Also called thalassemia trait, thalassemia minor is the carrier state for beta thalassemia. People who are carriers (heterozygotes) have just one thalassemia gene, are said to have thalassemia minor, and are essentially normal. The requested term Thalassaemia carrier will be added to a promoted PT Thalassaemia minor. In a related change, LLT Thalassaemia minor will be promoted to PT Status and linked to primary HLT Haemoglobinopathies congenital and secondary HLT Thalassaemic disorders. Additionally, American English spelled LLT Thalassemia carrier will be added to the newly promoted PT Thalassaemia minor, and LLT Thalassemia trait, LLT Thalassaemia trait and LLT Thalassemia minor will be moved from PT Thalassaemia to newly promoted PT Thalassaemia minor as well.

CR Number: 2018219002 **Implementation Date:** 07-Aug-18 Related CR: 2018212003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Thalassemia carrier*	Approved as Requested	Proposed LLT	
To PT	*Thalassaemia minor*		*Thalassemia carrier*	10081972 Current
			To PT	
			Thalassaemia minor	10043393

MSSO Comment:

Supplemental Update Report

CR Number: 2018219003 **Implementation Date:** 07-Aug-18 Related CR: 2018212003

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Thalassemia trait*	Approved as Requested	Proposed LLT	
From PT	*Thalassaemia*		*Thalassemia trait*	10054664 Current
To PT	*Thalassaemia minor*		From PT	
			Thalassaemia	10043388
			To PT	
			Thalassaemia minor	10043393

MSSO Comment:

CR Number: 2018219004 **Implementation Date:** 07-Aug-18 Related CR: 2018212003

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Thalassaemia trait*	Approved as Requested	Proposed LLT	
From PT	*Thalassaemia*		*Thalassaemia trait*	10043396 Current
To PT	*Thalassaemia minor*		From PT	
			Thalassaemia	10043388
			To PT	
			Thalassaemia minor	10043393

MSSO Comment:

CR Number: 2018219005 **Implementation Date:** 07-Aug-18 Related CR: 2018212003

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Thalassemia minor*	Approved as Requested	Proposed LLT	
From PT	*Thalassaemia*		*Thalassemia minor*	10054662 Current
To PT	*Thalassaemia minor*		From PT	
			Thalassaemia	10043388
			To PT	
			Thalassaemia minor	10043393

MSSO Comment:

Supplemental Update Report

CR Number: 2018219006 **Implementation Date:** 07-Aug-18 Related CR: 2018212003

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Thalassaemia minor*	Approved as Requested	Proposed LLT *Thalassaemia minor*	10043393
From PT	*Thalassaemia*		From PT *Thalassaemia*	10043388
HLT primary	*Haemoglobinopathies congenital*		HLT primary *Haemoglobinopathies congenital*	10018903
			SOC primary *Congenital, familial and genetic disorders*	10010331
			HLT secondary *Thalassaemic disorders*	10043389
			SOC secondary *Blood and lymphatic system disorders*	10005329

MSSO Comment:

CR Number: 2018212004 **Implementation Date:** 07-Aug-18 Related CR: 2018212004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Hippocampal atrophy*	Approved as Requested	Proposed PT *Hippocampal atrophy*	10081973
			HLT primary *Structural brain disorders NEC*	10042259
			SOC primary *Nervous system disorders*	10029205
			HLT secondary *Dementia NEC*	10012289
			SOC secondary *Psychiatric disorders*	10037175

MSSO Comment: The proposal to add a new term Hippocampal atrophy is approved as requested. Hippocampal atrophy is a condition that causes cognitive and memory dysfunction due to degeneration of the hippocampus. Hippocampal atrophy is fingerprint of Alzheimer's disease but also correlates to other types of dementia or cognitive dysfunctions. Therefore, Hippocampal atrophy will be added as PT to primary HLT Structural brain disorders NEC and secondary HLT Dementia NEC.

Supplemental Update Report

CR Number: 2018212005 **Implementation Date:** 07-Aug-18 Related CR: 2018212005

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New Term				
Proposed Term	*Senile xerosis*	Approved as Requested	Proposed LLT	
			Senile xerosis	10081977 Current
			To PT	
			Senile pruritus	10039986

MSSO Comment: The proposal to add a new term Senile xerosis is approved as requested. Senile xerosis is a type of eczema caused by dehydration of the skin, characterized by pruritic, dry, cracked and fissured skin and commonly occurs in elderly patients. Senile xerosis will be added as LLT to PT Senile pruritus as most often cited in medical literature synonymously.

CR Number: 2018212006 **Implementation Date:** 07-Aug-18 Related CR: 2018212006

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New Term				
Proposed Term	*Coxa magna*	Approved as Requested	Proposed LLT	
			Coxa magna	10081975 Current
			To PT	
			Hip deformity	10061209

MSSO Comment: The proposal to add a new term Coxa magna is approved as requested. Coxa magna is the asymmetrical, circumferential enlargement and deformation of the femoral head and neck and usually refers to a sequela of Legg-Calvé-Perthes disease or osteoarthritis. Coxa magna will be added as sub-concept LLT to PT Hip deformity.

Supplemental Update Report

CR Number: 2018212007 **Implementation Date:** 07-Aug-18 Related CR: 2018212007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cramp-fasciculation syndrome*	Approved as Requested	Proposed PT	
HLT primary	*Neuromuscular disorders NEC*		*Cramp-fasciculation syndrome*	10081974
SOC primary	*Nervous system disorders*		HLT primary	
			Neuromuscular disorders NEC	10029318
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Muscle related signs and symptoms NEC	10028326
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new PT Cramp-fasciculation syndrome to primary HLT Neuromuscular disorders NEC in SOC Nervous system disorders and secondary HLT Muscle related signs and symptoms NEC in SOC Musculoskeletal and connective tissue disorders is approved as requested. Cramp-fasciculation syndrome is a rare neuromuscular condition characterized by persistent muscle cramping and twitching (fasciculations) in otherwise healthy individuals. This can lead to muscle discomfort, pain, or tiredness. Muscles in the leg are most commonly affected, although this condition may involve several parts of the body. Symptoms are thought to be due to over-activity of the associated nerves. In most cases, CFS occurs sporadically in people with no family history of the condition.

CR Number: 2018213001 **Implementation Date:** 07-Aug-18 Related CR: 2018213001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*No prenatal care*	Approved Not as Requested	Proposed PT	
			Lack of prenatal care	10081979
			HLT primary	
			Pregnancy related circumstances	10036569
			SOC primary	
			Social circumstances	10041244

MSSO Comment: The proposal to add a new term No prenatal care is approved but not as requested. Prenatal care aims to promote maternal and fetal health, monitor risk factors, and treat complications as early as possible. Prenatal care improves clinical and psychological outcomes in pregnancy and postpartum and decreases maternal and child morbidity and mortality. Lack of prenatal care is associated with an increased risk of pregnancy complications and an important socioeconomic concept. No prenatal care will be rephrased and added as PT Lack of prenatal care to HLT Pregnancy related circumstances.

Supplemental Update Report

CR Number: 2018213002 **Implementation Date:** 07-Aug-18 Related CR: 2018213002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Subacute renal injury*	Approved Not as Requested	Proposed PT	
HLT primary	*Renal failure and impairment*		*Subacute kidney injury*	10081980
SOC primary	*Renal and urinary disorders*		HLT primary	
			Renal failure and impairment	10038443
			SOC primary	
			Renal and urinary disorders	10038359

MSSO Comment: The proposal to add a new PT Subacute renal injury to primary HLT Renal failure and impairment in SOC Renal and urinary disorders is approved but not as requested. Acute kidney injury (AKI),defined by KDIGO (Kidney Disease: Improving Global Outcomes) as increase in SCr by =0.3 mg/dl within 48 h or to =1.5 times baseline, known or presumed to have occurred within the prior 7 days, develops over hours to days and is usually diagnosed in hospitalized patients or following a procedure. Subacute kidney injury defines a presentation that develops more slowly than AKI but generally results in worsening creatinine in less than three months. The requested term will be modified and added in accordance with nephrology societies for acute kidney injury and subacute kidney injury (AKI, sAKI) as PT Subacute kidney injury to the proposed HLT Renal failure and impairment.

CR Number: 2018213003 **Implementation Date:** 07-Aug-18 Related CR: 2018213003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Anti-glomerular basement membrane disease*	Approved as Requested	Proposed PT	
HLT primary	*Glomerulonephritis and nephrotic syndrome*		*Anti-glomerular basement membrane disease*	10081981
SOC primary	*Renal and urinary disorders*		HLT primary	
			Glomerulonephritis and nephrotic syndrome	10018365
			SOC primary	
			Renal and urinary disorders	10038359
			HLT secondary	
			Autoimmune disorders NEC	10027657
			SOC secondary	
			Immune system disorders	10021428

MSSO Comment: The proposal to add a new PT Anti-glomerular basement membrane disease to primary HLT Glomerulonephritis and nephrotic syndrome in SOC Renal and urinary disorders is approved as requested. Anti–glomerular basement membrane (anti-GBM) disease is an autoimmune disorder characterized by the presence of circulating pathogenic autoantibodies directed against proteins in the glomerular and alveolar basement membranes. Anti-glomerular basement membrane disease will be added as PT as proposed to primary HLT Glomerulonepharitis and nephrotic syndrome, and to secondary HLT Autoimmune disorders NEC. Furthermore, the commonly used acronym Anti-GBM disease will be added as LLT to the new PT Anti-glomerular basement membrane disease.

Supplemental Update Report

CR Number: 2018219007 **Implementation Date:** 07-Aug-18 Related CR: 2018213003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Anti-GBM disease*	Approved as Requested	Proposed LLT	
To PT	*Anti-glomerular basement membrane disease*		*Anti-GBM disease*	10081982 Current
			To PT	
			Anti-glomerular basement membrane disease	10081981

MSSO Comment:

CR Number: 2018213004 **Implementation Date:** 07-Aug-18 Related CR: 2018213004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Iliocostal impingement syndrome*	Approved Not as Requested	Proposed PT	
HLT primary	*Musculoskeletal and connective tissue conditions NEC*		*Iliocostal friction syndrome*	10081983
			HLT primary	
SOC primary	*Musculoskeletal and connective tissue disorders*		*Musculoskeletal and connective tissue pain and discomfort*	10068757
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new PT Iliocostal impingement syndrome to primary HLT Musculoskeletal and connective tissue conditions NEC in SOC Musculoskeletal and connective tissue disorders is approved but not as requested. Iliocostalis syndrome is a condition caused by friction of the lower ribs against the iliac crest, which leads to irritation of soft tissues. It is characterized by undiagnosed chronic side pain. Also known as iliocostal friction syndrome, iliocostalis syndrome occurs most often among individuals suffering from osteoporosis. The requested term will be modified to the more prevalent wording in literature to Iliocostal friction syndrome and added as PT to HLT Musculoskeletal and connective tissue pain and discomfort.

Supplemental Update Report

CR Number: 2018218001 **Implementation Date:** 14-Aug-18 Related CR: 2018218001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Anal exam*	Approved Not as Requested	Proposed PT	
HLT primary	*Physical examination procedures and organ system status*		*Anal examination*	10081984
			HLT primary	
SOC primary	*Investigations*		*Physical examination procedures and organ system status*	10071941
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Anal exam to primary HLT Physical examination procedures and organ system status in SOC Investigations is approved but not as requested. Examination of the anus pertains to an inspection of the distal or terminal orifice of the digestive tract, located in the gluteal cleft. The proposed unqualified investigation term, PT Anal exam, will be reworded as PT Anal examination to conform with existing PT Anal examination abnormal and PT Anal examination normal, and the new PT will be linked to HLT Physical examination procedures and organ system status.

CR Number: 2018218002 **Implementation Date:** 14-Aug-18 Related CR: 2018218002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cryotherapy skin burn*	Rejected		

MSSO Comment: The proposal to add a new LLT Cryotherapy skin burn is not approved. The proposed term implies a causal relationship between two concepts, and therefore represents a combination term. The MSSO refrains from adding such terms as to avoid overpopulation of MedDRA. The requested term can be represented by split coding with LLT Cryotherapy and a new LLT Cold burn. Please consider Section 3.5.4 of the MedDRA Term Selection: Points to Consider document provides the option for splitting and coding verbatim terms of a ‘due to’ nature. In a related change, PT Cold burn will be added to HLT Thermal burns. Please note that when a PT is added to the terminology, an identical LLT is created automatically for data entry purposes.

Supplemental Update Report

CR Number: 2018226003 **Implementation Date:** 14-Aug-18 Related CR: 2018218002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cold burn*	Approved as Requested	Proposed PT	
HLT primary	*Thermal burns*		*Cold burn*	10081985
SOC primary	*Injury, poisoning and procedural complications*		HLT primary	
			Thermal burns	10043418
			SOC primary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment:

CR Number: 2018219001 **Implementation Date:** 05-Sep-18 Related CR: 2018219001

Change Requested	Add a new SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed SMQ	*Cytokinese release syndrome*	Rejected After Suspension		

MSSO Comment: The proposal to add a new SMQ Cytokinese release syndrome is not approved after suspension. An international team of regulatory and industry representatives evaluated this request and does not recommend the development of this SMQ based on the following considerations. Cytokine release syndrome (CRS) is an important toxicity associated with cancer immunotherapy; however, there is currently no universally agreed case definition and it presents with a large variety of signs and symptoms including fever and other features mimicking infection; renal and hepatic impairment; and gastrointestinal, cardiovascular, and neurological manifestations. It is largely a diagnosis of exclusion, being a systemic inflammatory response without any other obvious etiology such as sepsis. The diagnosis also is made on a temporal relationship to immunotherapy; however this timing component cannot be captured in MedDRA. The signs and symptoms are not specific to CRS and there is considerable overlap with other concepts such as anaphylaxis. Even with an algorithmic approach and restricting it to the relevant patient populations receiving cancer immunotherapy, the query is likely to be non-specific and would generate a lot of noise. With increasing awareness of CRS, reporters should be encouraged to use more specific terms to describe the diagnosis, even if it is a provisional one. MedDRA already contains terms such as PT Cytokine release syndrome and PT Cytokine storm to aid in the coding and retrieval of cases of this condition.

Supplemental Update Report

CR Number: 2018220001 **Implementation Date:** 14-Aug-18 Related CR: 2018220001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Arthroplasty metallosis*	Approved Not as Requested	Proposed PT	
			Periprosthetic metallosis	10081986
			HLT primary	
			Musculoskeletal procedural complications	10028392
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Musculoskeletal and connective tissue conditions NEC	10080711
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new term Arthroplasty metallosis is approved but not as requested. Metallosis is a clinical term used to define chronic infiltration of metallic wear debris with reactive, chronic inflammatory change within the periprosthetic bony and soft tissues. This pathologic phenomenon can happen as a rare complication of failed arthroplasties due to articulation and wear of nonbearing surfaces. The requested term will be rephrased and added as PT Periprosthetic metallosis to primary HLT Musculoskeletal procedural complications and secondary HLT Musculoskeletal and connective tissue conditions NEC.

CR Number: 2018220793 **Implementation Date:** 14-Aug-18 Related CR: 2018220793

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hordeolum excision*	Approved Not as Requested	Proposed PT	
To PT	*Curetting of chalazion*		*Hordeolum excision*	10081987
			HLT primary	
			Eyelid therapeutic procedures	10015994
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT Hordeolum excision to PT Curetting of chalazion is approved but not as requested. Hordeola (internal and external) are caused by an acute staphylococcal infection, however, in cases which resist penicillin therapy, incision and drainage may be indicated. Hordeolum excision will be added as a PT to HLT Eyelid therapeutic procedures since hordeola and chalazia are different lesions.

Supplemental Update Report

CR Number: 2018220892 **Implementation Date:** 14-Aug-18 Related CR: 2018220892

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Biospy*	Rejected		

MSSO Comment: The proposal to add a new LLT Biospy is not approved. PT/LLT Biopsy is an existing term which is appropriately placed as an investigational concept under HLT Histopathology procedures NEC, in the uni-axial SOC Investigations. MedDRA rules do not allow the addition of an identical term under a different SOC. Dorland's Medical Dictionary defines biopsy as follows: the removal and examination, usually microscopic, of tissue from the living body, performed to establish precise diagnosis. If a biopsy is performed concurrently with a therapeutic procedure, a separate term can be selected to represent the therapeutic procedure in addition to the selection of an appropriate biopsy term.

CR Number: 2018220907 **Implementation Date:** 14-Aug-18 Related CR: 2018220907

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Vaccinia test positive*	Approved Not as Requested	Proposed LLT	
To PT	*Orthopoxvirus test positive*		*Vaccinia virus test positive*	10070363 Current
			From PT	
			Orthopoxvirus test positive	10070349
			To PT	
			Vaccinia test positive	10069612

MSSO Comment: The proposal to demote the PT Vaccinia test positive under PT Orthopoxvirus test positive is approved but not as requested. Instead of merging PT Vaccinia test positive under PT Orthopoxvirus test positive, LLT Vaccinia virus test positive will be moved from PT Orthopoxvirus test positive to the more specific PT Vaccinia test positive. Vaccinia virus is the live poxvirus used as the smallpox vaccine.

CR Number: 2018221001 **Implementation Date:** 14-Aug-18 Related CR: 2018221001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pulmonary hypersensitivity*	Rejected		

MSSO Comment: The proposal to add a new LLT Pulmonary hypersensitivity is not approved. Hypersensitivity pneumonitis, also called extrinsic allergic alveolitis, is a respiratory syndrome involving the lung parenchyma and specifically the alveoli, terminal bronchioli, and alveolar interstitium, due to a delayed allergic reaction. Such reaction is secondary to a repeated and prolonged inhalation of different types of organic dusts or other substances to which the patient is sensitized and hyper responsive, primarily consisting of organic dusts of animal or vegetable origin, more rarely from chemicals. The requested term is generally used synonymously with and can be represented by LLT Pneumonitis hypersensitivity. In a related change, PT Hypersensitivity pneumonitis will be added in the natural word order to primary HLT Lower respiratory tract inflammatory and immunologic conditions, secondary HLT Allergic conditions NEC. Existing PT Alveolitis allergic will be demoted under this new PT Hypersensitivity pneumonitis.

Supplemental Update Report

CR Number: 2018226004 **Implementation Date:** 14-Aug-18 Related CR: 2018221001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hypersensitivity pneumonitis*	Approved as Requested	Proposed PT	
			Hypersensitivity pneumonitis	10081988
HLT primary	*Lower respiratory tract inflammatory and immunologic conditions*		HLT primary	
			Lower respiratory tract inflammatory and immunologic conditions	10024972
SOC primary	*Respiratory, thoracic and mediastinal disorders*		SOC primary	
			Respiratory, thoracic and mediastinal disorders	10038738
			HLT secondary	
			Allergic conditions NEC	10027654
			SOC secondary	
			Immune system disorders	10021428

MSSO Comment:

CR Number: 2018226005 **Implementation Date:** 14-Aug-18 Related CR: 2018221001

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Alveolitis allergic*	Approved as Requested	PT to merge	
			Alveolitis allergic	10001890 Current
To PT	*Hypersensitivity pneumonitis*		To PT	
			Hypersensitivity pneumonitis	10081988

MSSO Comment:

Supplemental Update Report

CR Number: **2018221002** **Implementation Date:** 14-Aug-18 Related CR: 2018221002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Bladder lesion*	Rejected		

MSSO Comment: The proposal to add a new term Bladder lesion is not approved. The MSSO refrains from adding new "lesion" terms, in accordance with Section 5.1 of the MedDRA Introductory Guide: "Lesion terms may be considered for inclusion in MedDRA when the word “lesion” is part of a medical concept, e.g., PT Glomerulonephritis minimal lesion or a well-documented medical concept, e.g., LLT Brain lesion. However, the term will not be added when adding a broad 'lesion' term only adds an additional imprecise term to existing 'disorder' concepts, e.g., 'renal lesion,' when one could use for coding the existing LLT Renal disorder under PT Renal disorder." In addition, anatomically-specific lesion excision terms in MedDRA generally do not have a counterpart term representing the corresponding anatomically-specific lesion.

CR Number: **2018224001** **Implementation Date:** 16-Aug-18 Related CR: 2018224001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Bone destruction*	Approved as Requested	Proposed LLT	
			Bone destruction	10081992 Current
			To PT	
			Resorption bone increased	10038642

MSSO Comment: The proposal to add a new term Bone destruction is approved as requested. Destruction of bone is common in cancers like multiple myeloma and breast- and prostate cancer metastasizing to bone, in inflammatory diseases such as inflammatory bowel disorder and in certain autoimmune diseases such as rheumatoid arthritis. Bone destruction is triggered by bone-resorbing osteoclasts hyperactivity. Bone destruction will be added as an LLT to PT Resorption bone increased.

CR Number: **2018224002** **Implementation Date:** 16-Aug-18 Related CR: 2018224002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Pernio-like erythema*	Approved as Requested	Proposed LLT	
			Pernio-like erythema	10081993 Current
			To PT	
			Chillblains	10008528

MSSO Comment: The proposal to add a new term Pernio-like erythema is approved as requested. Chilblains, also known as pernio, are localized cutaneous inflammatory lesions of the extremeties precipitated by cold or high humidity. Chilblain may be idiopathic or may be secondary to other systemic diseases such as cryopathies or lupus erythematosus. Cutaneous manifestations of Sjögren's syndrome also are described in literature as pernio-like lesions or pernio-like erythema. Cutaneous descriptive findings with "like" are best placed as LLTs to the dermatological base concept. Therefore, Pernio-like erythema will be added as an LLT to PT Chillblains.

Supplemental Update Report

CR Number: 2018225002 **Implementation Date:** 16-Aug-18 Related CR: 2018225002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Partial splenic embolization*	Approved as Requested	Proposed LLT	
			Partial splenic embolization	10081997 Current
			To PT	
			Partial splenic embolisation	10081995

MSSO Comment: The proposal to add a new term Partial splenic embolization is approved as requested. Partial splenic artery embolization is an adjuvant procedure used for a wide range of indications, including the control of bleeding in blunt splenic injuries, portal hypertension complications in cirrhotic patients, hypersplenism due to various etiologies, and cytopenia induced by anticancer chemotherapy. Partial splenic embolization will be added as LLT to PT Partial splenic embolisation, the counterpart term in British English. In a related change, PT Partial splenic embolisation will be added to HLT Lymphoid tissue therapeutic procedures.

CR Number: 2018228005 **Implementation Date:** 16-Aug-18 Related CR: 2018225002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Partial splenic embolisation*	Approved as Requested	Proposed PT	
HLT primary	*Lymphoid tissue therapeutic procedures*		*Partial splenic embolisation*	10081995
SOC primary	*Surgical and medical procedures*		HLT primary	
			Lymphoid tissue therapeutic procedures	10025308
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment:

CR Number: 2018225003 **Implementation Date:** 16-Aug-18 Related CR: 2018225003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Tumor thrombectomy*	Approved as Requested	Proposed LLT	
			Tumor thrombectomy	10081996 Current
			To PT	
			Tumour thrombectomy	10081994

MSSO Comment: The proposal to add a new term Tumor thrombectomy is approved as requested. Tumour thrombosis is a collective term for intravascular metastases with thrombotic elements. Tumour thrombi propagate in the Inferior Vena Cava from retroperitoneal primaries such as renal cell carcinoma. Tumor thrombectomy will be added as LLT to PT Tumour thrombectomy to the British English counterpart. In a related change, PT Tumour thrombectomy will be added to HLT Vascular therapeutic procedures NEC.

Supplemental Update Report

CR Number: 2018228004 **Implementation Date:** 16-Aug-18 Related CR: 2018225003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Tumour thrombectomy*	Approved as Requested	Proposed PT	
HLT primary	*Vascular therapeutic procedures NEC*		*Tumour thrombectomy*	10081994
SOC primary	*Surgical and medical procedures*		HLT primary	
			Vascular therapeutic procedures NEC	10047094
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment:

CR Number: 2018225004 **Implementation Date:** 16-Aug-18 Related CR: 2018225004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Target skin lesion*	Approved Not as Requested	Proposed PT	
HLT primary	*Bullous conditions*		*Target skin lesion*	10081998
SOC primary	*Skin and subcutaneous tissue disorders*		HLT primary	
			Dermal and epidermal conditions NEC	10012424
			SOC primary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment: The proposal to add a new PT Target skin lesion to primary HLT Bullous conditions in SOC Skin and subcutaneous tissue disorders is approved but not as requested. A target lesion or bull's-eye lesion, named for its resemblance to the bull's-eye of a shooting target, is the typical lesion of erythema multiforme in which a vesicle is surrounded by an often hemorrhagic maculopapule. Target lesion consists of three zones: a dark centre of small papule, vesicle, or bulla (iris); a pale intermediate zone; and a peripheral rim of erythema. Target lesions are also typical of erythema chronicum migrans, and a variety of other conditions which may be idiopathic, or may follow infections, drug therapy, or immunodeficiency. Target skin lesion will be added as a PT to HLT Dermal and epidermal conditions NEC. Although the pattern of the concentric rings is constant in all target skin lesions, vesicles or bullae are not always the basic appearance and therefore Target skin lesion will be linked to a less specific HLT than the proposed placement under HLT Bullous conditions.

Supplemental Update Report

CR Number: 2018226001 **Implementation Date:** 16-Aug-18 Related CR: 2018226001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hemiataxia*	Approved as Requested	Proposed PT	
HLT primary	*Coordination and balance disturbances*		*Hemiataxia*	10081999
SOC primary	*Nervous system disorders*		HLT primary	
			Coordination and balance disturbances	10072984
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Gait disturbances	10017578
			SOC secondary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Hemiataxia to primary HLT Coordination and balance disturbances in SOC Nervous system disorders is approved as requested. Hemiataxia is a loss of muscle control affecting one side of the body, usually as a result of a stroke or cerebellar injury. Hemiataxia will be added as a PT to primary HLT Coordination and balance disturbances, and to secondary HLT Gait disturbances.

CR Number: 2018226002 **Implementation Date:** 16-Aug-18 Related CR: 2018226002

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Parafoveal telangiectasia*	Approved as Requested	Proposed LLT	
From PT	*Retinal telangiectasia*		*Parafoveal telangiectasia*	10064761 Current
To PT	*Macular telangiectasia*		From PT	
			Retinal telangiectasia	10038899
			To PT	
			Macular telangiectasia	10081199

MSSO Comment: The proposal to move the LLT Parafoveal telangiectasia from PT Retinal telangiectasia to PT Macular telangiectasia is approved as requested. Parafoveal telangiectasia is a rare group of disorders consisting of distention or expansion of small capillaries in the macula, and usually associated with retinal bleeding. Accordingly, LLT Parafoveal telangiectasia will more appropriately be placed as a sub-concept LLT under PT Macular telangiectasia.

Supplemental Update Report

CR Number: 2018227001 **Implementation Date:** 23-Aug-18 Related CR: 2018227001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*NMDA-R encephalitis*	Approved Not as Requested	Proposed LLT	
			NMDA-R encephalitis	10082006 Current
			To PT	
			Encephalitis autoimmune	10072378

MSSO Comment: The proposal to add a new PT NMDA-R encephalitis is approved but not as requested. NMDA-R encephalitis will be added as a sub-concept LLT to PT Encephalitis autoimmune as a synonym of the existing LLT Anti-NMDA receptor encephalitis.

CR Number: 2018227002 **Implementation Date:** 23-Aug-18 Related CR: 2018227002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Psychophysiological insomnia*	Approved Not as Requested	Proposed PT	
			Psychophysiologic insomnia	10082004
			HLT primary	
			Dyssomnias	10013980
			SOC primary	
			Psychiatric disorders	10037175
			HLT secondary	
			Sleep disturbances NEC	10040996
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new term Psychophysiological insomnia is approved but not as requested. Psychophysiologic insomnia, as named in the International Classification of Sleep Disorders, is a disorder of somatized tension and learned sleep-preventing associations that results in a complaint of insomnia and associated decreased functioning during wakefulness. Psychophysiologic insomnia will be added as a PT to primary HLT Dyssomnias and secondary HLT Sleep disturbances NEC.

CR Number: 2018227003 **Implementation Date:** 01-Oct-18 Related CR: 2018227003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Cystocoele*	Rejected After Suspension		

MSSO Comment: The proposal to add a new term Cystocoele is not approved after suspension. Cystocele, is a hernial protrusion of the urinary bladder, usually through the vaginal wall. Although "cystocoele" may represent an archaic British English spelling of this concept, cystocoele is essentially not used in modern medical literature nor is this spelling represented in medical dictionaries.

Supplemental Update Report

CR Number: 2018227004 **Implementation Date:** 01-Oct-18 Related CR: 2018227004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Rectocoele*	Rejected After Suspension		

MSSO Comment: The proposal to add a new term Rectocoele is not approved after suspension. A rectocele is a hernial protrusion of part of the rectum into the vagina; called also proctocele and rectovaginal hernia. Although "rectocoele" may represent an archaic British English spelling of this concept, rectocoele is essentially not used in modern medical literature, nor is this spelling represented in medical dictionaries.

CR Number: 2018227005 **Implementation Date:** 23-Aug-18 Related CR: 2018227005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Phototherapeutic keratectomy*	Approved as Requested	Proposed PT	
			Phototherapeutic keratectomy	10082005
			HLT primary	
			Corneal and scleral therapeutic procedures	10010988
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Phototherapeutic keratectomy is approved as requested. Excimer laser phototherapeutic keratectomy has been found to be an effective treatment for corneal surface irregularity, epithelial instability, and superficial opacity, such as scars, degenerations, dystrophies, bullous keratopathy, and band-shaped keratopathy. Phototherapeutic keratectomy is considered a bridge between medical and surgical management of different corneal diseases. Phototherapeutic keratectomy will be added as a new PT to HLT Corneal and scleral therapeutic procedures.

Supplemental Update Report

CR Number: 2018227006 **Implementation Date:** 23-Aug-18 Related CR: 2018227006

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Pulpitis*	Approved Not as Requested	Proposed PT	
Status	*non-current*		*Digital pulpitis*	10082003
			HLT primary	
			Dermatitis and eczema	10012435
			SOC primary	
			Skin and subcutaneous tissue disorders	10040785
			HLT secondary	
			Soft tissue disorders NEC	10041288
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to change status of LLT Pulpitis to non-current is approved but not as requested. Although pulpitis may be used to describe a dermatitis or inflammation of the tip of digits, pulpitis of a tooth appears to be the most commonly used context of the unqualified use of "pulpitis." Instead of changing the status of PT Pulpitis to non-current, PT Digital pulpitis will be added to primary HLT Dermatitis and eczema, and to secondary HLT Soft tissue disorders NEC, to specifically represent pulpitis of the fingers or toes.

CR Number: 2018227008 **Implementation Date:** 22-Aug-18 Related CR: 2018227008

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Removal of medical device occlusion*	Approved as Requested	Proposed PT	
HLT primary	*Therapeutic procedures NEC*		*Removal of medical device occlusion*	10082000
SOC primary	*Surgical and medical procedures*		HLT primary	
			Therapeutic procedures NEC	10027700
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT Removal of medical device occlusion to primary HLT Therapeutic procedures NEC in SOC Surgical and medical procedures is approved as requested. A medical device or a component of a medical device, such as a catheter, tubing, reservoir, pump chamber, etc., may become occluded by organic or inorganic substances, and thus may necessitate a corrective procedure to remove such an occlusion to enable proper function of the device.

Supplemental Update Report

CR Number: 2018228001 **Implementation Date:** 22-Aug-18 Related CR: 2018228001

Change Requested	Swap a PT with an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vogt-Koyanagi-Harada syndrome*	Approved Not as Requested	Proposed PT	
With LLT	*Vogt-Koyanagi-Harada disease*		*Vogt-Koyanagi-Harada disease*	10082001
			HLT primary	
			Iris and uveal tract infections, irritations and inflammations	10022953
			SOC primary	
			Eye disorders	10015919
			HLT secondary	
			Immune and associated conditions NEC	10027682
			SOC secondary	
			Immune system disorders	10021428

MSSO Comment: The proposal to swap the PT Vogt-Koyanagi-Harada syndrome with the LLT Vogt-Koyanagi-Harada disease is approved but not as requested. Vogt-Koyanagi-Harada disease (VKHD) is a rare granulomatous inflammatory disease that affects pigmented structures, such as eye, inner ear, meninges, skin and hair. Vogt-Koyanagi-Harada disease will be added as a PT to primary HLT Iris and uveal tract infections, irritations and inflammations, secondary HLT Immune and associated conditions NEC, and secondary HLT Central nervous system inflammatory disorders NEC. In a related change, Vogt-Koyanagi-Harada syndrome will be demoted to an LLT under new PT Vogt-Koyanagi-Harada disease.

CR Number: 2018234026 **Implementation Date:** 22-Aug-18 Related CR: 2018228001

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vogt-Koyanagi-Harada disease*	Approved as Requested	Proposed PT	
To HLT	*Central nervous system inflammatory disorders NEC*		*Vogt-Koyanagi-Harada disease*	10082001
			To HLT	
			Central nervous system inflammatory disorders NEC	10007952

MSSO Comment:

Supplemental Update Report

CR Number: **2018234027** **Implementation Date:** 22-Aug-18 Related CR: 2018228001

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Vogt-Koyanagi-Harada syndrome*	Approved as Requested	PT to merge	
To PT	*Vogt-Koyanagi-Harada disease*		*Vogt-Koyanagi-Harada syndrome*	10047680 Current
			To PT	
			Vogt-Koyanagi-Harada disease	10082001

MSSO Comment:

CR Number: **2018228002** **Implementation Date:** 22-Aug-18 Related CR: 2018228002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vogt-Koyanagi-Harada disease*	Rejected		
To PT	*Vogt-Koyanagi-Harada syndrome*			

MSSO Comment: The proposal to add a new LLT Vogt-Koyanagi-Harada disease to PT Vogt-Koyanagi-Harada syndrome is not approved. LLT Vogt-Koyanagi-Harada disease was added in change request 2018228001.

CR Number: **2018228003** **Implementation Date:** 22-Aug-18 Related CR: 2018228003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Salzmann Nodular Degeneration*	Approved Not as Requested	Proposed LLT	
			Salzmann nodular degeneration	10082002 Current
			To PT	
			Corneal degeneration	10010996

MSSO Comment: The proposal to add a new LLT Salzmann Nodular Degeneration is approved but not as requested. Salzmann's nodular degeneration is a rare, idiopathic, noninflammatory, slowly progressive degeneration of the cornea, characterized by nodular appearing dense irregularly arranged collagen tissue with hyalinization between epithelium and Bowman's layer or beyond. Proposed term Salzmann Nodular Degeneration will be modified according to MedDRA capitalization conventions, and added as sub-concept LLT Salzmann nodular degeneration to PT Corneal degeneration.

Supplemental Update Report

CR Number: 2018228007 **Implementation Date:** 23-Aug-18 Related CR: 2018228007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Radiation rhinitis*	Approved as Requested	Proposed PT	
			Radiation rhinitis	10082007
			HLT primary	
			Radiation injuries	10037759
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Nasal congestion and inflammations	10028736
			SOC secondary	
			Respiratory, thoracic and mediastinal disorders	10038738

MSSO Comment: The proposal to add a new term Radiation rhinitis is approved as requested. Rhinosinusitis is a common post-radiotherapy side-effect in nasopharyngeal carcinoma patients. Radiation therapy for nasal and paranasal sinus cancer can cause inflammation of the nasal mucosa. Nasal passages may become blocked or stuffy, and nasal mucosa may turn thick and dry, even narrowing in some occasions due to the formation of of bands and scars. Radiation rhinitis will be placed as a PT primarily linked to HLT Radiation injuries, with a secondary link to HLT Nasal congestion and inflammations.

CR Number: 2018229001 **Implementation Date:** 23-Aug-18 Related CR: 2018229001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Placental calcification*	Approved as Requested	Proposed PT	
			Placental calcification	10082008
			HLT primary	
			Placental abnormalities (excl neoplasms)	10035130
			SOC primary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new PT Placental calcification is approved as requested. Placental calcification occurs with advancing gestation, and is especially associated with smoking, placental pathologies such as abruption or infarction, and increasing maternal serum calcium levels. It is easily seen sonographically as hyperechoic deposits. Calcium salts can be deposited throughout the placenta but are most common on the basal plate. Placental calcification will be added as a PT under HLT Placental abnormalities (excl neoplasms).

Supplemental Update Report

CR Number: 2018229002 **Implementation Date:** 23-Aug-18 Related CR: 2018229002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Implantable loop monitor replacement*	Approved as Requested	Proposed LLT *Implantable loop monitor replacement*	10082010 Current
			To PT *Implantable cardiac monitor replacement*	10082009

MSSO Comment: The proposal to add a new LLT Implantable loop monitor replacement is approved as requested. An implantable loop recorder is a subcutaneous, single-lead, electrocardiographic monitoring device used for long-term diagnosis in patients with recurrent unexplained episodes of palpitations or syncope. The device is typically implanted in the left parasternal region and it can be removed or replaced when its battery becomes depleted, usually around 3 years after implantation. Implantable loop monitor replacement will be placed as a sub-element LLT of a new PT Implantable cardiac monitor replacement. In a related change, Implantable cardiac monitor replacement will be added as a PT to HLT Cardiac device therapeutic procedures.

CR Number: 2018235003 **Implementation Date:** 23-Aug-18 Related CR: 2018229002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Implantable cardiac monitor replacement*	Approved as Requested	Proposed PT *Implantable cardiac monitor replacement*	10082009
HLT primary	*Cardiac device therapeutic procedures*		HLT primary *Cardiac device therapeutic procedures*	10007600
SOC primary	*Surgical and medical procedures*		SOC primary *Surgical and medical procedures*	10042613

MSSO Comment:

CR Number: 2018229003 **Implementation Date:** 23-Aug-18 Related CR: 2018229003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Dermatitis aggravated*	Rejected		
To PT	*Dermatitis*			

MSSO Comment: The proposal to add a new LLT Dermatitis aggravated to PT Dermatitis is not approved. The MSSO refrains from adding new terms with qualifiers such as aggravation, worsening, or exacerbation unless such terms represent an internationally accepted unique medical concept. MedDRA cannot accommodate a separate term for an aggravated state of every potential disease or condition. Please consider The MedDRA Term selection: Points to consider document in its item 3.9 – Modification of Pre-existing Conditions, for your coding needs.

Supplemental Update Report

CR Number: 2018229004 **Implementation Date:** 23-Aug-18 Related CR: 2018229004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*CYP3A4 gene status assay*	Approved as Requested	Proposed PT	
HLT primary	*Gene analyses*		*CYP3A4 gene status assay*	10082011
SOC primary	*Investigations*		HLT primary	
			Gene analyses	10071950
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT CYP3A4 gene status assay to primary HLT Gene analyses in SOC Investigations is approved as requested. Cytochrome P450 3A4 (abbreviated CYP3A4) is an important enzyme in the body, mainly found in the liver and in the intestine. In humans, the CYP3A4 protein is encoded by the CYP3A4 gene. It oxidizes small foreign organic molecules (xenobiotics), such as toxins or drugs, so that they can be removed from the body. Variability in CYP3A4 function can be determined noninvasively by both in vivo and in vitro tests.

CR Number: 2018229005 **Implementation Date:** 23-Aug-18 Related CR: 2018229005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*CYP3A4 polymorphism*	Approved as Requested	Proposed PT	
HLT primary	*Acquired gene mutations and other alterations*		*CYP3A4 polymorphism*	10082012
SOC primary	*General disorders and administration site conditions*		HLT primary	
			Acquired gene mutations and other alterations	10071951
			SOC primary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT CYP3A4 polymorphism to primary HLT Acquired gene mutations and other alterations in SOC General disorders and administration site conditions is approved as requested. Up to 28 single nucleotide polymorphisms have been identified in the CYP3A4 gene. Although it has been found that this does not translate into significant interindividual variability in vivo, some alleles have been reported to have minimal function compared to the wild-type leading to decreased catalytic activity with certain ligands, including testosterone and nifedipine.

Supplemental Update Report

CR Number: 2018232001 **Implementation Date:** 23-Aug-18 Related CR: 2018232001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Bone hyperplasia*	Approved as Requested	Proposed LLT	
			Bone hyperplasia	10082013 Current
			To PT	
			Bone hypertrophy	10005973

MSSO Comment: The proposal to add a new term Bone hyperplasia is approved as requested. Because the proposed term Bone hyperplasia is often used synonymously with bone hypertrophy, Bone hyperplasia will be added as a synonym LLT to PT Bone hypertrophy. In a related changes, because Exostosis is a benign bony growth projecting outward from the surface of a bone, and hyperostosis represents hypertrophy of bone, not necessarily in the form of a bony projection, LLT Bone hypertrophy will be promoted from PT Exostosis, to a PT and linked to HLT Bone disorders NEC; also, LLT Hyperostosis, and LLT Hyperostosis of skull will each be moved from PT Exostosis to the newly promoted PT Bone hypertrophy for better alignment.

CR Number: 2018235004 **Implementation Date:** 23-Aug-18 Related CR: 2018232001

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Bone hypertrophy*	Approved as Requested	Proposed LLT	
From PT	*Exostosis*		*Bone hypertrophy*	10005973
HLT primary	*Bone disorders NEC*		From PT	
			Exostosis	10015688
			HLT primary	
			Bone disorders NEC	10027658
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment:

Supplemental Update Report

CR Number: 2018235005 **Implementation Date:** 23-Aug-18 Related CR: 2018232001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hyperostosis*	Approved as Requested	Proposed LLT	
From PT	*Exostosis*		*Hyperostosis*	10020698 Current
To PT	*Bone hypertrophy*		From PT	
			Exostosis	10015688
			To PT	
			Bone hypertrophy	10005973

MSSO Comment:

CR Number: 2018235006 **Implementation Date:** 23-Aug-18 Related CR: 2018232001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hyperostosis of skull*	Approved as Requested	Proposed LLT	
From PT	*Exostosis*		*Hyperostosis of skull*	10020699 Current
To PT	*Bone hypertrophy*		From PT	
			Exostosis	10015688
			To PT	
			Bone hypertrophy	10005973

MSSO Comment:

CR Number: 2018232002 **Implementation Date:** 23-Aug-18 Related CR: 2018232002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cheek swelling*	Approved Not as Requested	Proposed LLT	
HLT primary	*Angioedemas*		*Cheek swelling*	10082014 Current
SOC primary	*Skin and subcutaneous tissue disorders*		To PT	
			Swelling face	10042682

MSSO Comment: The proposal to add a new PT Cheek swelling to primary HLT Angioedemas in SOC Skin and subcutaneous tissue disorders is approved but not as requested. Cheeks are one of the regions of face which is most frequently involved in swelling of face, due to its softness and laxitude. Because cheek swelling can be considered a sub-concept of facial swelling, Cheek swelling will be added as a sub-concept LLT to PT Swelling face, rather than as a proposed new PT.

Supplemental Update Report

CR Number: 2018232003 **Implementation Date:** 23-Aug-18 Related CR: 2018232003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Retinoscopy*	Approved Not as Requested	Proposed PT	
HLT primary	*Ophthalmic histopathology and imaging procedures*		*Retinoscopy*	10082015
SOC primary	*Investigations*		HLT primary	
			Ophthalmic function diagnostic procedures	10030864
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Retinoscopy to primary HLT Ophthalmic histopathology and imaging procedures in SOC Investigations is approved but not as requested. Retinoscopy is a technique to obtain an objective measurement of the refractive error of a patient's eyes. The examiner uses a retinoscope to shine light into the patient's eye and observes the reflection (reflex) off the patient's retina. While moving the streak or spot of light across the pupil the examiner observes the relative movement of the reflex or manually places lenses over the eye (using a trial frame and trial lenses) to "neutralize" the reflex. Although retinoscopy does not entail imaging the interior of the eye in a detailed manner, abnormal characteristics of the retinal reflex may also indicate the existence of ocular pathology. Retinoscopy will be added as a PT to HLT Ophthalmic function diagnostic procedures, because the principal objective of retinoscopy is to assess the refractive status of the eye.

CR Number: 2018232004 **Implementation Date:** 23-Aug-18 Related CR: 2018232004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Skiascopy*	Approved as Requested	Proposed LLT	
To PT	*Retinoscopy*		*Skiascopy*	10082018 Current
			To PT	
			Retinoscopy	10082015

MSSO Comment: The proposal to add a new LLT Skiascopy to PT Retinoscopy is approved as requested. Skiascopy is a recognized synonym of PT Retinoscopy that was added in change request 2018232003.

CR Number: 2018232005 **Implementation Date:** 23-Aug-18 Related CR: 2018232005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Retinoscopy normal*	Approved as Requested	Proposed PT	
HLT primary	*Ophthalmic function diagnostic procedures*		*Retinoscopy normal*	10082016
SOC primary	*Investigations*		HLT primary	
			Ophthalmic function diagnostic procedures	10030864
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Retinoscopy normal to primary HLT Ophthalmic function diagnostic procedures in SOC Investigations is approved as requested. Retinoscopy is a technique to obtain an objective measurement of the refractive error of a patient's eyes, using a retinoscope and trial lenses. A normal retinoscopy result may represent that a significant refractive error was not measured, and that there was not an abnormality of the light reflex that was observed.

Supplemental Update Report

CR Number: 2018232006 **Implementation Date:** 23-Aug-18 Related CR: 2018232006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Retinoscopy abnormal*	Approved as Requested	Proposed PT	
HLT primary	*Ophthalmic function diagnostic procedures*		*Retinoscopy abnormal*	10082017
SOC primary	*Investigations*		HLT primary	
			Ophthalmic function diagnostic procedures	10030864
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Retinoscopy abnormal to primary HLT Ophthalmic function diagnostic procedures in SOC Investigations is approved as requested. Retinoscopy is a technique to obtain an objective measurement of the refractive error of a patient's eyes, using a retinoscope and trial lenses. An abnormal retinoscopy finding may represent a refractive error that was detected, or that an abnormality of the light reflex was observed during the investigative procedure that may indicate the presence of ocular pathology.

CR Number: 2018232007 **Implementation Date:** 29-Oct-18 Related CR: 2018232007

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Myopic chorioretinal degeneration*	Rejected After Suspension		
To PT	*Myopic traction maculopathy*			

MSSO Comment: The proposal to demote the PT Myopic chorioretinal degeneration under PT Myopic traction maculopathy is not approved after suspension. Myopic chorioretinal degeneration is generally considered to be a degenerative process that is not limited to the macula, as it can also occur in the extra macular regions of the retina such as the peripapillary area. The article provided by the submitter is a proposed classification of myopic maculopathy based on five categories. Although Category 1 is described as diffuse chorioretinal atrophy, the publication did not appear to imply that diffuse chorioretinal atrophy, or that myopic chorioretinal degeneration are sub-types of myopic traction maculopathy. Myopic chorioretinal degeneration results from myopic axial elongation causing stretching of the ocular layers and progressive thinning of the retina, choroid, and sclera. Myopic traction maculopathy is a schisis-like thickening of the retina in highly myopic eyes with posterior staphyloma. It has been suggested that the schisis-like thickening represents edema from vitreous-retinal traction rather than a true schism. PT Myopic chorioretinal degeneration and PT Myopic traction maculopathy are thus distinct concepts appropriately represented as PT terms. In a related change, PT Myopic chorioretinal degeneration will be moved from HLT Choroid and vitreous structural change, deposit and degeneration to HLT Retinal structural change, deposit and degeneration, because the retinal pathology is a principal underlying cause of visual impairment associated with myopic chorioretinal degeneration, and to align the PT Myopic chorioretinal degeneration with PT Myopic traction maculopathy.

Supplemental Update Report

CR Number: 2018302003 **Implementation Date:** 29-Oct-18 Related CR: 2018232007

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Myopic chorioretinal degeneration*	Approved as Requested	Proposed PT	
From HLT	*Choroid and vitreous structural change, deposit and degeneration*		*Myopic chorioretinal degeneration*	10079959
To HLT	*Retinal structural change, deposit and degeneration*		From HLT	
			Choroid and vitreous structural change, deposit and degeneration	10008776
			To HLT	
			Retinal structural change, deposit and degeneration	10038896

MSSO Comment:

CR Number: 2018232008 **Implementation Date:** 23-Aug-18 Related CR: 2018232008

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Eyelid gold weight insertion*	Approved as Requested	PT to merge	
To PT	*Eyelid weights application*		*Eyelid gold weight insertion*	10081926 Current
			To PT	
			Eyelid weights application	10080109

MSSO Comment: The proposal to demote the PT Eyelid gold weight insertion under PT Eyelid weights application is approved as requested. The application of a weight to the upper eyelid allows an improperly working eyelid to close with gravity. Several medical disorders, including facial paralysis, create a condition of lagophthalmos, in which the upper eyelid does not close because the orbicularis oculi muscle fails to function. The surgical insertion of a gold weight to the upper eyelid is a specific type of eyelid weight application. Accordingly, PT Eyelid gold weight insertion can be demoted as a sub-concept LLT to PT Eyelid weights application.

CR Number: 2018233001 **Implementation Date:** 28-Aug-18 Related CR: 2018233001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Episodic Migraine*	Approved Not as Requested	Proposed LLT	
			Episodic migraine	10082019 Current
			To PT	
			Migraine	10027599

MSSO Comment: The proposal to add a new LLT Episodic Migraine is approved but not as requested. Defined in opposition to the diagnosis of Chronic migraine as the presence of migrainous headache on 14 or fewer days per month, Episodic migraine - like other migraine temporal profile related terms - will be added as a sub-concept LLT to PT Migraine. The spelling of the proposed term will be corrected to Episodic migraine in accordance with MedDRA capitalization rules.

Supplemental Update Report

CR Number: 2018234001 **Implementation Date:** 28-Aug-18 Related CR: 2018234001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Puffy eyes*	Approved Not as Requested	Proposed LLT	
HLT primary	*Electrolyte imbalance NEC*		*Puffy eyes*	10082020 Current
SOC primary	*Metabolism and nutrition disorders*		To PT	
			Eye swelling	10015967

MSSO Comment: The proposal to add a new PT Puffy eyes to primary HLT Electrolyte imbalance NEC in SOC Metabolism and nutrition disorders is approved but not as requested. Puffy eyes is a colloquial expression for the appearance of swelling in the soft tissues around the eyes, and may affect upper, lower, or both eyelids, and/or periorbital tissues. Puffy eyes is usually caused by an accumulation of fluid, but is not diagnostic of a specific condition, as causes can include, but are not limited to: electrolyte imbalances or other causes of edema; allergic, infective or toxic conjunctivitis; angioedema; age-related orbital fat protrusion, etc. Thus, the commonly used descriptive expression Puffy eyes will be added as a synonym LLT to PT Eye swelling. If the cause of puffy eyes is identified, such a concept can be represented by adding an additional MedDRA term.

CR Number: 2018234002 **Implementation Date:** 31-Aug-18 Related CR: 2018234002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Mononuclear cell count increased*	Approved as Requested	Proposed PT	
			Mononuclear cell count increased	10082032
			HLT primary	
			White blood cell analyses	10047938
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Mononuclear cell count increased is approved as requested. A peripheral blood mononuclear cell is any peripheral blood cell having a round nucleus. These cells consist of lymphocytes (T cells, B cells, NK cells) and monocytes. The peripheral blood mononuclear cell count is a routinely used and meaningful index for infection and blood diseases. This new qualified term will better capture the specificity of the reported medical outcome, and complement existing PT Mononuclear cell count. Mononuclear cell count increased will be added as PT to the HLT White blood cell analyses.

Supplemental Update Report

CR Number: 2018234003 **Implementation Date:** 31-Aug-18 Related CR: 2018234003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Mononuclear cell count decreased*	Approved as Requested	Proposed PT *Mononuclear cell count decreased*	10082036
			HLT primary *White blood cell analyses*	10047938
			SOC primary *Investigations*	10022891

MSSO Comment: The proposal to add a new PT Mononuclear cell count decreased is approved as requested. A peripheral blood mononuclear cell is any peripheral blood cell having a round nucleus. These cells consist of lymphocytes (T cells, B cells, NK cells) and monocytes. The peripheral blood mononuclear cell count is a routinely used and meaningful index for infection and blood diseases. This new qualified term will better capture the specificity of the reported medical outcome, and complement existing PT Mononuclear cell count. Mononuclear cell count decreased will be added as PT to the HLT White blood cell analyses.

CR Number: 2018234004 **Implementation Date:** 31-Aug-18 Related CR: 2018234004

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Loss of thoracic lordosis*	Approved as Requested	LLT to change *Loss of thoracic lordosis*	10067713 Non-Current
Status	*non-current*		Status *non-current*	

MSSO Comment: The proposal to change status of LLT Loss of thoracic lordosis to non-current is approved as requested. The vertebral column is constituted by a succession of three physiological curves: lumbar lordosis, dorsal kyphosis, cervical lordosis. The term Loss of thoracic lordosis, which is intended to represent the loss of a physiologic thoracic lordosis, does not exist in normal spine curvatures. Therefore, the LLT Loss of thoracic lordosis will be made non-current.

Supplemental Update Report

CR Number: 2018234005 **Implementation Date:** 31-Aug-18 Related CR: 2018234005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Nephritis bacterial*	Approved as Requested	Proposed PT	
			Nephritis bacterial	10082040
			HLT primary	
			Bacterial infections NEC	10004047
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Renal infections and inflammations (excl nephritis)	10038472
			SOC secondary	
			Renal and urinary disorders	10038359

MSSO Comment: The proposal to add a new PT Nephritis bacterial is approved as requested. The proposed term will be added to represent a broad concept for the various forms of bacterial infections of the kidneys. Nephritis bacterial will be added as a PT to primary HLT Bacterial infections NEC and secondary HLT Renal infections and inflammations (excl nephritis). In related a change, PT Acute focal bacterial nephritis will be demoted as a sub-concept LLT to the newly added PT Nephritis bacterial.

CR Number: 2018243006 **Implementation Date:** 31-Aug-18 Related CR: 2018234005

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Acute focal bacterial nephritis*	Approved as Requested	PT to merge	
To PT	*Nephritis bacterial*		*Acute focal bacterial nephritis*	10071736 Current
			To PT	
			Nephritis bacterial	10082040

MSSO Comment:

Supplemental Update Report

CR Number: 2018234006 **Implementation Date:** 31-Aug-18 Related CR: 2018234006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Adverse product reaction*	Approved Not as Requested	Proposed LLT *Adverse reaction to product* To PT *Adverse reaction*	 10082046 Current 10067484

MSSO Comment: The proposal to add a new term Adverse product reaction is approved but not as requested. A term broader than adverse drugs reaction would be adequate for safety concerns related to combination products. The proposed term will rephrased for clarity as Adverse reaction to product and will be added as a sub-element LLT to PT Adverse reaction.

CR Number: 2018234007 **Implementation Date:** 31-Aug-18 Related CR: 2018234007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Erythematous leg nodule*	Approved Not as Requested	Proposed LLT *Erythematous nodule* To PT *Skin mass*	 10082043 Current 10067868

MSSO Comment: The proposal to add a new term Erythematous leg nodule is approved but not as requested. A broader than requested new term named Erythematous nodule will be added to represent inflammatory nodules often located on the lower extremity. Erythematous nodule can be considered a sub-element LLT of PT Skin mass. The requested concept can be represented by the combination of this new LLT and other additional existing LLTs, such as Erythema of extremities, and/or Localised erythema.

CR Number: 2018234008 **Implementation Date:** 31-Aug-18 Related CR: 2018234008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT To PT	*Wrong drug strength administered* *Wrong dose administered*	Approved Not as Requested	Proposed LLT *Wrong drug strength administered* To PT *Incorrect dose administered*	 10082044 Current 10064355

MSSO Comment: The proposal to add a new LLT Wrong drug strength administered to PT Wrong dose administered is approved but not as requested. Drug strength is the amount of drug in a given dosage form. Administration of a wrong drug strength is one of the possible circumstances leading to a wrong dose administration. Therefore, the proposed term Wrong drug strength administered will be added as an LLT to PT Incorrect dose administered. The new LLT will be mapped to PT Incorrect dose administered instead of the proposed term Wrong dose administered, which is an LLT to PT Incorrect dose administered.

Supplemental Update Report

CR Number: 2018234009 **Implementation Date:** 31-Aug-18 Related CR: 2018234009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Peripheral venous perforation*	Approved as Requested	Proposed LLT	
To PT	*Venous perforation*		*Peripheral venous perforation*	10082047 Current
			To PT	
			Venous perforation	10075733

MSSO Comment: The proposal to add a new LLT Peripheral venous perforation to PT Venous perforation is approved as requested. Although perforation of the great vessels during placement of central venous lines is the most severe complication of venous accesses, peripheral venous cannulas may also cause perforation of a peripheral vein, most frequently in the hands or forearms.

CR Number: 2018234010 **Implementation Date:** 31-Aug-18 Related CR: 2018234010

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hyperplasia adrenal*	Approved as Requested	Proposed LLT	
From PT	*Hyperadrenalism*		*Hyperplasia adrenal*	10020719
			From PT	
			Hyperadrenalism	10020562
			HLT primary	
			Adrenal gland disorders NEC	10001354
			SOC primary	
			Endocrine disorders	10014698
			HLT secondary	
			Metabolic disorders NEC	10027428
			SOC secondary	
			Metabolism and nutrition disorders	10027433

MSSO Comment: The proposal to promote the LLT Hyperplasia adrenal from PT Hyperadrenalism is approved as requested. Even if hyperadrenalism and adrenal hyperplasia often concur, there are conditions in which one may occur without the other. Hyperplasia adrenal may be associated with both adrenal hyper and hypofunction, and therefore, the LLT Hyperplasia adrenal will be promoted to PT under primary HLT Adrenal gland disorders NEC and secondary HLT Metabolic disorders NEC. In related changes, LLT Adrenal cortex hyperplasia and LLT Hyperplasia adrenal cortex will each be moved from PT Hyperadrenocorticism to the newly promoted PT Hyperplasia adrenal.

Supplemental Update Report

CR Number: 2018243003 **Implementation Date:** 31-Aug-18 Related CR: 2018234010

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Adrenal cortex hyperplasia*	Approved as Requested	Proposed LLT	
From PT	*Hyperadrenocorticism*		*Adrenal cortex hyperplasia*	10001333 Current
To PT	*Hyperplasia adrenal*		From PT	
			Hyperadrenocorticism	10020564
			To PT	
			Hyperplasia adrenal	10020719

MSSO Comment:

CR Number: 2018243004 **Implementation Date:** 31-Aug-18 Related CR: 2018234010

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hyperplasia adrenal cortex*	Approved as Requested	Proposed LLT	
From PT	*Hyperadrenocorticism*		*Hyperplasia adrenal cortex*	10020720 Current
To PT	*Hyperplasia adrenal*		From PT	
			Hyperadrenocorticism	10020564
			To PT	
			Hyperplasia adrenal	10020719

MSSO Comment:

Supplemental Update Report

CR Number: 2018234011 **Implementation Date:** 01-Oct-18 Related CR: 2018234011

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Product packaging difficult to open*	Approved After Suspension	Proposed LLT	
From PT	*Product use complaint*		*Product packaging difficult to open*	10079403
			From PT	
			Product use complaint	10079400
			HLT primary	
			Product packaging issues	10069291
			SOC primary	
			Product issues	10077536

MSSO Comment: The proposal to promote the LLT Product packaging difficult to open from PT Product use complaint is approved as requested after suspension. Product packaging difficult to open refers to an intrinsic deficiency of the product rather than to any kind of human error, complaint, or medication issue. Therefore, Product packaging difficult to open will be promoted from PT Product use complaint and to a PT level and linked to HLT Product packaging issues.

CR Number: 2018234012 **Implementation Date:** 31-Aug-18 Related CR: 2018234012

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Immature granulocyte percentage increased*	Approved Not as Requested	Proposed PT	
			Immature granulocyte percentage increased	10082033
			HLT primary	
			White blood cell analyses	10047938
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new LLT Immature granulocyte percentage increased is approved but not as requested. Immature granulocyte percentage increased will be added as as a PT to HLT White blood cell analyses, as percentage counterpart of existing PT Immature granulocyte count increased. An increase in immature granulocytes can be explained by causes different than shift to the left, such as an increase in immature cells from leukemia.

CR Number: 2018234013 **Implementation Date:** 31-Aug-18 Related CR: 2018234013

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Intraocular inflammation*	Approved Not as Requested	Proposed LLT	
To PT	*Endophthalmitis*		*Intraocular inflammation*	10082041 Current
			To PT	
			Eye inflammation	10015943

MSSO Comment: The proposal to add a new LLT Intraocular inflammation to PT Endophthalmitis is approved but not as requested. Although intraocular inflammation can be used in the context of endophthalmitis, it is also used in association with uveitis and other types of interocular inflammatory pathology. Intraocular inflammation will thus be added a sub-concept LLT to PT Eye inflammation.

Supplemental Update Report

CR Number: 2018234014 **Implementation Date:** 31-Aug-18 Related CR: 2018234014

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Sigmoid-shaped ventricular septum*	Approved as Requested	Proposed PT	
			Sigmoid-shaped ventricular septum	10082038
			HLT primary	
			Myocardial disorders NEC	10028590
			SOC primary	
			Cardiac disorders	10007541

MSSO Comment: The proposal to add a new term Sigmoid-shaped ventricular septum is approved as requested. The cardiac inter-ventricular septum is generally in parallel alignment with anterior aspect of root of aorta. An abnormal aortic angle with that of inter-ventricular septum may make the IVS appear sigmoid. A sigmoid-shaped ventricular septum is generally considered a normal part of the aging process and is of little clinical significance. However, certain patients with this disorder may experience clinical symptoms such as dyspnea upon effort and syncope. Sigmoid-shaped ventricular septum will thus be added as PT to HLT Myocardial disorders NEC.

CR Number: 2018234015 **Implementation Date:** 31-Aug-18 Related CR: 2018234015

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Tracheal squamous cell metaplasia*	Approved as Requested	Proposed PT	
			Tracheal squamous cell metaplasia	10082034
			HLT primary	
			Tracheal disorders (excl infections and neoplasms)	10044288
			SOC primary	
			Respiratory, thoracic and mediastinal disorders	10038738

MSSO Comment: The proposal to add a new term Tracheal squamous cell metaplasia is approved as requested. Squamous metaplasia of the trachea is a benign non-cancerous change of surface lining epithelial cells to a different squamous morphology. Tracheal squamous cell metaplasia will be added as a PT to HLT Tracheal disorders (excl infections and neoplasms).

Supplemental Update Report

CR Number: **2018234016** **Implementation Date:** 31-Aug-18 Related CR: 2018234016

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ocular stem cell transplant*	Approved as Requested	Proposed PT	
HLT primary	*Eye therapeutic procedures NEC*		*Ocular stem cell transplant*	10082039
SOC primary	*Surgical and medical procedures*		HLT primary	
			Eye therapeutic procedures NEC	10027675
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT Ocular stem cell transplant to primary HLT Eye therapeutic procedures NEC in SOC Surgical and medical procedures is approved as requested. Stem cells are unspecialized cells that have been a major focus of the field of regenerative medicine, and a variety of investigations are being conducted to identify stem cell transplant therapy procedures for a broad variety of ocular disorders including those of the retina, cornea, and lens.

CR Number: **2018234017** **Implementation Date:** 31-Aug-18 Related CR: 2018234017

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Urethral necrosis*	Approved as Requested	Proposed PT	
HLT primary	*Urethral disorders NEC*		*Urethral necrosis*	10082037
SOC primary	*Renal and urinary disorders*		HLT primary	
			Urethral disorders NEC	10046448
			SOC primary	
			Renal and urinary disorders	10038359
			HLT secondary	
			Site specific necrosis and vascular insufficiency NEC	10052781
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new PT Urethral necrosis to primary HLT Urethral disorders NEC in SOC Renal and urinary disorders is approved as requested. Urethral necrosis may result from a variety of etiologies, such as infection of the lower urinary tract, local neoplastic disease, traumatic injury, ionizing radiation, and as a complication of urological and gynecological surgery and other procedures. Urethral necrosis will be added as a PT to primary HLT Urethral disorders NEC, and to secondary HLT Site specific necrosis and vascular insufficiency NEC.

Supplemental Update Report

CR Number: 2018234018 **Implementation Date:** 31-Aug-18 Related CR: 2018234018

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Puncture site bruise*	Approved as Requested	Proposed PT	
HLT primary	*Administration site reactions NEC*		*Puncture site bruise*	10082035
SOC primary	*General disorders and administration site conditions*		HLT primary	
			Administration site reactions NEC	10057196
			SOC primary	
			General disorders and administration site conditions	10018065
			HLT secondary	
			Bruising, ecchymosis and purpura	10006513
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new PT Puncture site bruise to primary HLT Administration site reactions NEC in SOC General disorders and administration site conditions is approved as requested. A variety of diagnostic and therapeutic procedures may involve non-vascular puncture sites, such as lumbar puncture, joint aspiration, pleural fluid drainage, etc., and a puncture site bruise may be a complication of such a procedure. Puncture site bruise will be added as a PT to primary HLT Administration site reactions NEC, under HLGT Administration site reactions which is biaxial to primary SOC General disorders and administration site conditions, and to secondary SOC Injury, poisoning and procedural complications; PT Puncture site bruise will also be linked to secondary HLT Bruising, ecchymosis and purpura, and to secondary HLT Skin injuries and mechanical dermatoses.

CR Number: 2018243005 **Implementation Date:** 31-Aug-18 Related CR: 2018234018

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Puncture site bruise*	Approved as Requested	Proposed PT	
To HLT	*Skin injuries and mechanical dermatoses*		*Puncture site bruise*	10082035
			To HLT	
			Skin injuries and mechanical dermatoses	10040877

MSSO Comment:

Supplemental Update Report

CR Number: 2018234019 **Implementation Date:** 31-Aug-18 Related CR: 2018234019

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Portal vein embolism*	Approved as Requested	Proposed PT	
HLT primary	*Hepatic vascular disorders*		*Portal vein embolism*	10082030
SOC primary	*Hepatobiliary disorders*		HLT primary	
			Hepatic vascular disorders	10019712
			SOC primary	
			Hepatobiliary disorders	10019805
			HLT secondary	
			Hepatic and portal embolism and thrombosis	10019630
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new PT Portal vein embolism to primary HLT Hepatic vascular disorders in SOC Hepatobiliary disorders is approved as requested. Although not a frequently described concept in the medical literature, a portal vein embolus may occur, for example, in the context of a migrating thrombus originated by blood stasis in the stump of the splenic vein after splenectomy. Portal vein embolism will be added as a PT to primary HLT Hepatic vascular disorders, and to secondary HLT Hepatic and portal embolism and thrombosis.

CR Number: 2018234020 **Implementation Date:** 31-Aug-18 Related CR: 2018234020

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Beta-thalassemia trait*	Approved Not as Requested	Proposed LLT	
To PT	*Thalassaemia beta*		*Beta-thalassemia trait*	10082045 Current
			To PT	
			Thalassaemia minor	10043393

MSSO Comment: The proposal to add a new LLT Beta-thalassemia trait to PT Thalassaemia beta is approved but not as requested. Individuals who have Beta-thalassemia trait, also called thalassemia minor, carry the genetic trait for thalassemia, but do not usually experience related health problems, except perhaps a mild anemia. Beta-thalassemia trait will thus be added as an LLT to the recently promoted PT Thalassaemia minor (change request 2018219006).

CR Number: 2018234021 **Implementation Date:** 17-Sep-18 Related CR: 2018234021

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Ciliary body inflammation*	Approved After Suspension	Proposed LLT	
			Ciliary body inflammation	10082087 Current
			To PT	
			Iridocyclitis	10022941

MSSO Comment: The proposal to add a new term Ciliary body inflammation is approved as requested after suspension. Ciliary body inflammation is a component of anterior uveitis or iridocyclitis. Accordingly, Ciliary body inflammation will be added as a sub-concept LLT to PT Iridocyclitis.

Supplemental Update Report

CR Number: 2018234022 **Implementation Date:** 31-Aug-18 Related CR: 2018234022

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Spinal stroke*	Approved as Requested	Proposed PT	
			Spinal stroke	10082031
			HLT primary	
			Central nervous system haemorrhages and cerebrovascular accidents	10007948
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Cerebrovascular and spinal vascular disorders NEC	10008193
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new term Spinal stroke is approved as requested. A spinal stroke occurs when the blood supply to the spinal cord is impaired. The majority of spinal strokes are ischemic, and less commonly hemorrhagic. Spinal stroke will be added as a new PT to primary HLT Central nervous system haemorrhages and cerebrovascular accidents, and to secondary HLT Cerebrovascular and spinal vascular disorders NEC. In a related change, Spinal cord infarction will be moved from HLT Spinal cord and nerve root disorders NEC to HLT Central nervous system haemorrhages and cerebrovascular accidents for a better representation.

CR Number: 2018243007 **Implementation Date:** 31-Aug-18 Related CR: 2018234022

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Spinal cord infarction*	Approved as Requested	Proposed PT	
From HLT	*Spinal cord and nerve root disorders NEC*		*Spinal cord infarction*	10058571
To HLT	*Central nervous system haemorrhages and cerebrovascular accidents*		From HLT	
			Spinal cord and nerve root disorders NEC	10041544
			To HLT	
			Central nervous system haemorrhages and cerebrovascular accidents	10007948

MSSO Comment:

Supplemental Update Report

CR Number: 2018234023 **Implementation Date:** 31-Aug-18 Related CR: 2018234023

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vestibulectomy*	Approved Not as Requested	Proposed LLT	
To PT	*Vaginectomy*		*Vaginal vestibulectomy*	10082042 Current
			To PT	
			Vaginectomy	10051694

MSSO Comment: The proposal to add a new LLT Vestibulectomy to PT Vaginectomy is approved but not as requested. The term will be renamed to Vaginal vestibulectomy to avoid ambiguity with the vestibule in the inner ear. A vestibulectomy is a gynecological surgical procedure that can be used to treat vulvar pain and vulvar vestibulitis. The vestibulum vaginae, or vestibule of vagina is the space between the labia minora into which the urethra and vagina open. The surgery takes place below the urinary meatus, down to the border of the perineal area and includes the fourchette. The amount of vaginal tissue removed during the surgery can vary. Vaginal vestibulectomy will be added as a sub-concept LLT to PT Vaginectomy.

CR Number: 2018234024 **Implementation Date:** 28-Aug-18 Related CR: 2018234024

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Lymphoepithelioma*	Approved as Requested	Proposed LLT	
			Lymphoepithelioma	10082022 Current
			To PT	
			Undifferentiated nasopharyngeal carcinoma	10073328

MSSO Comment: The proposal to add a new LLT Lymphoepithelioma is approved as requested. Lymphoepithelial carcinoma (also known as Lymphoepithelioma) is a rare subtype of oral carcinoma. The World Health Organization has defined it as “a poorly differentiated squamous cell carcinoma or histologically undifferentiated carcinoma accompanied by a prominent reactive lymphoplasmacytic infiltrate, morphologically similar to nasopharyngeal carcinoma.” Lymphoepithelioma has been diagnosed in the oral cavity, oropharynx, nasal cavity, and paranasal sinuses, and in numerous other organs of the head and neck region. Non nasopharyngeal lymphoepitheliomas (particularly those in lung) are usually noted as "lymphoepithelioma-like" carcinomas, in an attempt to indicate the similarity in histology, but in different location and with different behavior. Lymphoepithelioma will be added as a sub-concept LLT to PT Undifferentiated nasopharyngeal carcinoma. In a related change, LLT Lymphoepithelial carcinoma will be added to PT Undifferentiated nasopharyngeal carcinoma to facilitate coding, as it is a frequently used synonym of Lymphoepithelioma.

CR Number: 2018240001 **Implementation Date:** 28-Aug-18 Related CR: 2018234024

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Lymphoepithelial carcinoma*	Approved as Requested	Proposed LLT	
To PT	*Undifferentiated nasopharyngeal carcinoma*		*Lymphoepithelial carcinoma*	10082023 Current
			To PT	
			Undifferentiated nasopharyngeal carcinoma	10073328

MSSO Comment:

Supplemental Update Report

CR Number: 2018234025 **Implementation Date:** 28-Aug-18 Related CR: 2018234025

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Schmincke-reynaud tumor*	Approved Not as Requested	Proposed LLT	
			Schmincke-Regaud tumor	10082021 Current
			To PT	
			Undifferentiated nasopharyngeal carcinoma	10073328

MSSO Comment: The proposal to add a new LLT Schmincke-reynaud tumor is approved but not as requested. Lymphoepithelioma may also be referred to as Schmincke-Regaud tumor, after the German pathologist Alexander Schminke and French radiologist Claude Regaud. Schmincke-Regaud tumor, incorporating corrected spelling of the proposed term, will be added as an LLT to PT Undifferentiated nasopharyngeal carcinoma, to complement LLT Lymphoepithelioma which was added to this PT in CR 2018234024.

CR Number: 2018234028 **Implementation Date:** 28-Aug-18 Related CR: 2018234028

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Nasoalveolar cyst*	Approved as Requested	Proposed LLT	
To PT	*Nasal cyst*		*Nasoalveolar cyst*	10082024 Current
			To PT	
			Nasal cyst	10051712

MSSO Comment: The proposal to add a new LLT Nasoalveolar cyst to PT Nasal cyst is approved as requested. Nasoalveolar cysts are classified as epithelial cysts and are non-odontogenic soft-tissue lesions of the nasoalar region, which is the lateral to anterior maxillary area between the upper lip and the nasal apertura.

CR Number: 2018235001 **Implementation Date:** 28-Aug-18 Related CR: 2018235001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Scale for the assessment and rating of ataxia*	Approved Not as Requested	Proposed LLT	
HLT primary	*Physical examination procedures and organ system status*		*Scale for the assessment and rating of ataxia*	10082026 Current
			To PT	
SOC primary	*Investigations*		*Ataxia assessment scale*	10082025

MSSO Comment: The proposal to add a new PT Scale for the assessment and rating of ataxia to primary HLT Physical examination procedures and organ system status in SOC Investigations is approved but not as requested. Scale for the assessment and rating of ataxia is a clinical scale that is based on a semi-quantitative assessment of cerebellar ataxia. In an accord with the aim of this scale application, the HLT Neurologic diagnostic procedures better represents the concept. Scale for the assessment and rating of ataxia will be added as an LLT to new PT Ataxia assessment scale. In a related change, Ataxia assessment scale will be added as PT to HLT Neurologic diagnostic procedures, since there are other well recognized ataxia scales different than the one proposed, such as International cooperative ataxia rating scale, which will also be added proactively as an LLT to new PT Ataxia assessment scale.

Supplemental Update Report

CR Number: 2018240002 **Implementation Date:** 28-Aug-18 Related CR: 2018235001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ataxia assessment scale*	Approved as Requested	Proposed PT	
HLT primary	*Neurologic diagnostic procedures*		*Ataxia assessment scale*	10082025
SOC primary	*Investigations*		HLT primary	
			Neurologic diagnostic procedures	10029285
			SOC primary	
			Investigations	10022891

MSSO Comment:

CR Number: 2018240003 **Implementation Date:** 28-Aug-18 Related CR: 2018235001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*International cooperative ataxia rating scale*	Approved as Requested	Proposed LLT		
To PT	*Ataxia assessment scale*		*International cooperative ataxia rating scale*	10082027	Current
			To PT		
			Ataxia assessment scale	10082025	

MSSO Comment:

CR Number: 2018235002 **Implementation Date:** 28-Aug-18 Related CR: 2018235002

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Incomplete dose administered*	Approved as Requested	Proposed LLT		
From PT	*Underdose*		*Incomplete dose administered*	10074777	Current
To PT	*Incorrect dose administered*		From PT		
			Underdose	10057362	
			To PT		
			Incorrect dose administered	10064355	

MSSO Comment: The proposal to move the LLT Incomplete dose administered from PT Underdose to PT Incorrect dose administered is approved as requested. For the purposes of term selection and analysis of MedDRA-coded data, underdose is the administration of less than the minimum recommended dose (in quantity and/or concentration). Because incomplete dose and underdose are not necessarily synonymous, the proposed move results in better placement.

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CR Number: 2018236001 **Implementation Date:** 31-Aug-18 Related CR: 2018236001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Woakes' syndrome*	Approved Not as Requested	Proposed PT	
To PT	*Nasal polyps*		*Woakes' syndrome*	10082048
			HLT primary	
			Nasal disorders NEC	10028731
			SOC primary	
			Respiratory, thoracic and mediastinal disorders	10038738

MSSO Comment: The proposal to add a new LLT Woakes' syndrome to PT Nasal polyps is approved but not as requested. The hallmark of Woakes' syndrome is recurrent nasal polyposis, in addition to potential manifestations such as broadening of the nose, frontal sinus aplasia, bronchiectasis, and dyscrinia. Since the major characteristic of this disorder is nasal polyposis, Woakes' syndrome will placed as a PT under HLT Nasal disorders NEC.

CR Number: 2018236002 **Implementation Date:** 31-Aug-18 Related CR: 2018236002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Armpit pain*	Approved as Requested	Proposed LLT	
			Armpit pain	10082049 Current
			To PT	
			Axillary pain	10048750

MSSO Comment: The proposal to add a new LLT Armpit pain is approved as requested. Armpit pain, which is a colloquial synonym for pain in the axillary area, will be added as a synonym LLT under PT Axillary pain.

CR Number: 2018236003 **Implementation Date:** 31-Aug-18 Related CR: 2018236003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Keyhole operation*	Rejected		

MSSO Comment: The proposal to add a new LLT Keyhole operation is not approved. The requested term represents a colloquial expression which may not have a universally-accepted international interpretation. Please consider existing terms, such as LLT Laparoscopic surgery, for your coding needs.

Supplemental Update Report

CR Number: 2018236004 **Implementation Date:** 31-Aug-18 Related CR: 2018236004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*External beam radiotherapy*	Approved as Requested	Proposed LLT *External beam radiotherapy* To PT *Radiotherapy*	10082052 Current 10037794

MSSO Comment: The proposal to add a new LLT External beam radiotherapy is approved as requested. External radiation (or external beam radiation) is the most common type of radiation therapy used for cancer treatment, using a linear accelerator to aim high-energy rays from outside the body into the tumor. External beam radiotherapy will be added as a sub-concept LLT to PT Radiotherapy.

CR Number: 2018236005 **Implementation Date:** 31-Aug-18 Related CR: 2018236005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hexadactyly*	Approved as Requested	Proposed LLT *Hexadactyly* To PT *Polydactyly*	10082050 Current 10036063

MSSO Comment: The proposal to add a new LLT Hexadactyly is approved as requested. Hexadactyly, the occurrence of six digits on one hand or foot, will be added as a sub-concept LLT to PT Polydactyly.

CR Number: 2018236006 **Implementation Date:** 31-Aug-18 Related CR: 2018236006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Facioplegia*	Approved Not as Requested	Proposed LLT *Facioplegia* To PT *Facial paralysis*	10082051 Current 10016062
To PT	*Facial paresis*			

MSSO Comment: The proposal to add a new LLT Facioplegia to PT Facial paresis is approved but not as requested. Facioplegia, which represents complete paralysis, rather than weakness of facial musculature, will be added as a synonym LLT to PT Facial paralysis.

Supplemental Update Report

CR Number: 2018236007 **Implementation Date:** 30-Aug-18 Related CR: 2018236007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Uterine hypokinesia*	Approved as Requested	Proposed PT	
			Uterine hypokinesia	10082029
			HLT primary	
			Maternal complications of labour NEC	10026907
			SOC primary	
			Pregnancy, puerperium and perinatal conditions	10036585
			HLT secondary	
			Uterine tone disorders	10013375
			SOC secondary	
			Reproductive system and breast disorders	10038604

MSSO Comment: The proposal to add a new term Uterine hypokinesia is approved as requested. Hypokinesia is reflected by a decrease in the duration and frequency of uterine contractions whose properties are assessed by cardiotocography. Uterine hypokinesia will be added as a PT to primary HLT Maternal complications of labour NEC and secondary HLT Uterine tone disorders.

CR Number: 2018239001 **Implementation Date:** 28-Aug-18 Related CR: 2018239001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Incision site impaired healing*	Approved as Requested	Proposed PT	
			Incision site impaired healing	10082028
			HLT primary	
			Non-site specific procedural complications	10029559
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Healing abnormal NEC	10019237
			SOC secondary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Incision site impaired healing is approved as requested. Incision site impaired healing is a recognized type of incision site disorder, and will thus be added as a new PT to primary HLT Non-site specific procedural complications, to secondary HLT Healing abnormal NEC, and to secondary HLT Skin and subcutaneous conditions NEC.

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CR Number: 2018240004 **Implementation Date:** 28-Aug-18 Related CR: 2018239001

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Incision site impaired healing*	Approved as Requested	Proposed PT	
To HLT	*Skin and subcutaneous conditions NEC*		*Incision site impaired healing*	10082028
			To HLT	
			Skin and subcutaneous conditions NEC	10042356

MSSO Comment:

CR Number: 2018241001 **Implementation Date:** 05-Sep-18 Related CR: 2018241001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Focal hepatic steatosis*	Approved as Requested	Proposed LLT	
			Focal hepatic steatosis	10082053 Current
			To PT	
			Hepatic steatosis	10019708

MSSO Comment: The proposal to add a new term Focal hepatic steatosis is approved as requested. Hepatic steatosis may be either diffuse or focal in its distribution. Focal hepatic steatosis may be seen either in circumscribed areas near anatomical landmarks or may appear as multiple nodular areas producing a pseudotumor appearance. Typically, focal steatosis is identified in characteristic locations such as the gallbladder fossa, the medial segment near the falciform ligament, the subcapsular region, and the porta hepatis. Focal hepatic steatosis will be added as a sub-element LLT of PT Hepatic steatosis.

CR Number: 2018241002 **Implementation Date:** 07-Sep-18 Related CR: 2018241002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Neonatal epileptic seizure*	Approved After Suspension	Proposed LLT	
			Neonatal epileptic seizure	10082068
			To PT	
			Neonatal seizure	10082067

MSSO Comment: The proposal to add a new term Neonatal epileptic seizure is approved as requested after suspension. Neonatal seizures are epileptic fits occurring from birth to the end of the first month of life. The neonatal period is the most vulnerable of all periods of life for developing seizures, particularly in the first 1–2 days to the first week from birth. They may be short-lived events lasting for a few days only. However, they often signify serious malfunction of or damage to the immature brain and constitute a neurological emergency demanding urgent diagnosis and management. Neonatal epileptic seizure will be added as an LLT to PT Neonatal seizure. In a related change, Neonatal seizure will be added as a new PT to primary HLT Seizures and seizure disorders NEC, and to secondary HLT Neonatal neurological system disorders NEC. In addition, PT Convulsion neonatal will be demoted to an LLT under new PT Neonatal seizure.

Supplemental Update Report

CR Number: 2018250011 **Implementation Date:** 07-Sep-18 Related CR: 2018241002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neonatal seizure*	Approved as Requested	Proposed PT	
HLT primary	*Seizures and seizure disorders NEC*		*Neonatal seizure*	10082067
SOC primary	*Nervous system disorders*		HLT primary	
			Seizures and seizure disorders NEC	10039912
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Neonatal neurological system disorders NEC	10028964
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment:

CR Number: 2018250012 **Implementation Date:** 07-Sep-18 Related CR: 2018241002

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Convulsion neonatal*	Approved as Requested	PT to merge	
To PT	*Neonatal seizure*		*Convulsion neonatal*	10010911 Current
			To PT	
			Neonatal seizure	10082067

MSSO Comment:

Supplemental Update Report

CR Number: 2018241003 **Implementation Date:** 05-Sep-18 Related CR: 2018241003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Tachyarrythmia neonatal*	Approved Not as Requested	Proposed PT	
			Neonatal tachyarrhythmia	10082055
			HLT primary	
			Rate and rhythm disorders NEC	10037908
			SOC primary	
			Cardiac disorders	10007541
			HLT secondary	
			Neonatal cardiovascular disorders (excl cardiorespiratory arrest)	10028926
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new term Tachyarrythmia neonatal is approved but not as requested. The most commonly presenting pathological tachyarrhythmias in the newborn include narrow complex supraventricular tachycardia and sinus tachycardia. The proposed term tachyarrhythmia neonatal will be modified with regard to corrected spelling and natural word order to Neonatal tachyarrhythmia and added as a new PT to primary HLT Rate and rhythm disorders NEC, and to secondary HLT Neonatal cardiovascular disorders (excl cardiorespiratory arrest).

CR Number: 2018241004 **Implementation Date:** 05-Sep-18 Related CR: 2018241004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Bradyarrythmia neonatal*	Approved Not as Requested	Proposed PT	
			Neonatal bradyarrhythmia	10082054
			HLT primary	
			Rate and rhythm disorders NEC	10037908
			SOC primary	
			Cardiac disorders	10007541
			HLT secondary	
			Neonatal cardiovascular disorders (excl cardiorespiratory arrest)	10028926
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new term Bradyarrythmia neonatal is approved but not as requested. The mechanisms of neonatal bradyarrhythmia include sinus bradycardia, abnormalities of sinus node function and abnormalities of atrioventricular conduction. In the instances where sinus bradycardia is pathologic, it usually results from non-cardiac disease. The proposed term Bradyarrythmia neonatal will be modified with regard to corrected spelling and natural word order to Neonatal bradyarrhythmia and added as a new PT to primary HLT Rate and rhythm disorders NEC, and to secondary HLT Neonatal cardiovascular disorders (excl cardiorespiratory arrest).

Supplemental Update Report

CR Number: 2018241005 **Implementation Date:** 05-Sep-18 Related CR: 2018241005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Respiratory insufficiency neonatal*	Approved Not as Requested	Proposed LLT	
			Neonatal respiratory insufficiency	10082057 Current
			To PT	
			Neonatal respiratory failure	10028975

MSSO Comment: The proposal to add a new term Respiratory insufficiency neonatal is approved but not as requested. Respiratory insufficiency in neonates is the inability of the lungs to provide adequate oxygen intake or carbon dioxide expulsion as needed by the body and its cells, due to abnormalities such as airway obstructive conditions, respiratory system developmental immaturity, and other infective and pathological disorders. If not managed successfully, Neonatal respiratory insufficiency can progress to respiratory failure. The proposed term, Respiratory insufficiency neonatal, will be added in natural word order as Neonatal respiratory insufficiency as a sub-concept LLT to PT Neonatal respiratory failure.

CR Number: 2018241006 **Implementation Date:** 05-Sep-18 Related CR: 2018241006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Persistent pulmonary hypertension in the newborn (PPHN)*	Rejected		

MSSO Comment: The proposal to add a new term Persistent pulmonary hypertension in the newborn (PPHN) is not approved. Persistent pulmonary hypertension of the newborn is defined as the failure of the normal circulatory transition that occurs after birth. It is a syndrome characterized by marked pulmonary hypertension that causes hypoxemia secondary to right-to-left shunting of blood at the foramen ovale and ductus arteriosus. The proposed concept, Persistent pulmonary hypertension in the newborn, already exist in MedDRA in LLT Newborn persistent pulmonary hypertension, which will be promoted from PT Persistent foetal circulation to a PT under primary HLT Persistent foetal circulation disorders, secondary HLT Pulmonary hypertensions and to secondary HLT Neonatal respiratory disorders NEC. In a related change, the PT Congenital pulmonary hypertension, will be moved from HLT Newborn respiratory disorders NEC to the HLT Pulmonary hypertensions.

Supplemental Update Report

CR Number: 2018248012 **Implementation Date:** 05-Sep-18 Related CR: 2018241006

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Newborn persistent pulmonary hypertension*	Approved as Requested	Proposed LLT	
From PT	*Persistent foetal circulation*		*Newborn persistent pulmonary hypertension*	10053592
HLT primary	*Persistent foetal circulation disorders*		From PT	
			Persistent foetal circulation	10034708
			HLT primary	
			Persistent foetal circulation disorders	10034709
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Pulmonary hypertensions	10037401
			SOC secondary	
			Respiratory, thoracic and mediastinal disorders	10038738

MSSO Comment:

CR Number: 2018248013 **Implementation Date:** 05-Sep-18 Related CR: 2018241006

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Newborn persistent pulmonary hypertension*	Approved as Requested	Proposed PT	
To HLT	*Neonatal respiratory disorders NEC*		*Newborn persistent pulmonary hypertension*	10053592
			To HLT	
			Neonatal respiratory disorders NEC	10028972

MSSO Comment:

Supplemental Update Report

CR Number: 2018248014 **Implementation Date:** 05-Sep-18 Related CR: 2018241006

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Congenital pulmonary hypertension*	Approved as Requested	Proposed PT	
From HLT	*Newborn respiratory disorders NEC*		*Congenital pulmonary hypertension*	10050701
To HLT	*Pulmonary hypertensions*		From HLT	
			Newborn respiratory disorders NEC	10027689
			To HLT	
			Pulmonary hypertensions	10037401

MSSO Comment:

CR Number: 2018241007 **Implementation Date:** 05-Sep-18 Related CR: 2018241007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Pneumothorax neonatal*	Approved Not as Requested	Proposed PT	
			Neonatal pneumothorax	10082056
			HLT primary	
			Pneumothorax and pleural effusions NEC	10035761
			SOC primary	
			Respiratory, thoracic and mediastinal disorders	10038738
			HLT secondary	
			Neonatal respiratory disorders NEC	10028972
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new term Pneumothorax neonatal is approved but not as requested. Pneumothorax can occur in the newborn infant, and, if not recognized, may have fatal consequences. It may be associated with respiratory distress syndrome, transient tachypnea of the newborn, invasive mechanical ventilation, or it may occur spontaneously without a documented etiology. The proposed term, Pneumothorax neonatal, will be added in natural word order as PT Neonatal pneumothorax to primary HLT Pneumothorax and pleural effusions NEC, and to secondary HLT Neonatal respiratory disorders NEC.

Supplemental Update Report

CR Number: 2018241008 **Implementation Date:** 05-Sep-18 Related CR: 2018241008

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Culture positive neonatal sepsis*	Approved as Requested	Proposed LLT *Culture positive neonatal sepsis*	10082058 Current
		To PT *Sepsis neonatal*	10040049

MSSO Comment: The proposal to add a new term Culture positive neonatal sepsis is approved as requested. Although the requested term could be separately coded with the current PT/LLT Culture positive and PT/LLT Sepsis neonatal, the concept culture positive neonatal sepsis represents clinical signs of sepsis in a newborn, corroborated by a positive culture finding that identifies a causative microbial organism. Accordingly, Culture positive neonatal sepsis will thus be added as a sub-concept LLT to PT Sepsis neonatal.

CR Number: 2018241009 **Implementation Date:** 05-Sep-18 Related CR: 2018241009

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Culture negative neonatal sepsis*	Approved as Requested	Proposed LLT *Culture negative neonatal sepsis*	10082059 Current
		To PT *Sepsis neonatal*	10040049

MSSO Comment: The proposal to add a new term Culture negative neonatal sepsis is approved as requested. Although the requested term could be separately coded with the current PT/LLT Culture negative and PT/LLT Sepsis neonatal, the concept culture negative neonatal sepsis represents clinical signs of sepsis in a newborn, corroborated by a negative culture finding that identifies a causative microbial organism. Accordingly, Culture negative neonatal sepsis will thus be added as a sub-concept LLT to PT Sepsis neonatal.

CR Number: 2018241010 **Implementation Date:** 05-Sep-18 Related CR: 2018241010

Change Requested	Final Disposition	Final Placement	MedDRA Code #
Add a New Term			
Proposed Term *Administration site complication neonatal*	Rejected		

MSSO Comment: The proposal to add a new term Administration site complication neonatal is not approved. MedDRA cannot accommodate a separate term for a sub-type of each of the multitude of site related reactions and disorder term concepts, that is qualified for a specific patient age group. Should there be an administration site complication that is pathologically unique to the neonatal age group, the MSSO would consider a proposal for such a new term.

Supplemental Update Report

CR Number: 2018241011 **Implementation Date:** 05-Sep-18 Related CR: 2018241011

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Catheter site irritation*	Approved Not as Requested	Proposed LLT	
From PT	*Catheter site inflammation*		*Catheter site irritation*	10068003
To PT	*catheter site irritation*		From PT	
			Catheter site inflammation	10052267
			HLT primary	
			Implant and catheter site reactions	10021544
			SOC primary	
			General disorders and administration site conditions	10018065
			HLT secondary	
			Implant and catheter site reactions	10021544
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to move the LLT Catheter site irritation from PT Catheter site inflammation to PT catheter site irritation is approved but not as requested. Because irritation is not necessarily a sub-concept of inflammation, LLT Catheter site irritation will be promoted to PT under HLT Implant and catheter site reactions which is bi-axial to primary SOC General disorders and administration site conditions and to secondary SOC Injury, poisoning and procedural complications.

CR Number: 2018241012 **Implementation Date:** 07-Sep-18 Related CR: 2018241012

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cervical cryotherapy*	Approved Not as Requested	Proposed PT	
			Cervix cryotherapy	10082060
			HLT primary	
			Cervix therapeutic procedures	10008294
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT Cervical cryotherapy is approved but not as requested. Cervix cryotherapy has been used for decades to safely and effectively ablate the cervix transformation zone and CIN lesion. This method uses compressed gas to create extremely cold temperatures that necrose cervical epithelium. The proposed term will be renamed to Cervix cryotherapy for a higher anatomical specificity which avoids confusion with the neck region, and will be added as a PT to HLT Cervix therapeutic procedures. In a related change, the existing synonym LLT Cryocautery of cervix will be moved from PT Cervix cautery to the new PT Cervix cryotherapy.

Supplemental Update Report

CR Number: 2018248015 **Implementation Date:** 07-Sep-18 Related CR: 2018241012

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cryocautery of cervix*	Approved as Requested	Proposed LLT	
From PT	*Cervix cautery*		*Cryocautery of cervix*	10011473 Current
To PT	*Cervix cryotherapy*		From PT	
			Cervix cautery	10008349
			To PT	
			Cervix cryotherapy	10082060

MSSO Comment:

CR Number: 2018241013 **Implementation Date:** 13-Sep-18 Related CR: 2018241013

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pustulotic arthro-osteitis*	Approved as Requested	Proposed PT	
To SMQ	*Arthritis (SMQ)*		*Pustulotic arthro-osteitis*	10081810
Term scope	*Broad*		To SMQ	
			Arthritis (SMQ)	20000216
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Pustulotic arthro-osteitis to Arthritis (SMQ) as a broad term is approved as requested. New term for version 22.0. Pustulotic arthro-osteitis is a rare chronic inflammatory disease, which is classified as a seronegative spondyloarthritis. Similar PT Seronegative arthritis is included as well with the same scope.

Supplemental Update Report

CR Number: 2018241014 **Implementation Date:** 13-Sep-18 Related CR: 2018241014

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cardiac device reprogramming*	Approved as Requested	Proposed PT *Cardiac device reprogramming*	10081886
To SMQ	*Cardiac failure (SMQ)*		To SMQ *Cardiac failure (SMQ)*	20000004
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Cardiac device reprogramming to Cardiac failure (SMQ) as a broad term is approved as requested. New PT for version 22.0. Related PT Ventricular assist device insertion or PT Cardiac resynchronisation therapy is included as well as procedural concepts with the same broad scope.

CR Number: 2018241015 **Implementation Date:** 13-Sep-18 Related CR: 2018241015

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cardiac device reprogramming*	Approved as Requested	Proposed PT *Cardiac device reprogramming*	10081886
To SMQ	*Cardiomyopathy (SMQ)*		To SMQ *Cardiomyopathy (SMQ)*	20000150
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Cardiac device reprogramming to Cardiomyopathy (SMQ) as a broad term is approved as requested. New PT for version 22.0. Related PT Ventricular assist device insertion or PT Cardiac resynchronisation therapy is included as well as procedural concepts with the same broad scope.

Supplemental Update Report

CR Number: 2018241016 **Implementation Date:** 13-Sep-18 Related CR: 2018241016

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Missing dose response relationship*	Approved as Requested	Proposed PT *Missing dose response relationship*	10081872
To SMQ	*Lack of efficacy/effect (SMQ)*		To SMQ *Lack of efficacy/effect (SMQ)*	20000032
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Missing dose response relationship to Lack of efficacy/effect (SMQ) as a narrow term is approved as requested. New PT for version 22.0. Dose-response relationship describes the change in effect on an organism caused by differing levels of exposure. PT Missing dose response relationship fulfills the criteria of lack of effect. All PTs are narrow in scope.

CR Number: 2018241017 **Implementation Date:** 13-Sep-18 Related CR: 2018241017

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Atypical dose response relationship*	Approved as Requested	Proposed PT *Atypical dose response relationship*	10081873
To SMQ	*Lack of efficacy/effect (SMQ)*		To SMQ *Lack of efficacy/effect (SMQ)*	20000032
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Atypical dose response relationship to Lack of efficacy/effect (SMQ) as a narrow term is approved as requested. New PT for version 22.0. Dose–response relationship describes the change in effect on an organism caused by differing levels of exposure. PT Atypical dose response relationship fulfills the criteria of lack of efficacy or less than expected effect. All PTs are narrow in scope.

Supplemental Update Report

CR Number: 2018241018 **Implementation Date:** 13-Sep-18 Related CR: 2018241018

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Subacute kidney injury*	Approved as Requested	Proposed PT	
To SMQ	*Rhabdomyolysis/myopathy (SMQ)*		*Subacute kidney injury*	10081980
Term scope	*Broad*		To SMQ	
			Rhabdomyolysis/myopathy (SMQ)	20000002
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Subacute kidney injury to Rhabdomyolysis/myopathy (SMQ) as a broad term is approved as requested. New PT for version 22.0. The same criteria as for included PT Acute kidney injury are applicable for PT Subacute kidney injury.

CR Number: 2018241019 **Implementation Date:** 13-Sep-18 Related CR: 2018241019

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Subacute kidney injury*	Approved as Requested	Proposed PT	
To SMQ	*Anaphylactic/anaphylactoid shock conditions (SMQ)*		*Subacute kidney injury*	10081980
Term scope	*Broad*		To SMQ	
			Anaphylactic/anaphylactoid shock conditions (SMQ)	20000071
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Subacute kidney injury to Anaphylactic/anaphylactoid shock conditions (SMQ) as a broad term is approved as requested. New PT for version 22.0. The same criteria as for included PT Acute kidney injury are applicable for PT Subacute kidney injury.

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CR Number: 2018241020 **Implementation Date:** 13-Sep-18 Related CR: 2018241020

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Subacute kidney injury*	Approved as Requested	Proposed PT	
To SMQ	*Hypoglycaemic and neurogenic shock conditions (SMQ)*		*Subacute kidney injury*	10081980
Term scope	*Broad*		To SMQ	
			Hypoglycaemic and neurogenic shock conditions (SMQ)	20000072
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Subacute kidney injury to Hypoglycaemic and neurogenic shock conditions (SMQ) as a broad term is approved as requested. New PT for version 22.0. The same criteria as for included PT Acute kidney injury are applicable for PT Subacute kidney injury.

CR Number: 2018241021 **Implementation Date:** 13-Sep-18 Related CR: 2018241021

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Subacute kidney injury*	Approved as Requested	Proposed PT	
To SMQ	*Hypovolaemic shock conditions (SMQ)*		*Subacute kidney injury*	10081980
Term scope	*Broad*		To SMQ	
			Hypovolaemic shock conditions (SMQ)	20000069
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Subacute kidney injury to Hypovolaemic shock conditions (SMQ) as a broad term is approved as requested. New PT for version 22.0. The same criteria as for included PT Acute kidney injury are applicable for PT Subacute kidney injury.

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CR Number: 2018241022 **Implementation Date:** 13-Sep-18 Related CR: 2018241022

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Subacute kidney injury*	Approved as Requested	Proposed PT	
			Subacute kidney injury	10081980
To SMQ	*Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (SMQ)*		To SMQ	
			Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (SMQ)	20000067
Term scope	*Broad*		Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Subacute kidney injury to Shock-associated circulatory or cardiac conditions (excl torsade de pointes) (SMQ) as a broad term is approved as requested. New PT for version 22.0. The same criteria as for included PT Acute kidney injury are applicable for PT Subacute kidney injury.

CR Number: 2018241023 **Implementation Date:** 13-Sep-18 Related CR: 2018241023

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Subacute kidney injury*	Approved as Requested	Proposed PT	
			Subacute kidney injury	10081980
To SMQ	*Toxic-septic shock conditions (SMQ)*		To SMQ	
			Toxic-septic shock conditions (SMQ)	20000070
Term scope	*Broad*		Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Subacute kidney injury to Toxic-septic shock conditions (SMQ) as a broad term is approved as requested. New PT for version 22.0. The same criteria as for included PT Acute kidney injury are applicable for PT Subacute kidney injury.

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CR Number: 2018241024 **Implementation Date:** 13-Sep-18 Related CR: 2018241024

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Subacute kidney injury*	Approved as Requested	Proposed PT *Subacute kidney injury*	10081980
To SMQ	*Torsade de pointes/QT prolongation (SMQ)*		To SMQ *Torsade de pointes/QT prolongation (SMQ)*	20000001
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Subacute kidney injury to Torsade de pointes/QT prolongation (SMQ) as a broad term is approved as requested. New PT for version 22.0. The same criteria as for included PT Acute kidney injury are applicable for PT Subacute kidney injury.

CR Number: 2018241025 **Implementation Date:** 13-Sep-18 Related CR: 2018241025

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Corneal graft failure*	Approved as Requested	Proposed PT *Corneal graft failure*	10081851
To SMQ	*Corneal disorders (SMQ)*		To SMQ *Corneal disorders (SMQ)*	20000156
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Corneal graft failure to Corneal disorders (SMQ) as a narrow term is approved as requested. PT Corneal graft failure, was added in MedDRA version 22.0, represents a specific immunologic response of the host to the donor corneal tissue, or other non-immune mediated graft failures, such as primary donor failure, or “high-risk” recipient complications, as those derived from vascularization of the cornea. PT Corneal graft failure fulfills the inclusion criterion of Corneal disorders (SMQ), "All terms involving the cornea," as a narrow scope term.

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CR Number: 2018241026 **Implementation Date:** 13-Sep-18 Related CR: 2018241026

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Aphakic glaucoma*	Approved as Requested	Proposed PT *Aphakic glaucoma*	10081898
To SMQ	*Glaucoma (SMQ)*		To SMQ *Glaucoma (SMQ)*	20000146
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Aphakic glaucoma to Glaucoma (SMQ) as a narrow term is approved as requested. PT Aphakic glaucoma, added in MedDRA version 22.0, is a common long-term complication seen following congenital cataract surgery. Because aphakic glaucoma, a specific type of glaucoma, and is not a primary congenital disorder per se, PT Aphakic glaucoma will be added as a narrow scope term to Glaucoma (SMQ).

CR Number: 2018241027 **Implementation Date:** 13-Sep-18 Related CR: 2018241027

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Aphakic glaucoma*	Approved as Requested	Proposed PT *Aphakic glaucoma*	10081898
To SMQ	*Lens disorders (SMQ)*		To SMQ *Lens disorders (SMQ)*	20000155
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Aphakic glaucoma to Lens disorders (SMQ) as a narrow term is approved as requested. PT Aphakic glaucoma, added in MedDRA version 22.0, is a common long-term complication seen following congenital cataract surgery. Because aphakic glaucoma is a complication following cataract surgery, it fulfills the following inclusion criterion for Lens disorders (SMQ), "Terms for resulting complications such as PT Aphakia," and will be added as a narrow term to this SMQ. Note: PT Aphakia is a narrow term in this SMQ.

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CR Number: 2018241028 **Implementation Date:** 13-Sep-18 Related CR: 2018241028

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Eyelid gold weight insertion*	Approved as Requested	Proposed PT	
To SMQ	*Periorbital and eyelid disorders (SMQ)*		*Eyelid gold weight insertion*	10081926 Current
Term scope	*Narrow*		To SMQ	
			Periorbital and eyelid disorders (SMQ)	20000179
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Eyelid gold weight insertion to Periorbital and eyelid disorders (SMQ) as a narrow term is approved as requested. PT Eyelid gold weight insertion was added in MedDRA version 22.0. The term represents an upper eyelid gold-weight insertion procedure which allows an improperly working eyelid to close with gravity. PT Eyelid gold weight insertion will be added as a narrow scope term to Periorbital and eyelid disorders (SMQ), fulfilling the inclusion criterion, "Terms for eyelid procedures."

CR Number: 2018241029 **Implementation Date:** 13-Sep-18 Related CR: 2018241029

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hypotony maculopathy*	Approved as Requested	Proposed PT	
To SMQ	*Retinal disorders (SMQ)*		*Hypotony maculopathy*	10081899
Term scope	*Narrow*		To SMQ	
			Retinal disorders (SMQ)	20000158
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Hypotony maculopathy to Retinal disorders (SMQ) as a narrow term is approved as requested. PT Hypotony maculopathy, added in version 22.0, is a condition characterized by a low intraocular pressure associated with fundus abnormalities, including chorioretinal folds, optic nerve head edema in the acute setting , and vascular tortuosity. PT Hypotony maculopathy will be added as a narrow scope term to Retinal disorders (SMQ), because "Terms relating to the macula" are included in this SMQ.

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CR Number: 2018241030 **Implementation Date:** 13-Sep-18 Related CR: 2018241030

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Scleral reinforcement*	Approved as Requested	Proposed PT *Scleral reinforcement*	10081858
To SMQ	*Scleral disorders (SMQ)*		To SMQ *Scleral disorders (SMQ)*	20000182
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Scleral reinforcement to Scleral disorders (SMQ) as a narrow term is approved as requested. PT Scleral reinforcement, added in MedDRA version 22.0, represents a surgical procedure used to reduce or stop further macular damage caused by high degenerative myopia. PT Scleral reinforcement will be added as a narrow scope term to Scleral disorders (SMQ), as it fulfills the inclusion criterion for this SMQ: "Terms for procedures related to sclera".

CR Number: 2018241031 **Implementation Date:** 13-Sep-18 Related CR: 2018241031

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cerebral artery stent insertion*	Approved as Requested	Proposed PT *Cerebral artery stent insertion*	10081893
To SMQ	*Embolic and thrombotic events, arterial (SMQ)*		To SMQ *Embolic and thrombotic events, arterial (SMQ)*	20000082
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Cerebral artery stent insertion to Embolic and thrombotic events, arterial (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ for therapeutic procedures for embolism and thrombosis. All terms in this SMQ are narrow scope.

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CR Number: 2018241032 **Implementation Date:** 13-Sep-18 Related CR: 2018241032

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Jugular vein embolism*	Approved as Requested	Proposed PT *Jugular vein embolism*	10081850
To SMQ	*Embolic and thrombotic events, venous (SMQ)*		To SMQ *Embolic and thrombotic events, venous (SMQ)*	20000084
Term scope	*Narrow*		Term scope *Narrow* Term_category *A* Term_weight *0*	

MSSO Comment: The proposal to add PT Jugular vein embolism to Embolic and thrombotic events, venous (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ for venous embolism terms. All terms in this SMQ are narrow scope.

CR Number: 2018241033 **Implementation Date:** 13-Sep-18 Related CR: 2018241033

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cuboid syndrome*	Approved as Requested	Proposed PT *Cuboid syndrome*	10081921
To SMQ	*Tendinopathies and ligament disorders (SMQ)*		To SMQ *Tendinopathies and ligament disorders (SMQ)*	20000223
Term scope	*Narrow*		Term scope *Narrow* Term_category *A* Term_weight *0*	

MSSO Comment: The proposal to add PT Cuboid syndrome to Tendinopathies and ligament disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ for signs/symptoms specific to tendons and ligaments. Cuboid syndrome is caused by an injury to the joint and ligaments surrounding the cuboid bone in the foot. It causes pain on the lateral side of the foot. Similar terms such as PT Ligament injury are included as narrow scope terms.

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CR Number: 2018241034 **Implementation Date:** 13-Sep-18 Related CR: 2018241034

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Anti-glomerular basement membrane disease*	Approved as Requested	Proposed PT *Anti-glomerular basement membrane disease*	10081981
To SMQ	*Vasculitis (SMQ)*		To SMQ *Vasculitis (SMQ)*	20000174
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Anti-glomerular basement membrane disease to Vasculitis (SMQ) as a broad term is approved as requested. Anti–glomerular basement membrane (anti-GBM) disease is an autoimmune disorder characterized by the presence of circulating pathogenic autoantibodies directed against proteins in the glomerular and alveolar basement membranes, resulting in inflammation of the capillaries. A related term, PT Goodpasture's syndrome, which includes glomerulonephritis and pulmonary hemorrhage is already included as a broad scope term.

CR Number: 2018241035 **Implementation Date:** 13-Sep-18 Related CR: 2018241035

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Subacute kidney injury*	Approved as Requested	Proposed PT *Subacute kidney injury*	10081980
To SMQ	*Acute renal failure (SMQ)*		To SMQ *Acute renal failure (SMQ)*	20000003
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Subacute kidney injury to Acute renal failure (SMQ) as a narrow term is approved as requested. Subacute kidney injury defines a presentation that develops more slowly than AKI, but generally results in worsening creatinine in less than three months. The narrow scope of this SMQ encompasses diagnoses and symptoms that are unique for, or directly lead to, acute renal failure. Subacute kidney injury should be added to the narrow scope of this SMQ.

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CR Number: 2018241036 **Implementation Date:** 13-Sep-18 Related CR: 2018241036

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Subacute kidney injury*	Approved as Requested	Proposed PT	
To SMQ	*Dehydration (SMQ)*		*Subacute kidney injury*	10081980
Term scope	*Broad*		To SMQ	
			Dehydration (SMQ)	20000232
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Subacute kidney injury to Dehydration (SMQ) as a broad term is approved as requested. Dehydration can be both the cause and the consequence of acute kidney injury. Likewise, and by extension, the new PT Subacute kidney injury may retrieve cases of Dehydration, and should be added (together with its acute counterpart) to the broad scope of this SMQ.

CR Number: 2018241037 **Implementation Date:** 13-Sep-18 Related CR: 2018241037

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Nuclear magnetic resonance imaging pancreas*	Approved as Requested	Proposed PT	
To SMQ	*Acute pancreatitis (SMQ)*		*Nuclear magnetic resonance imaging pancreas*	10081952
Term scope	*Broad*		To SMQ	
			Acute pancreatitis (SMQ)	20000022
			Term scope	
			Broad	
			Term_category	
			B	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Nuclear magnetic resonance imaging pancreas to Acute pancreatitis (SMQ) as a broad term is approved as requested. Pancreatic MRI (mainly gadolinium-enhanced MRI) is also useful in evaluating acute pancreatitis, especially for the detection of necrosis. Category B of this SMQ lists laboratory values and tests used in the diagnosis of acute pancreatitis.

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CR Number: 2018241038 **Implementation Date:** 13-Sep-18 Related CR: 2018241038

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Large intestine infection*	Approved as Requested	Proposed PT *Large intestine infection*	10081959
To SMQ	*Pseudomembranous colitis (SMQ)*		To SMQ *Pseudomembranous colitis (SMQ)*	20000080
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Large intestine infection to Pseudomembranous colitis (SMQ) as a broad term is approved as requested. This SMQ includes some PTs in the broad scope (such as Bacterial diarrhoea; Enterocolitis bacterial; Enterocolitis infectious), which are related to abdominal and gastrointestinal infections that may be useful in retrieving cases of colitis pseudo-membranous. Infectious colitis was one of these PTs, and has now been demoted under the new PT Large intestine infection, which should in its turn be added to the broad scope of the SMQ.

CR Number: 2018241039 **Implementation Date:** 13-Sep-18 Related CR: 2018241039

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Palatal polyp*	Approved as Requested	Proposed PT *Palatal polyp*	10081960
To SMQ	*Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ)*		To SMQ *Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ)*	20000114
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Palatal polyp to Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ) as a narrow term is approved as requested. This SMQ includes terms related to lesions and disorders falling wholly or partly within any part of oral cavity of pharynx. The palate is part of the oral cavity, and therefore this term should be included in this SMQ, which is only composed of narrow scope terms.

CR Number: 2018241040 **Implementation Date:** 13-Sep-18 Related CR: 2018241040

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Lower oesophageal sphincter magnetic augmentation*	Approved as Requested	Proposed PT *Lower oesophageal sphincter magnetic augmentation*	10081862
To SMQ	*Gastrointestinal nonspecific symptoms and therapeutic procedures (SMQ)*		To SMQ *Gastrointestinal nonspecific symptoms and therapeutic procedures (SMQ)*	20000140
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Lower oesophageal sphincter magnetic augmentation to Gastrointestinal nonspecific symptoms and therapeutic procedures (SMQ) as a broad term is approved as requested. Lower esophageal sphincter magnetic augmentation is a procedure meant to reduce gastro-esophageal reflux. It consists of the laparoscopic implantation of a device made up of a small expandable ring of linked magnetic beads, whose magnetic attractive forces augment the pressure of the lower esophageal sphincter, thereby impeding or reducing gastro-esophageal reflux. The broad scope of this SMQ includes surgical and medical procedures used to correct any nonspecific functional or inflammatory condition affecting any part of the gastrointestinal tract, especially those likely to be caused by drugs. Moreover, PT Gastrooesophageal reflux disease is in the narrow search of one of the “sibling” SMQs (Gastrointestinal nonspecific dysfunction (SMQ)).

CR Number: 2018241041 **Implementation Date:** 13-Sep-18 Related CR: 2018241041

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Autosomal recessive megaloblastic anaemia*	Approved as Requested	Proposed PT *Autosomal recessive megaloblastic anaemia*	10081878
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Autosomal recessive megaloblastic anaemia to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

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CR Number: 2018241042 **Implementation Date:** 13-Sep-18 Related CR: 2018241042

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Brachyolmia*	Approved as Requested	Proposed PT *Brachyolmia*	10081832
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Brachyolmia to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2018241043 **Implementation Date:** 13-Sep-18 Related CR: 2018241043

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*CHILD syndrome*	Approved as Requested	Proposed PT *CHILD syndrome*	10081963
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT CHILD syndrome to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

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CR Number: 2018241044 **Implementation Date:** 13-Sep-18 Related CR: 2018241044

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Coffin-Lowry syndrome*	Approved as Requested	Proposed PT *Coffin-Lowry syndrome*	10081806
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow* Term_category *A* Term_weight *0*	

MSSO Comment: The proposal to add PT Coffin-Lowry syndrome to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2018241045 **Implementation Date:** 13-Sep-18 Related CR: 2018241045

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Confined placental mosaicism*	Approved as Requested	Proposed PT *Confined placental mosaicism*	10081934
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow* Term_category *A* Term_weight *0*	

MSSO Comment: The proposal to add PT Confined placental mosaicism to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

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CR Number: 2018241046 **Implementation Date:** 13-Sep-18 Related CR: 2018241046

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Donohue syndrome*	Approved as Requested	Proposed PT	
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		*Donohue syndrome*	10081896
Term scope	*Narrow*		To SMQ	
			Congenital, familial and genetic disorders (SMQ)	20000077
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Donohue syndrome to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2018241047 **Implementation Date:** 13-Sep-18 Related CR: 2018241047

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Laband syndrome*	Approved as Requested	Proposed PT	
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		*Laband syndrome*	10081859
Term scope	*Narrow*		To SMQ	
			Congenital, familial and genetic disorders (SMQ)	20000077
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Laband syndrome to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

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CR Number: 2018241048 **Implementation Date:** 13-Sep-18 Related CR: 2018241048

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*L-arginine-glycine amidinotransferase deficiency*	Approved as Requested	Proposed PT	
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		*L-arginine-glycine amidinotransferase deficiency*	10081857
Term scope	*Narrow*		To SMQ	
			Congenital, familial and genetic disorders (SMQ)	20000077
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT L-arginine-glycine amidinotransferase deficiency to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2018241049 **Implementation Date:** 13-Sep-18 Related CR: 2018241049

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*PAPSS2 gene mutation*	Approved as Requested	Proposed PT	
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		*PAPSS2 gene mutation*	10081833
Term scope	*Narrow*		To SMQ	
			Congenital, familial and genetic disorders (SMQ)	20000077
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT PAPSS2 gene mutation to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

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CR Number: 2018241050 **Implementation Date:** 13-Sep-18 Related CR: 2018241050

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Paroxysmal extreme pain disorder*	Approved as Requested	Proposed PT *Paroxysmal extreme pain disorder*	10081856
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Paroxysmal extreme pain disorder to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2018241051 **Implementation Date:** 13-Sep-18 Related CR: 2018241051

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*PSTPIP1-associated myeloid-related proteinaemia inflammatory syndrome*	Approved as Requested	Proposed PT *PSTPIP1-associated myeloid-related proteinaemia inflammatory syndrome*	10081947
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT PSTPIP1-associated myeloid-related proteinaemia inflammatory syndrome to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

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CR Number: 2018241052 **Implementation Date:** 13-Sep-18 Related CR: 2018241052

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ring chromosome*	Approved as Requested	Proposed PT *Ring chromosome*	10081894
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Ring chromosome to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2018241053 **Implementation Date:** 13-Sep-18 Related CR: 2018241053

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Trisomy 16*	Approved as Requested	Proposed PT *Trisomy 16*	10081933
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Trisomy 16 to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

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CR Number: 2018241054 **Implementation Date:** 13-Sep-18 Related CR: 2018241054

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*TRPV4 gene mutation*	Approved as Requested	Proposed PT *TRPV4 gene mutation*	10081831
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT TRPV4 gene mutation to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2018241055 **Implementation Date:** 13-Sep-18 Related CR: 2018241055

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Tympanomeningeal fissure*	Approved as Requested	Proposed PT *Tympanomeningeal fissure*	10081914
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Tympanomeningeal fissure to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

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CR Number: 2018241056 **Implementation Date:** 13-Sep-18 Related CR: 2018241056

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Anti-glomerular basement membrane disease*	Approved as Requested	Proposed PT	
To SMQ	*Systemic lupus erythematosus (SMQ)*		*Anti-glomerular basement membrane disease*	10081981
Term scope	*Broad*		To SMQ	
			Systemic lupus erythematosus (SMQ)	20000045
			Term scope	
			Broad	
			Term_category	
			F	
			Term_weight	
			1	

MSSO Comment: The proposal to add PT Anti-glomerular basement membrane disease to Systemic lupus erythematosus (SMQ) as a broad term is approved as requested. Anti–glomerular basement membrane (anti-GBM) disease is an autoimmune disorder characterized by the presence of circulating pathogenic autoantibodies directed against proteins in the glomerular and alveolar basement membranes. It meets criteria for inclusion in Category F of the broad search terms of this SMQ (i.e., renal disorders). All related PTs in this category, including PT Autoimmune nephritis, have a weight of 1.

CR Number: 2018241057 **Implementation Date:** 13-Sep-18 Related CR: 2018241057

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cuboid syndrome*	Approved as Requested	Proposed PT	
To SMQ	*Accidents and injuries (SMQ)*		*Cuboid syndrome*	10081921
Term scope	*Narrow*		To SMQ	
			Accidents and injuries (SMQ)	20000135
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Cuboid syndrome to Accidents and injuries (SMQ) as a narrow term is approved as requested. Cuboid syndrome, or cuboid subluxation, occurs as a result of trauma or injury to the joint and ligaments near the cuboid bone. It meets the criteria for inclusion in this SMQ as a narrow search term since it describes an anatomically specific type of injury.

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CR Number: 2018241058 **Implementation Date:** 13-Sep-18 Related CR: 2018241058

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Iliocostal friction syndrome*	Approved as Requested	Proposed PT *Iliocostal friction syndrome*	10081983
To SMQ	*Osteoporosis/osteopenia (SMQ)*		To SMQ *Osteoporosis/osteopenia (SMQ)*	20000178
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Iliocostal friction syndrome to Osteoporosis/osteopenia (SMQ) as a broad term is approved as requested. Iliocostal friction syndrome is a condition caused by friction of the lower ribs against the iliac crest, which leads to chronic side pain. It occurs most often among individuals suffering from osteoporosis and meets the criteria for inclusion in the broad search terms of this SMQ.

CR Number: 2018241059 **Implementation Date:** 13-Sep-18 Related CR: 2018241059

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Macroorchidism*	Approved as Requested	Proposed PT *Macroorchidism*	10081860
To SMQ	*Fertility disorders (SMQ)*		To SMQ *Fertility disorders (SMQ)*	20000210
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Macroorchidism to Fertility disorders (SMQ) as a narrow term is approved as requested. Macroorchidism, or enlarged testicular volume, has many etiologies (e.g., endocrine, genetic, idiopathic, neoplastic) and can be associated with fertility issues. It meets the criteria for inclusion in the narrow search terms of this SMQ.

Supplemental Update Report

CR Number: 2018241060 **Implementation Date:** 13-Sep-18 Related CR: 2018241060

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Plasma cell myeloma refractory*	Approved as Requested	Proposed PT *Plasma cell myeloma refractory*	10081847
To SMQ	*Haematological malignant tumours (SMQ)*		To SMQ *Haematological malignant tumours (SMQ)*	20000227
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Plasma cell myeloma refractory to Haematological malignant tumours (SMQ) as a narrow term is approved as requested. This term, which describes a specific type of hematological malignancy, meets the criteria for inclusion in this SMQ (which contains only narrow search terms).

CR Number: 2018241061 **Implementation Date:** 13-Sep-18 Related CR: 2018241061

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*PSTPIP1-associated myeloid-related proteinaemia inflammatory syndrome*	Approved as Requested	Proposed PT *PSTPIP1-associated myeloid-related proteinaemia inflammatory syndrome*	10081947
To SMQ	*Myelodysplastic syndrome (SMQ)*		To SMQ *Myelodysplastic syndrome (SMQ)*	20000217
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT PSTPIP1-associated myeloid-related proteinaemia inflammatory syndrome to Myelodysplastic syndrome (SMQ) as a broad term is approved as requested. PSTPIP1-gene associated autoinflammatory diseases is a group of clinically diverse syndromes including one, PAMI, which manifests mainly with haematologic abnormalities. At least one patient in a reported cohort with this disorder went on to develop a myelodysplastic syndrome. This term will be added to the broad search terms of this SMQ as a potential risk factor for the development of myelodysplasia.

Supplemental Update Report

CR Number: 2018241062 **Implementation Date:** 13-Sep-18 Related CR: 2018241062

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Puncture site haematoma*	Approved as Requested	Proposed PT	
To SMQ	*Haemorrhage terms (excl laboratory terms) (SMQ)*		*Puncture site haematoma*	10081957
Term scope	*Narrow*		To SMQ	
			Haemorrhage terms (excl laboratory terms) (SMQ)	20000039
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Puncture site haematoma to Haemorrhage terms (excl laboratory terms) (SMQ) as a narrow term is approved as requested. This term, like the related PT Puncture site haemorrhage, meets the criteria for inclusion in this SMQ (which contains only narrow search terms).

CR Number: 2018241063 **Implementation Date:** 13-Sep-18 Related CR: 2018241063

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cerebral artery stent insertion*	Approved as Requested	Proposed PT	
To SMQ	*Ischaemic central nervous system vascular conditions (SMQ)*		*Cerebral artery stent insertion*	10081893
Term scope	*Narrow*		To SMQ	
			Ischaemic central nervous system vascular conditions (SMQ)	20000063
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Cerebral artery stent insertion to Ischaemic central nervous system vascular conditions (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes the related PT Brain stent insertion. All terms in this SMQ are narrow in scope.

Supplemental Update Report

CR Number: 2018241064 **Implementation Date:** 13-Sep-18 Related CR: 2018241064

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hippocampal atrophy*	Approved as Requested	Proposed PT *Hippocampal atrophy*	10081973
To SMQ	*Dementia (SMQ)*		To SMQ *Dementia (SMQ)*	20000073
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Hippocampal atrophy to Dementia (SMQ) as a narrow term is approved as requested. This term, which describes a pathological feature commonly observed in Alzheimer's disease, fits the criteria for inclusion in the narrow search terms of this SMQ (which includes PT Corticobasal deneration and PT Hippocampal sclerosis).

CR Number: 2018241065 **Implementation Date:** 13-Sep-18 Related CR: 2018241065

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Jugular vein embolism*	Approved as Requested	Proposed PT *Jugular vein embolism*	10081850
To SMQ	*Ischaemic central nervous system vascular conditions (SMQ)*		To SMQ *Ischaemic central nervous system vascular conditions (SMQ)*	20000063
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Jugular vein embolism to Ischaemic central nervous system vascular conditions (SMQ) as a narrow term is approved as requested. This term describes embolism from the jugular vein which, in susceptible individuals, can be associated with ischemic vascular events in the brain. All terms in this SMQ are narrow in scope.

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CR Number: 2018241066 **Implementation Date:** 13-Sep-18 Related CR: 2018241066

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Paroxysmal extreme pain disorder*	Approved as Requested	Proposed PT	
To SMQ	*Peripheral neuropathy (SMQ)*		*Paroxysmal extreme pain disorder*	10081856
Term scope	*Narrow*		To SMQ	
			Peripheral neuropathy (SMQ)	20000034
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Paroxysmal extreme pain disorder to Peripheral neuropathy (SMQ) as a narrow term is approved as requested. Paroxysmal extreme pain disorder is a condition characterized by skin redness and warmth (flushing) and attacks of severe pain in various parts of the body. Paroxysmal extreme pain disorder is considered a form of peripheral neuropathy because it affects the peripheral nervous system. It meets the criteria for inclusion in the narrow search terms of this SMQ which describe specific types of peripheral neuropathy.

CR Number: 2018242001 **Implementation Date:** 17-Sep-18 Related CR: 2018242001

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Haematological infection*	Approved Not as Requested After Suspension	Proposed LLT	
From PT	*Sepsis*		*Septicaemia*	10040072 Current
			From PT	
			Sepsis	10040047
			HLT primary	
			Sepsis, bacteraemia, viraemia and fungaemia NEC	10040054
			SOC primary	
			Infections and infestations	10021881

MSSO Comment: The proposal to promote the LLT Haematological infection from PT Sepsis is approved but not as requested after suspension. Septicaemia/haematological infection are not synonyms of sepsis which is a severe complication of septicaemia. Instead of promoting LLT Haematological infection, the MSSO will promote the LLT Septicaemia to a PT under HLT Sepsis, bacteraemia, viraemia and fungaemia NEC. However, in a related change, LLT Haematological infection will be moved from PT Sepsis to the promoted PT Septicaemia. Furthermore, the following LLTs under PT Sepsis will be moved to the recently promoted PT Septicaemia as well: LLT Hematological infection, LLT Other specified septicaemias, LLT Other specified septicemias, LLT Pyaemia, LLT Pyemia, LLT Septicaemia NOS, LLT Septicemia, LLT Septicopyaemia, LLT Septicopyemia, LLT Unspecified septicaemia, LLT Unspecified septicemia.

Supplemental Update Report

CR Number: 2018260031 **Implementation Date:** 17-Sep-18 Related CR: 2018242001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Hematological infection*	Approved as Requested	Proposed LLT		
From PT	*Sepsis*		*Hematological infection*	10069761	Current
To PT	*Septicaemia*		From PT		
			Sepsis	10040047	
			To PT		
			Septicaemia	10040072	Current

MSSO Comment:

CR Number: 2018260032 **Implementation Date:** 17-Sep-18 Related CR: 2018242001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Haematological infection*	Approved as Requested	Proposed LLT		
From PT	*Sepsis*		*Haematological infection*	10069762	Current
To PT	*Septicaemia*		From PT		
			Sepsis	10040047	
			To PT		
			Septicaemia	10040072	Current

MSSO Comment:

CR Number: 2018260033 **Implementation Date:** 17-Sep-18 Related CR: 2018242001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Other specified septicaemias*	Approved as Requested	Proposed LLT		
From PT	*Sepsis*		*Other specified septicaemias*	10032890	Non-Current
To PT	*Septicaemia*		From PT		
			Sepsis	10040047	
			To PT		
			Septicaemia	10040072	Current

MSSO Comment:

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CR Number: 2018260034 **Implementation Date:** 17-Sep-18 Related CR: 2018242001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Other specified septicemias*	Approved as Requested	Proposed LLT	
From PT	*Sepsis*		*Other specified septicemias*	10032891 Non-Current
To PT	*Septicaemia*		From PT	
			Sepsis	10040047
			To PT	
			Septicaemia	10040072 Current

MSSO Comment:

CR Number: 2018260035 **Implementation Date:** 17-Sep-18 Related CR: 2018242001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pyaemia*	Approved as Requested	Proposed LLT	
From PT	*Sepsis*		*Pyaemia*	10037583 Current
To PT	*Septicaemia*		From PT	
			Sepsis	10040047
			To PT	
			Septicaemia	10040072 Current

MSSO Comment:

CR Number: 2018260036 **Implementation Date:** 17-Sep-18 Related CR: 2018242001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pyemia*	Approved as Requested	Proposed LLT	
From PT	*Sepsis*		*Pyemia*	10037609 Current
To PT	*Septicaemia*		From PT	
			Sepsis	10040047
			To PT	
			Septicaemia	10040072 Current

MSSO Comment:

Supplemental Update Report

CR Number: 2018260037 **Implementation Date:** 17-Sep-18 Related CR: 2018242001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Septicaemia NOS*	Approved as Requested	Proposed LLT	
From PT	*Sepsis*		*Septicaemia NOS*	10040082 Current
To PT	*Septicaemia*		From PT	
			Sepsis	10040047
			To PT	
			Septicaemia	10040072 Current

MSSO Comment:

CR Number: 2018260039 **Implementation Date:** 17-Sep-18 Related CR: 2018242001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Septicopyaemia*	Approved as Requested	Proposed LLT	
From PT	*Sepsis*		*Septicopyaemia*	10059291 Current
To PT	*Septicaemia*		From PT	
			Sepsis	10040047
			To PT	
			Septicaemia	10040072 Current

MSSO Comment:

CR Number: 2018260040 **Implementation Date:** 17-Sep-18 Related CR: 2018242001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Septicopyemia*	Approved as Requested	Proposed LLT	
From PT	*Sepsis*		*Septicopyemia*	10059281 Current
To PT	*Septicaemia*		From PT	
			Sepsis	10040047
			To PT	
			Septicaemia	10040072 Current

MSSO Comment:

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CR Number: 2018260041 **Implementation Date:** 17-Sep-18 Related CR: 2018242001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Unspecified septicaemia*	Approved as Requested	Proposed LLT	
From PT	*Sepsis*		*Unspecified septicaemia*	10060437 Current
To PT	*Septicaemia*		From PT	
			Sepsis	10040047
			To PT	
			Septicaemia	10040072 Current

MSSO Comment:

CR Number: 2018260042 **Implementation Date:** 17-Sep-18 Related CR: 2018242001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Unspecified septicemia*	Approved as Requested	Proposed LLT	
From PT	*Sepsis*		*Unspecified septicemia*	10046161 Current
To PT	*Septicaemia*		From PT	
			Sepsis	10040047
			To PT	
			Septicaemia	10040072 Current

MSSO Comment:

CR Number: 2018260044 **Implementation Date:** 17-Sep-18 Related CR: 2018242001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Septicemia*	Approved as Requested	Proposed LLT	
From PT	*Sepsis*		*Septicemia*	10040089 Current
To PT	*Septicaemia*		From PT	
			Sepsis	10040047
			To PT	
			Septicaemia	10040072 Current

MSSO Comment:

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CR Number: 2018243001 **Implementation Date:** 07-Sep-18 Related CR: 2018243001

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Dermatitis NOS aggravated*	Rejected		
Status	*non-current*			

MSSO Comment: The proposal to change status of LLT Dermatitis NOS aggravated to non-current is not approved. As of MedDRA Version 6.1, no additional “NOS” terms will be accepted into the terminology. Additionally, all “NOS” terms previously existing at the PT level have been demoted to the LLT level in the terminology. However, the MSSO prefers not to change NOS terms status, unless clearly indicated, as they are still used by MedDRA users whose data may be altered unnecessarily.

CR Number: 2018243002 **Implementation Date:** 07-Sep-18 Related CR: 2018243002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Splinter infection*	Rejected		

MSSO Comment: The proposal to add a new LLT Splinter infection is not approved. MedDRA cannot accommodate a unique term for every possible cause and effect situation. The requested term, Splinter infection can be represented by split coding, for example, with LLT Splinter plus an appropriate term for the reported infection (such as: LLT Skin infection; LLT Soft tissue infection; LLT Localised infection; LLT Wound infection; etc.). Please also note that LLT Splinter bleeding referenced in the initial justification is under PT Splinter haemorrhage, which pertains to the shape and appearance of a small haemorrhage often under the fingernails, rather than to a haemorrhage caused by an actual splinter foreign body.

CR Number: 2018247001 **Implementation Date:** 07-Sep-18 Related CR: 2018247001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Pustulous drug eruption*	Approved Not as Requested	Proposed LLT	
			Pustular drug eruption	10082061 Current
			To PT	
			Drug eruption	10013687

MSSO Comment: The proposal to add a new term Pustulous drug eruption is approved but not as requested. A pustular drug eruption may present as an acute onset of aseptic pustules in a febrile patient with leukocytosis after exposure to an offending drug, and has been regarded as an uncommon manifestation of adverse drug reactions. The proposed term, Pustulous drug eruption will be expressed as Pustular drug eruption, the commonly used term in the medical literature, and added as a sub-concept LLT to PT Drug eruption.

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CR Number: 2018248001 **Implementation Date:** 07-Sep-18 Related CR: 2018248001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*PANCREATIC DUCT DRAINAGE*	Approved Not as Requested	Proposed PT	
			Pancreatic duct drainage	10082063
			HLT primary	
			Pancreatic therapeutic procedures	10033634
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term PANCREATIC DUCT DRAINAGE is approved but not as requested. Drainage of a dilated pancreatic duct, often performed with the pancreaticojejunostomy procedure, is a recognized, effective means of relieving intractable pain of chronic pancreatitis. Pancreatic duct drainage will be expressed in accordance with MedDRA capitalization conventions, and will be added as a PT to HLT Pancreatic therapeutic procedures.

CR Number: 2018248002 **Implementation Date:** 07-Sep-18 Related CR: 2018248002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*INTRACRANIAL INFECTION*	Approved Not as Requested	Proposed PT	
			Intracranial infection	10082062
			HLT primary	
			Central nervous system and spinal infections	10007935
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Nervous system infections NEC	10021888
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new term INTRACRANIAL INFECTION is approved but not as requested. The Centers for Disease Control and Prevention defines intracranial infection as a brain infection that meets specific established criteria. An intracranial infection can be suspected in the presence of symptoms like headache, dizziness, fever >38 ° C, localizing neurologic signs, changing level of consciousness, or confusion. The determination of organisms cultured from brain tissue or dura, and/or the evidence of a brain abscess, subdural or epidural infection, or encephalitis during a surgical operation or in the course of an histopathologic examination, would confirm the diagnose. Intracranial infection, expressed in accordance with MedDRA capitalization conventions, will be added as a PT to primary HLT Central nervous system and spinal infections, and to secondary HLT Nervous system infections NEC.

Supplemental Update Report

CR Number: 2018248003 **Implementation Date:** 07-Sep-18 Related CR: 2018248003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*GASTROINTESTINAL DECOMPRESSION*	Approved Not as Requested	Proposed PT	
			Gastrointestinal decompression	10082064
			HLT primary	
			Gastrointestinal therapeutic procedures NEC	10018013
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term GASTROINTESTINAL DECOMPRESSION is approved but not as requested. Gastrointestinal decompression is the removal of contents of the intestinal tract by use of suction, usually through a tube inserted into the upper gastrointestinal tract. The tube may be inserted through the nasopharynx or oropharynx, or via gastrostomy. Gastrointestinal decompression will be added in accordance with MedDRA capitalization conventions, as a PT to HLT Gastrointestinal therapeutic procedures NEC.

CR Number: 2018248004 **Implementation Date:** 07-Sep-18 Related CR: 2018248004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Arterial puncture*	Approved as Requested	Proposed PT	
			Arterial puncture	10082065
			HLT primary	
			Arterial therapeutic procedures (excl aortic)	10003167
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Arterial puncture is approved as requested. An arterial puncture procedure is most commonly performed to obtain a specimen of blood for arterial blood gas measurement. The proposed term, Arterial puncture will be added as a PT to HLT Arterial therapeutic procedures (excl aortic).

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CR Number: 2018248005 **Implementation Date:** 07-Sep-18 Related CR: 2018248005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Peritoneal dialysate leakage*	Approved as Requested	Proposed PT	
			Peritoneal dialysate leakage	10082066
			HLT primary	
			Dialysis related complications	10071945
			SOC primary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new term Peritoneal dialysate leakage is approved as requested. A Peritoneal dialysate leakage refers to the appearance of any moisture around the peritoneal dialysis catheter, however, the spectrum of dialysate leaks also includes any dialysate loss from the peritoneal cavity other than via the lumen of the catheter. Peritoneal dialysate leakage will be added as a new PT to HLT Dialysis related complications.

CR Number: 2018248006 **Implementation Date:** 08-Oct-18 Related CR: 2018248006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Infant irritability*	Approved After Suspension	Proposed PT	
			Infant irritability	10082189
			HLT primary	
			Neurological signs and symptoms NEC	10029306
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Neonatal neurological system disorders NEC	10028964
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new term Infant irritability is approved as requested after suspension. This change request is made in the context of a wider effort to standardize adverse event severity terminology for neonates from the International Neonatal Consortium (INC) and part of a mapping initiative to MedDRA. Irritability in infants, may present with long crying periods, fretfulness, jitteriness or trembling. Irritability may be a sign of multiple conditions such as constipation, abdominal pain, an earache, viral or bacterial infection, or even a consequence of maternal substance abuse. Infant irritability will be added as a PT to primary HLT Neurological signs and symptoms NEC and secondary HLT Neonatal neurological system disorders NEC.

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CR Number: 2018248007 **Implementation Date:** 08-Oct-18 Related CR: 2018248007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Infant sedation*	Approved After Suspension	Proposed PT	
			Infant sedation	10082187
			HLT primary	
			Disturbances in consciousness NEC	10013509
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Neonatal neurological system disorders NEC	10028964
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new term Infant sedation is approved as requested after suspension. This change request is made in the context of a wider effort to standardize adverse event severity terminology for neonates from the International Neonatal Consortium (INC) and part of a mapping initiative to MedDRA. Infant sedation is defined as a state of a lowered level of consciousness. Infant sedation will be added as a PT to primary HLT Disturbances in consciousness NEC and secondary HLT Neonatal neurological system disorders NEC.

CR Number: 2018248008 **Implementation Date:** 08-Oct-18 Related CR: 2018248008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Sinus tachycardia neonatal*	Approved Not as Requested After Suspension	Proposed PT	
			Neonatal sinus tachycardia	10082191
			HLT primary	
			Supraventricular arrhythmias	10042600
			SOC primary	
			Cardiac disorders	10007541
			HLT secondary	
			Neonatal cardiovascular disorders (excl cardiorespiratory arrest)	10028926
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new term Sinus tachycardia neonatal is approved but not as requested after suspension. This change request is made in the context of a wider effort to standardize adverse event severity terminology for neonates from the International Neonatal Consortium (INC) and part of a mapping initiative to MedDRA. In addition to the existing PT Neonatal tachycardia, the requested term provides more specific pathophysiologic information. Sinus tachycardia neonatal will be modified and added in the natural word order as PT Neonatal sinus tachycardia to primary HLT Supraventricular arrhythmias and secondary HLT Neonatal cardiovascular disorders (excl cardiorespiratory arrest).

Supplemental Update Report

CR Number: 2018248009 **Implementation Date:** 08-Oct-18 Related CR: 2018248009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Sinus bradycardia neonatal*	Approved Not as Requested After Suspension	Proposed PT	
			Neonatal sinus bradycardia	10082188
			HLT primary	
			Supraventricular arrhythmias	10042600
			SOC primary	
			Cardiac disorders	10007541
			HLT secondary	
			Neonatal cardiovascular disorders (excl cardiorespiratory arrest)	10028926
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new term Sinus bradycardia neonatal is approved but not as requested after suspension. This change request is made in the context of a wider effort to standardize adverse event severity terminology for neonates from the International Neonatal Consortium (INC) and part of a mapping initiative to MedDRA. In addition to the existing PT Neonatal bradycardia, the requested term provides more specific pathophysiologic information. Sinus bradycardia neonatal will be modified and added in the natural word order as PT Neonatal sinus bradycardia to primary HLT Supraventricular arrhythmias and secondary HLT Neonatal cardiovascular disorders (excl cardiorespiratory arrest).

CR Number: 2018248010 **Implementation Date:** 08-Oct-18 Related CR: 2018248010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Gastrointestinal hemorrhage neonatal*	Approved Not as Requested After Suspension	Proposed LLT	
			Gastrointestinal bleeding neonatal	10082192 Current
			To PT	
			Neonatal gastrointestinal haemorrhage	10074159

MSSO Comment: The proposal to add a new term Gastrointestinal hemorrhage neonatal is approved but not as requested after suspension. This change request is made in the context of a wider effort to standardize adverse event severity terminology for neonates from the International Neonatal Consortium (INC) and part of a mapping initiative to MedDRA. The requested term will be modified and added as LLT Gastrointestinal bleeding neonatal under PT Neonatal gastrointestinal haemorrhage to match the INC concept.

Supplemental Update Report

CR Number: 2018248011 **Implementation Date:** 08-Oct-18 Related CR: 2018248011

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Constipation neonatal*	Approved After Suspension	Proposed PT	
			Constipation neonatal	10082190
			HLT primary	
			Gastrointestinal atonic and hypomotility disorders NEC	10017933
			SOC primary	
			Gastrointestinal disorders	10017947
			HLT secondary	
			Neonatal gastrointestinal disorders	10028940
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new term Constipation neonatal is approved as requested after suspension. This change request is made in the context of a wider effort to standardize adverse event severity terminology for neonates from the International Neonatal Consortium (INC) and part of a mapping initiative to MedDRA. Constipation in neonates can indicate the presence of serious organic conditions, such as Hirschsprung's disease, pseudo-obstruction, spinal cord abnormality, hypothyroidism, diabetes insipidus, cystic fibrosis, gluten enteropathy, or congenital anorectal malformation. Constipation neonatal will be added as a PT with primary link to HLT Gastrointestinal atonic and hypomotility disorders NEC, and a secondary link to HLT Neonatal gastrointestinal disorders.

CR Number: 2018249001 **Implementation Date:** 13-Sep-18 Related CR: 2018249001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Loss of Balance*	Approved Not as Requested	Proposed LLT	
			Loss of balance	10082069 Current
			To PT	
			Balance disorder	10049848

MSSO Comment: The proposal to add a new PT Loss of Balance is approved but not as requested. The proposed term will be modified to Loss of balance to meet the MedDRA capitalization convention standards and added as an LLT to PT Balance disorder, aligned with similiar sub-concepts such LLT Unsteadiness.

Supplemental Update Report

CR Number: 2018250001 **Implementation Date:** 13-Sep-18 Related CR: 2018250001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Umbilical cord blood pH*	Approved Not as Requested	Proposed PT	
To PT	*Blood pH*		*Umbilical cord blood pH*	10082071
			HLT primary	
			Foetal and neonatal diagnostic procedures	10053100
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new LLT Umbilical cord blood pH to PT Blood pH is approved but not as requested. Umbilical cord blood gas analysis is the most objective way of assessing a newborn's metabolic condition at birth. Arterial cord pH and base deficit can determine perinatal hypoxia/asphyxia (potential causes of hypoxic-ischemic encephalopathy or cerebral palsy) and give insight into causes of intrapartum fetal distress. Umbilical cord blood pH will be added as a PT to HLT Foetal and neonatal diagnostic procedures because of its clinical relevance to neonatology.

CR Number: 2018250002 **Implementation Date:** 13-Sep-18 Related CR: 2018250002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Magnetic resonance elastography*	Approved Not as Requested	Proposed PT	
			Magnetic resonance elastography	10082070
			HLT primary	
			Imaging procedures NEC	10021404
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new LLT Magnetic resonance elastography is approved but not as requested. Magnetic Resonance Elastography is a rapidly developing technology for quantitatively assessing the mechanical properties of tissue by assessing the propagation of mechanical waves through the tissue with a special magnetic resonance imaging technique. It is currently used for the assessment of patients with chronic liver diseases and is emerging as a safe, reliable and noninvasive alternative to liver biopsy for staging hepatic fibrosis. Magnetic resonance elastography is also being investigated for application to pathologies of other organs including the brain, breast, blood vessels, heart, kidneys, lungs and skeletal muscle. Rather than adding Magnetic resonance elastography as an LLT, the proposed term will be placed as a PT to HLT Imaging procedures NEC.

Supplemental Update Report

CR Number: 2018250003 **Implementation Date:** 19-Oct-18 Related CR: 2018250003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Postpartum anxiety*	Approved Not as Requested After Suspension	Proposed PT	
To PT	*Anxiety disorder*		*Postpartum anxiety*	10082233
			HLT primary	
			Anxiety disorders NEC	10068761
			SOC primary	
			Psychiatric disorders	10037175
			HLT secondary	
			Postpartum psychiatric disorders	10036420
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new LLT Postpartum anxiety to PT Anxiety disorder is approved but not as requested after suspension. The postpartum period is a time of increased vulnerability for depression in women. Women with a prior psychiatric history are at increased risk for postpartum depression. Other risk factors include psychological, social, and biological contributions. In addition, to depressive symptoms, episodes of postpartum depression are often characterized by marked anxiety. Furthermore, many studies have observed that postpartum anxiety disorders are under-diagnosed and are in fact more common than postpartum depression. Postpartum anxiety will be added as a PT to primary HLT Anxiety disorders NEC and secondary HLT Postpartum psychiatric disorders.

CR Number: 2018250004 **Implementation Date:** 13-Sep-18 Related CR: 2018250004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Aggravated Heart failure NYHA class I*	Rejected		

MSSO Comment: The proposal to add a new LLT Aggravated Heart failure NYHA class I is not approved. The MSSO refrains from adding further concepts followed by aggravated. Furthermore, NYHA is a classification with a severity grading, for example an aggravated NYHA Class I could indicate worsening to NYHA Class II. Alternate option would be split coding using LLT Cardiac failure chronic aggravated and LLT Heart failure NYHA class I.

Supplemental Update Report

CR Number: **2018250005** **Implementation Date:** 13-Sep-18 Related CR: 2018250005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Aggravated Heart failure NYHA class II*	Rejected		

MSSO Comment: The proposal to add a new LLT Aggravated Heart failure NYHA class II is not approved. The MSSO refrains from adding further concepts followed by aggravated. Furthermore, NYHA is a classification with a severity grading, for example an aggravated NYHA Class II could indicate worsening to NYHA Class III. Alternate option would be split coding using LLT Cardiac failure chronic aggravated and LLT Heart failure NYHA class II.

CR Number: **2018250006** **Implementation Date:** 13-Sep-18 Related CR: 2018250006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Aggravated Heart failure NYHA class III*	Rejected		

MSSO Comment: The proposal to add a new LLT Aggravated Heart failure NYHA class III is not approved. The MSSO refrains from adding further concepts followed by aggravated. Furthermore, NYHA is a classification with a severity grading, for example an aggravated NYHA Class III could indicate worsening to NYHA Class IV. Alternate option would be split coding using LLT Cardiac failure chronic aggravated and LLT Heart failure NYHA class III.

CR Number: **2018250007** **Implementation Date:** 13-Sep-18 Related CR: 2018250007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Aggravated Heart failure NYHA class IV*	Rejected		

MSSO Comment: The proposal to add a new LLT Aggravated Heart failure NYHA class IV is not approved. The MSSO refrains from adding further concepts followed by aggravated. Please consider split coding using LLT Cardiac failure chronic aggravated and LLT Heart failure NYHA class IV.

Supplemental Update Report

CR Number: 2018250010 **Implementation Date:** 13-Sep-18 Related CR: 2018250010

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pharyngoesophageal dysphagia*	Approved as Requested	Proposed LLT	
To PT	*Dysphagia*		*Pharyngoesophageal dysphagia*	10082072 Current
			To PT	
			Dysphagia	10013950

MSSO Comment: The proposal to add a new LLT Pharyngoesophageal dysphagia to PT Dysphagia is approved as requested. Pharyngoesophageal dysphagia is an anatomical specific sub-concept indicating the two regions causing dysphagia. In a related change, the British English counterpart LLT Pharyngo-oesophageal dysphagia will be added to PT Dysphagia.

CR Number: 2018256004 **Implementation Date:** 13-Sep-18 Related CR: 2018250010

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pharyngo-oesophageal dysphagia*	Approved as Requested	Proposed LLT	
To PT	*Dysphagia*		*Pharyngo-oesophageal dysphagia*	10082073 Current
			To PT	
			Dysphagia	10013950

MSSO Comment:

CR Number: 2018253003 **Implementation Date:** 13-Sep-18 Related CR: 2018253003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Post-stenotic pneumonia*	Approved Not as Requested	Proposed LLT	
HLT primary	*Lower respiratory tract and lung infections*		*Post-stenotic pneumonia*	10082074 Current
SOC primary	*Infections and infestations*		To PT	
			Pneumonia	10035664

MSSO Comment: The proposal to add a new PT Post-stenotic pneumonia to primary HLT Lower respiratory tract and lung infections in SOC Infections and infestations is approved but not as requested. Post-stenotic pneumonia is an obstructive pneumonia, often caused by lung airway stenosis resulting from mass lesions in the lungs, including neoplasia. Post-stenotic pneumonia presents a heterogeneous microbial profile and a high hospital mortality rate which is not related to specific treatment, tumour histology or patient's characteristics. Post-stenotic pneumonia will be added as a sub-concept LLT to PT Pneumonia.

Supplemental Update Report

CR Number: 2018253004 **Implementation Date:** 17-Sep-18 Related CR: 2018253004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ovarian melanoma*	Approved Not as Requested	Proposed PT	
HLT primary	*Female reproductive neoplasms malignant NEC*		*Ovarian melanoma*	10082079
SOC primary	*Neoplasms benign, malignant and unspecified (incl cysts and polyps)*		HLT primary	
			Ovarian neoplasms malignant (excl germ cell)	10033129
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Ovarian and fallopian tube cysts and neoplasms	10033121
			SOC secondary	
			Reproductive system and breast disorders	10038604

MSSO Comment: The proposal to add a new PT Ovarian melanoma to primary HLT Female reproductive neoplasms malignant NEC in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is approved but not as requested. Most malignant melanomas encountered in the ovary are metastatic, while primary tumors are rare and may may arise within a mature cystic teratoma. Ovarian melanoma will be primarily placed to the more specific HLT Ovarian neoplasms malignant (excl germ cell) and to secondary HLT Ovarian and fallopian tube cysts and neoplasms.

CR Number: 2018254001 **Implementation Date:** 17-Sep-18 Related CR: 2018254001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ophiasis*	Approved as Requested	Proposed LLT	
To PT	*Alopecia areata*		*Ophiasis*	10082078 Current
			To PT	
			Alopecia areata	10001761

MSSO Comment: The proposal to add a new LLT Ophiasis to PT Alopecia areata is approved as requested. Ophiasis is a form of alopecia areata of long duration, involving hair loss in the temporal and occipital margins of the scalp, usually in a continuous band.

Supplemental Update Report

CR Number: 2018255001 **Implementation Date:** 17-Sep-18 Related CR: 2018255001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Carbohydrate antigen 72-4 increased*	Approved as Requested	Proposed PT	
HLT primary	*Cell marker analyses*		*Carbohydrate antigen 72-4 increased*	10082080
SOC primary	*Investigations*		HLT primary	
			Cell marker analyses	10072981
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Carbohydrate antigen 72-4 increased to primary HLT Cell marker analyses in SOC Investigations is approved as requested. Carbohydrate antigen 72-4 is a tumor marker useful in diagnosing and monitoring the status of gastrointestinal and gynecological cancers. Carbohydrate antigen 72-4 increased will be added as a new PT to HLT Cell marker analyses, complementing the existing unqualified PT Carbohydrate antigen 72-4.

CR Number: 2018255002 **Implementation Date:** 17-Sep-18 Related CR: 2018255002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Tumor ablation*	Approved as Requested	Proposed LLT	
			Tumor ablation	10082083 Current
			To PT	
			Tumour ablation	10082081

MSSO Comment: The proposal to add a new term Tumor ablation is approved as requested. Tumor ablation is a minimally invasive surgical method to treat solid benign or malignant tumor masses that cannot otherwise be treated by means of the application of chemicals, heat, or other forms of energy. Tumor ablation will be added as LLT to the British English spelled counterpart PT Tumour ablation. In a related change, new PT Tumour ablation will be added to HLT Therapeutic procedures NEC.

CR Number: 2018260003 **Implementation Date:** 17-Sep-18 Related CR: 2018255002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Tumour ablation*	Approved as Requested	Proposed PT	
HLT primary	*Therapeutic procedures NEC*		*Tumour ablation*	10082081
SOC primary	*Surgical and medical procedures*		HLT primary	
			Therapeutic procedures NEC	10027700
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment:

Supplemental Update Report

CR Number: 2018255003 **Implementation Date:** 17-Sep-18 Related CR: 2018255003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Respiratory tract operation*	Approved as Requested	Proposed PT	
			Respiratory tract operation	10082082
			HLT primary	
			Respiratory tract therapeutic procedures NEC	10052727
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Respiratory tract operation is approved as requested. Respiratory tract operation will be added as PT to HLT Respiratory tract therapeutic procedures NEC to provide a broad umbrella term for any type of surgery/operation of the entire respiratory tract if no further more specific Information is provided.

CR Number: 2018256001 **Implementation Date:** 17-Sep-18 Related CR: 2018256001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Iatrogenic metastasis*	Approved as Requested	Proposed PT	
			Iatrogenic metastasis	10082075
			HLT primary	
			Metastases to unknown and unspecified sites	10027471
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Non-site specific procedural complications	10029559
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new PT Iatrogenic metastasis is approved as requested. Iatrogenic metastasis is the desquamation and dissemination of tumor cells that develop into a local recurrence or distant metastasis from the tumor under treatment, resulting from various medical procedures used during diagnosis or treatment of a malignancy. Iatrogenic metastasis will be added as a new PT to primary HLT Metastases to unknown and unspecified sites, and to secondary HLT Non-site specific procedural complications. In a related change, the frequently used synonym Iatrogenic tumor implantation and Iatrogenic tumour implantation will be added as synonym LLTs to the new PT Iatrogenic metastasis.

Supplemental Update Report

CR Number: 2018260001 **Implementation Date:** 17-Sep-18 Related CR: 2018256001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Iatrogenic tumor implantation*	Approved as Requested	Proposed LLT		
To PT	*Iatrogenic metastasis*		*Iatrogenic tumor implantation*	10082076	Current
			To PT		
			Iatrogenic metastasis	10082075	

MSSO Comment:

CR Number: 2018260002 **Implementation Date:** 17-Sep-18 Related CR: 2018256001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Iatrogenic tumour implantation*	Approved as Requested	Proposed LLT		
To PT	*Iatrogenic metastasis*		*Iatrogenic tumour implantation*	10082077	Current
			To PT		
			Iatrogenic metastasis	10082075	

MSSO Comment:

CR Number: 2018256002 **Implementation Date:** 17-Sep-18 Related CR: 2018256002

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Transient hypogammaglobulinaemia*	Approved as Requested	Proposed LLT		
From PT	*Transient hypogammaglobulinaemia of infancy*		*Transient hypogammaglobulinaemia*	10060426	Non-Current
To PT	*Hypogammaglobulinaemia*		From PT		
			Transient hypogammaglobulinaemia of infancy	10044388	
			To PT		
			Hypogammaglobulinaemia	10020983	

MSSO Comment: The proposal to move the LLT Transient hypogammaglobulinaemia from PT Transient hypogammaglobulinaemia of infancy to PT Hypogammaglobulinaemia is approved as requested. This LLT was made non-current because transient hypogammaglobulinaemia can be present at infancy, or may be acquired later in life and such an unqualified transient hypogammaglobulinaemia term is rather nonspecific. In accordance with the MedDRA convention to place even non-current LLTs under the most appropriate PTs, LLT Transient hypogammaglobulinaemia will be moved to PT Hypogammaglobulinaemia.

Supplemental Update Report

CR Number: 2018256003 **Implementation Date:** 17-Sep-18 Related CR: 2018256003

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Transient hypogammaglobulinemia*	Approved as Requested	Proposed LLT	
From PT	*Transient hypogammaglobulinaemia of infancy*		*Transient hypogammaglobulinemia*	10044389 Non-Current
To PT	*Hypogammaglobulinaemia*		From PT	
			Transient hypogammaglobulinaemia of infancy	10044388
			To PT	
			Hypogammaglobulinaemia	10020983

MSSO Comment: The proposal to move the LLT Transient hypogammaglobulinemia from PT Transient hypogammaglobulinaemia of infancy to PT Hypogammaglobulinaemia is approved as requested. This LLT was made non-current because transient hypogammaglobulinemia can be present at infancy, or may be acquired later in life and such an unqualified transient hypogammaglobulinemia term is rather nonspecific. In accordance with the MedDRA convention to place even non-current LLTs under the most appropriate PTs, LLT Transient hypogammaglobulinemia will be moved to PT Hypogammaglobulinaemia.

CR Number: 2018256005 **Implementation Date:** 17-Sep-18 Related CR: 2018256005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Beta-thalassaemia trait*	Approved as Requested	Proposed LLT	
To PT	*Thalassaemia minor*		*Beta-thalassaemia trait*	10082086 Current
			To PT	
			Thalassaemia minor	10043393

MSSO Comment: The proposal to add a new LLT Beta-thalassaemia trait to PT Thalassaemia minor is approved as requested. This LLT represents the British English spelling for the recently added LLT Beta-thalassemia trait.

CR Number: 2018256006 **Implementation Date:** 17-Sep-18 Related CR: 2018256006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Schmincke-Regaud tumour*	Approved as Requested	Proposed LLT	
To PT	*Undifferentiated nasopharyngeal carcinoma*		*Schmincke-Regaud tumour*	10082085 Current
			To PT	
			Undifferentiated nasopharyngeal carcinoma	10073328

MSSO Comment: The proposal to add a new LLT Schmincke-Regaud tumour to PT Undifferentiated nasopharyngeal carcinoma is approved as requested. This LLT represents the British English spelling for the recently added LLT Schmincke-Regaud tumor.

Supplemental Update Report

CR Number: 2018256007 **Implementation Date:** 17-Sep-18 Related CR: 2018256007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Grey matter heterotopia*	Approved as Requested	Proposed LLT	
To PT	*Gray matter heterotopia*		*Grey matter heterotopia*	10082084
			To PT	
			Gray matter heterotopia	10080533 Current

MSSO Comment: The proposal to add a new LLT Grey matter heterotopia to PT Gray matter heterotopia is approved as requested. LLT Grey matter heterotopia represents the British English spelled counterpart of PT Gray matter heterotopia. Please see change request 2018256008 for swapping the two terms British English concept as PT following MedDRA spelling conventions.

CR Number: 2018256008 **Implementation Date:** 17-Sep-18 Related CR: 2018256008

Change Requested	Swap a PT with an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gray matter heterotopia*	Approved as Requested	Proposed PT	
With LLT	*Grey matter heterotopia*		*Gray matter heterotopia*	10080533 Current
			With LLT	
			Grey matter heterotopia	10082084

MSSO Comment: The proposal to swap the PT Gray matter heterotopia with the LLT Grey matter heterotopia is approved as requested. Grey matter heterotopia represents the British English spelling of the concept.

CR Number: 2018257001 **Implementation Date:** 24-Sep-18 Related CR: 2018257001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Congophilic angiopathy*	Approved as Requested	Proposed LLT	
To PT	*Cerebral amyloid angiopathy*		*Congophilic angiopathy*	10082093 Current
			To PT	
			Cerebral amyloid angiopathy	10068044

MSSO Comment: The proposal to add a new LLT Congophilic angiopathy to PT Cerebral amyloid angiopathy is approved as requested. Congophilic angiopathy is synonymously used to PT Cerebral amyloid angiopathy. The term congophilic is used because the presence of the abnormal aggregations of amyloid can be demonstrated by microscopic examination of brain tissue after application of a special stain called Congo red.

Supplemental Update Report

CR Number: 2018257002 **Implementation Date:** 24-Sep-18 Related CR: 2018257002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Hemorrhagic cholecystitis*	Approved as Requested	Proposed LLT *Hemorrhagic cholecystitis* To PT *Haemorrhagic cholecystitis*	 10082092 Current 10082088

MSSO Comment: The proposal to add a new term Hemorrhagic cholecystitis is approved as requested. Hemorrhagic cholecystitis is an uncommon, acute, serious complication of acute cholecystitis that may or may not be associated with lithiasis. Hemorrhagic cholecystitis will be added as an LLT to a British English counterpart PT Haemorrhagic cholecystitis. In a related change, PT Haemorrhagic cholecystitis will be added to primary HLT Cholecystitis and cholelithiasis and secondary HLT Gastrointestinal haemorrhages.

CR Number: 2018267011 **Implementation Date:** 24-Sep-18 Related CR: 2018257002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Haemorrhagic cholecystitis*	Approved as Requested	Proposed PT *Haemorrhagic cholecystitis*	 10082088
HLT primary	*Cholecystitis and cholelithiasis*		HLT primary *Cholecystitis and cholelithiasis*	 10008616
SOC primary	*Hepatobiliary disorders*		SOC primary *Hepatobiliary disorders*	 10019805
			HLT secondary *Gastrointestinal haemorrhages*	 10052742
			SOC secondary *Vascular disorders*	 10047065

MSSO Comment:

Supplemental Update Report

CR Number: 2018257003 **Implementation Date:** 24-Sep-18 Related CR: 2018257003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Frederick's syndrome*	Approved as Requested	Proposed PT	
			Frederick's syndrome	10082089
			HLT primary	
			Cardiac conduction disorders	10000032
			SOC primary	
			Cardiac disorders	10007541

MSSO Comment: The proposal to add a new term Frederick's syndrome is approved as requested. Frederick's syndrome is a symptom complex consisting of clinical features of pathology and electrocardiographic manifestations that occur with complete atrioventricular blockade with accelerated contraction of individual muscle fibers of the heart. Frederick's syndrome will be added as a PT to HLT Cardiac conduction disorders.

CR Number: 2018257004 **Implementation Date:** 24-Sep-18 Related CR: 2018257004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Hemorrhagic acalculous cholecystitis*	Rejected		

MSSO Comment: The proposal to add a new term Hemorrhagic acalculous cholecystitis is not approved. It is not feasible to provide all possible combination concepts to avoid overpopulation of MedDRA. The requested term represents a concept with two qualifiers and can be represented by the broad new PT Haemorrhagic cholecystitis added in change request 2018257002 and in with combination LLT Acalculous cholecystitis.

CR Number: 2018257005 **Implementation Date:** 24-Sep-18 Related CR: 2018257005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Red Vision*	Approved Not as Requested	Proposed LLT	
To PT	*Erythropsia*		*Red vision*	10082090 Current
			To PT	
			Erythropsia	10015290

MSSO Comment: The proposal to add a new LLT Red Vision to PT Erythropsia is approved but not as requested. The requested term will be added as LLT Red vision in accordance with MedDRA capitalisation conventions and added to PT Erythropsia. Red vision is the colloquial term for Erythropsia, defined as a chromatopsia in which objects appear tinged with red.

Supplemental Update Report

CR Number: 2018257006 **Implementation Date:** 24-Sep-18 Related CR: 2018257006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cardiac resynchronization therapy / pacemaker insertion*	Approved Not as Requested	Proposed LLT	
			Cardiac resynchronization therapy / pacemaker insertion	10082091 Current
To PT	*Cardiac pacemaker insertion*		To PT	
			Cardiac resynchronisation therapy	10059862

MSSO Comment: The proposal to add a new LLT Cardiac resynchronization therapy / pacemaker insertion to PT Cardiac pacemaker insertion is approved but not as requested. There are two types of Cardiac resynchronization therapy (CRT) devices. One is a special kind of pacemaker. It's called a cardiac resynchronization therapy pacemaker (CRT-P) or "biventricular pacemaker." While functioning like a normal pacemaker to treat slow heart rhythms, a CRT-P device also delivers small electrical impulses to the left and right ventricles to help them contract at the same time so you heart pumps more efficiently. Therefore, Cardiac resynchronization therapy / pacemaker insertion will be added to the more appropriate PT Cardiac resynchronisation therapy aligned with LLT Biventricular pacemaker insertion. In a related change, British English counterpart LLT Cardiac resynchronisation therapy / pacemaker insertion will be added as well to PT Cardiac resynchronisation therapy. Furthermore, the commonly used acronym CRT-P will be added as an LLT to PT Cardiac resynchronisation therapy.

CR Number: 2018267012 **Implementation Date:** 24-Sep-18 Related CR: 2018257006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cardiac resynchronisation therapy / pacemaker insertion*	Approved as Requested	Proposed LLT	
			Cardiac resynchronisation therapy / pacemaker insertion	10082094 Current
To PT	*Cardiac resynchronisation therapy*		To PT	
			Cardiac resynchronisation therapy	10059862

MSSO Comment:

CR Number: 2018267013 **Implementation Date:** 24-Sep-18 Related CR: 2018257006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*CRT-P*	Approved as Requested	Proposed LLT	
			CRT-P	10082095 Current
To PT	*Cardiac resynchronisation therapy*		To PT	
			Cardiac resynchronisation therapy	10059862

MSSO Comment:

Supplemental Update Report

CR Number: 2018257007 **Implementation Date:** 14-Nov-18 Related CR: 2018257007

Change Requested	Add a new SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed SMQ	*Diabetic retinopathy complications*	Rejected After Suspension		
To SMQ	*Retinal disorders (SMQ)*			

MSSO Comment: The proposal to add a new SMQ Diabetic retinopathy complications is not approved after suspension. An international team of regulatory and industry representatives evaluated this request and does not recommend the development of this SMQ based on the following considerations. Diabetic retinopathy is an important complication of diabetes mellitus and manifestations of the progression of diabetic retinopathy are sometimes referred to as diabetic retinopathy complications. Early worsening of diabetic retinopathy, a relatively recently identified complication, is a paradoxical temporary worsening of diabetic retinopathy associated with a rapid therapeutic improvement of inadequately controlled hyperglycemia. It may be associated with Glucagon-Like Receptor 1 Agonists (GLP1-RA) and has also been observed with insulin products. The mechanism is unknown and the risk of diabetic retinopathy progression is reversed after 18 months to 2 years. In contrast to most of the existing SMQ topics which focus on identifying potential cases of newly emergent diseases or conditions, this query would seek to identify cases of progression of diabetic retinopathy. However, unless specifically reported as “early worsening of diabetic retinopathy,” this disease concept may be difficult to ascertain in cases retrieved by the use of the proposed SMQ. The identification of this disorder usually necessitates a detailed review of sequential ophthalmologic examination records for a patient over a period of at least 12 months. With a limited number of products labeled for this complication, it would be challenging to conduct appropriate testing based solely on reported MedDRA AE terms to identify cases that are a true drug effect vs. a natural progression of the condition, and having to factor in the level of glycemic control and other etiologies. Furthermore, the manifestations of diabetic retinopathy such as vitreous hemorrhage, maculopathy, and neovascular glaucoma, can also be signs of other disorders and would likely retrieve a signficant number of cases that are not relevant to the progression of diabetic retinopathy. The need to monitor diabetic retinopathy complications is recognized, however an SMQ is not a suitable strategy for this purpose; detailed ophthalmologic records are needed to document that progression has occurred. To faciliate coding and retrieval of cases of diabetic retinopathy complications, a new LLT Early worsening of diabetic retinopathy has been added to PT Diabetic retinopathy for MedDRA Version 22.0.

CR Number: 2018257008 **Implementation Date:** 24-Sep-18 Related CR: 2018257008

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Multiple use of single-dose product*	Approved Not as Requested	Proposed LLT	
HLT primary	*Medication errors, product use errors and issues NEC*		*Multiple use of single-dose product*	10082096 Current
SOC primary	*Injury, poisoning and procedural complications*		To PT *Multiple use of single-use product*	10072342

MSSO Comment: The proposal to add a new PT Multiple use of single-dose product to primary HLT Medication errors, product use errors and issues NEC in SOC Injury, poisoning and procedural complications is approved but not as requested. A single-dose product for example is a container of a sterile medication for parenteral administration (injection or infusion) that is not required to meet the antimicrobial effectiveness testing requirements, and that is designed for use with a single patient as a single injection/infusion. Multiple use of single-dose product will be placed as an LLT under the broader PT Multiple use of single-use product, aligned with LLT Repeat use of single dose syringe.

Supplemental Update Report

CR Number: 2018257009 **Implementation Date:** 24-Sep-18 Related CR: 2018257009

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Incomplete course of vaccination*	Rejected		
From HLT	*Product administration errors and issues*			
To HLT	*Medication errors, product use errors and issues NEC*			

MSSO Comment: The proposal to move the PT Incomplete course of vaccination from HLT Product administration errors and issues to HLT Medication errors, product use errors and issues NEC is not approved. Every HLT under HLGT Medication errors and other product use errors and issues can represent can group terms in which the intentionality of the event can not be determined. Both HLTs considered in this request (Product administration errors and issues and Medication errors, product use errors and issues NEC) are equal in this circumstance. The act of a vaccine administration is inherent to the PT Incomplete course of vaccination, hence current placement under HLT Product administration errors and issues is more specific that the one proposed. For reports where it is clearly stated that the incomplete vaccination happened intentionally a second code can be taken i.e. LLT Intentional product use issue.

CR Number: 2018257010 **Implementation Date:** 24-Sep-18 Related CR: 2018257010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Arteriovenous fistula rupture*	Approved Not as Requested	Proposed LLT *Arteriovenous fistula access site rupture*	
			To PT *Arteriovenous fistula site haemorrhage*	10055123

MSSO Comment: The proposal to add a new term Arteriovenous fistula rupture is approved but not as requested. Arteriovenous vascular access fistulas may rupture, often resulting from the development of an aneurysm. Death from arteriovenous fistula site rupture hemorrhage is rare and likely to be under-reported, with incident rates of fewer than 1 episode for every 1,000 patient-years on dialysis. Arteriovenous fistula access site rupture will be added as an LLT to PT Arteriovenous fistula site haemorrhage. In a related change, LLT Arteriovenous graft rupture will be moved from PT Arteriovenous fistula site complication to the more specific PT Arteriovenous graft site haemorrhage.

CR Number: 2018267014 **Implementation Date:** 24-Sep-18 Related CR: 2018257010

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Arteriovenous graft rupture*	Approved as Requested	Proposed LLT *Arteriovenous graft rupture*	10077770 Current
From PT	*Arteriovenous fistula site complication*		From PT *Arteriovenous fistula site complication*	10055122
To PT	*Arteriovenous graft site haemorrhage*		To PT *Arteriovenous graft site haemorrhage*	10055126

MSSO Comment:

Supplemental Update Report

CR Number: 2018257011 **Implementation Date:** 24-Sep-18 Related CR: 2018257011

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Acute flaccid myelitis*	Approved as Requested	Proposed PT	
			Acute flaccid myelitis	10082097
			HLT primary	
			Myelitis (incl infective)	10028525
			SOC primary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new term Acute flaccid myelitis is approved as requested. Acute flaccid myelitis, a rare, serious idiopathic condition that affects the spinal cord grey matter, is characterized by acute weakness in the extremities with loss of muscle tone and decreased or absent reflexes, and may also be associated with difficulty swallowing, slurred speech, drooping eyelids, nerve pain, and respiratory impairment or failure. An etiology for acute flaccid myelitis has not been identified, however viral infection, environmental toxins, and genetic disorders are under investigation. Acute flaccid myelitis will be added as a new PT to HLT Myelitis (incl infective).

CR Number: 2018260004 **Implementation Date:** 10-Oct-18 Related CR: 2018260004

Change Requested	Add a New HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed HLT	*Hallucinations (excl sleep-related)*	Approved as Requested	Proposed HLT	
To HLGT	*Disturbances in thinking and perception*		*Hallucinations (excl sleep-related)*	10082212
			To HLGT	
			Disturbances in thinking and perception	10013511

MSSO Comment: The proposal to add a new HLT Hallucinations (excl sleep-related) to HLGT Disturbances in thinking and perception is approved as requested. These changes were recommended by the CIOMS SMQ Implementation Working Group to facilitate the retrieval of potential cases of hallucinations in lieu of a dedicated SMQ for hallucinations. The existing HLT Perception disturbances currently groups hallucination terms together with other disturbances in perception such as PT Deja vu and PT Time perception altered. These changes will group the specific terms for hallucinations together while separating out the other miscellaneous perception disturbances. Sleep-related hallucination concepts are not included in new HLT Hallucinations (excl sleep-related); PT Hypnagogic hallucination and PT Hypnopompic hallucination remain in HLT Narcolepsy and associated conditions.

Supplemental Update Report

CR Number: **2018260005** **Implementation Date:** 10-Oct-18 Related CR: 2018260005

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Charles Bonnet syndrome*	Approved as Requested	Proposed PT	
From HLT	*Perception disturbances*		*Charles Bonnet syndrome*	10063354
To HLT	*Hallucinations (excl sleep-related)*		From HLT	
			Perception disturbances	
			To HLT	
			Hallucinations (excl sleep-related)	10082212

MSSO Comment: The proposal to move the PT Charles Bonnet syndrome from HLT Perception disturbances to HLT Hallucinations (excl sleep-related) is approved as requested. These changes were recommended by the CIOMS SMQ Implementation Working Group to facilitate the retrieval of potential cases of hallucinations in lieu of a dedicated SMQ for hallucinations. The existing HLT Perception disturbances currently groups hallucination terms together with other disturbances in perception such as PT Deja vu and PT Time perception altered. These changes will group the specific terms for hallucinations together while separating out the other miscellaneous perception disturbances. Sleep-related hallucination concepts are not included in new HLT Hallucinations (excl sleep-related); PT Hypnagogic hallucination and PT Hypnopompic hallucination remain in HLT Narcolepsy and associated conditions.

CR Number: **2018260006** **Implementation Date:** 10-Oct-18 Related CR: 2018260006

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hallucination*	Approved as Requested	Proposed PT	
From HLT	*Perception disturbances*		*Hallucination*	10019063
To HLT	*Hallucinations (excl sleep-related)*		From HLT	
			Perception disturbances	
			To HLT	
			Hallucinations (excl sleep-related)	10082212

MSSO Comment: The proposal to move the PT Hallucination from HLT Perception disturbances to HLT Hallucinations (excl sleep-related) is approved as requested. These changes were recommended by the CIOMS SMQ Implementation Working Group to facilitate the retrieval of potential cases of hallucinations in lieu of a dedicated SMQ for hallucinations. The existing HLT Perception disturbances currently groups hallucination terms together with other disturbances in perception such as PT Deja vu and PT Time perception altered. These changes will group the specific terms for hallucinations together while separating out the other miscellaneous perception disturbances. Sleep-related hallucination concepts are not included in new HLT Hallucinations (excl sleep-related); PT Hypnagogic hallucination and PT Hypnopompic hallucination remain in HLT Narcolepsy and associated conditions.

Supplemental Update Report

CR Number: **2018260007** **Implementation Date:** 10-Oct-18 Related CR: 2018260007

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hallucination, auditory*	Approved as Requested	Proposed PT	
From HLT	*Perception disturbances*		*Hallucination, auditory*	10019070
To HLT	*Hallucinations (excl sleep-related)*		From HLT	
			Perception disturbances	
			To HLT	
			Hallucinations (excl sleep-related)	10082212

MSSO Comment: The proposal to move the PT Hallucination, auditory from HLT Perception disturbances to HLT Hallucinations (excl sleep-related) is approved as requested. These changes were recommended by the CIOMS SMQ Implementation Working Group to facilitate the retrieval of potential cases of hallucinations in lieu of a dedicated SMQ for hallucinations. The existing HLT Perception disturbances currently groups hallucination terms together with other disturbances in perception such as PT Deja vu and PT Time perception altered. These changes will group the specific terms for hallucinations together while separating out the other miscellaneous perception disturbances. Sleep-related hallucination concepts are not included in new HLT Hallucinations (excl sleep-related); PT Hypnagogic hallucination and PT Hypnopompic hallucination remain in HLT Narcolepsy and associated conditions.

CR Number: **2018260008** **Implementation Date:** 10-Oct-18 Related CR: 2018260008

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hallucination, gustatory*	Approved as Requested	Proposed PT	
From HLT	*Perception disturbances*		*Hallucination, gustatory*	10019071
To HLT	*Hallucinations (excl sleep-related)*		From HLT	
			Perception disturbances	
			To HLT	
			Hallucinations (excl sleep-related)	10082212

MSSO Comment: The proposal to move the PT Hallucination, gustatory from HLT Perception disturbances to HLT Hallucinations (excl sleep-related) is approved as requested. These changes were recommended by the CIOMS SMQ Implementation Working Group to facilitate the retrieval of potential cases of hallucinations in lieu of a dedicated SMQ for hallucinations. The existing HLT Perception disturbances currently groups hallucination terms together with other disturbances in perception such as PT Deja vu and PT Time perception altered. These changes will group the specific terms for hallucinations together while separating out the other miscellaneous perception disturbances. Sleep-related hallucination concepts are not included in new HLT Hallucinations (excl sleep-related); PT Hypnagogic hallucination and PT Hypnopompic hallucination remain in HLT Narcolepsy and associated conditions.

Supplemental Update Report

CR Number: **2018260009** **Implementation Date:** 10-Oct-18 Related CR: 2018260009

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hallucination, olfactory*	Approved as Requested	Proposed PT	
From HLT	*Perception disturbances*		*Hallucination, olfactory*	10019072
To HLT	*Hallucinations (excl sleep-related)*		From HLT	
			Perception disturbances	
			To HLT	
			Hallucinations (excl sleep-related)	10082212

MSSO Comment: The proposal to move the PT Hallucination, olfactory from HLT Perception disturbances to HLT Hallucinations (excl sleep-related) is approved as requested. These changes were recommended by the CIOMS SMQ Implementation Working Group to facilitate the retrieval of potential cases of hallucinations in lieu of a dedicated SMQ for hallucinations. The existing HLT Perception disturbances currently groups hallucination terms together with other disturbances in perception such as PT Deja vu and PT Time perception altered. These changes will group the specific terms for hallucinations together while separating out the other miscellaneous perception disturbances. Sleep-related hallucination concepts are not included in new HLT Hallucinations (excl sleep-related); PT Hypnagogic hallucination and PT Hypnopompic hallucination remain in HLT Narcolepsy and associated conditions.

CR Number: **2018260010** **Implementation Date:** 10-Oct-18 Related CR: 2018260010

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hallucination, synaesthetic*	Approved as Requested	Proposed PT	
From HLT	*Perception disturbances*		*Hallucination, synaesthetic*	10062824
To HLT	*Hallucinations (excl sleep-related)*		From HLT	
			Perception disturbances	
			To HLT	
			Hallucinations (excl sleep-related)	10082212

MSSO Comment: The proposal to move the PT Hallucination, synaesthetic from HLT Perception disturbances to HLT Hallucinations (excl sleep-related) is approved as requested. These changes were recommended by the CIOMS SMQ Implementation Working Group to facilitate the retrieval of potential cases of hallucinations in lieu of a dedicated SMQ for hallucinations. The existing HLT Perception disturbances currently groups hallucination terms together with other disturbances in perception such as PT Deja vu and PT Time perception altered. These changes will group the specific terms for hallucinations together while separating out the other miscellaneous perception disturbances. Sleep-related hallucination concepts are not included in new HLT Hallucinations (excl sleep-related); PT Hypnagogic hallucination and PT Hypnopompic hallucination remain in HLT Narcolepsy and associated conditions.

Supplemental Update Report

CR Number: **2018260011** **Implementation Date:** 10-Oct-18 Related CR: 2018260011

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hallucination, tactile*	Approved as Requested	Proposed PT	
From HLT	*Perception disturbances*		*Hallucination, tactile*	10019074
To HLT	*Hallucinations (excl sleep-related)*		From HLT	
			Perception disturbances	
			To HLT	
			Hallucinations (excl sleep-related)	10082212

MSSO Comment: The proposal to move the PT Hallucination, tactile from HLT Perception disturbances to HLT Hallucinations (excl sleep-related) is approved as requested. These changes were recommended by the CIOMS SMQ Implementation Working Group to facilitate the retrieval of potential cases of hallucinations in lieu of a dedicated SMQ for hallucinations. The existing HLT Perception disturbances currently groups hallucination terms together with other disturbances in perception such as PT Deja vu and PT Time perception altered. These changes will group the specific terms for hallucinations together while separating out the other miscellaneous perception disturbances. Sleep-related hallucination concepts are not included in new HLT Hallucinations (excl sleep-related); PT Hypnagogic hallucination and PT Hypnopompic hallucination remain in HLT Narcolepsy and associated conditions.

CR Number: **2018260012** **Implementation Date:** 10-Oct-18 Related CR: 2018260012

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hallucination, visual*	Approved as Requested	Proposed PT	
From HLT	*Perception disturbances*		*Hallucination, visual*	10019075
To HLT	*Hallucinations (excl sleep-related)*		From HLT	
			Perception disturbances	
			To HLT	
			Hallucinations (excl sleep-related)	10082212

MSSO Comment: The proposal to move the PT Hallucination, visual from HLT Perception disturbances to HLT Hallucinations (excl sleep-related) is approved as requested. These changes were recommended by the CIOMS SMQ Implementation Working Group to facilitate the retrieval of potential cases of hallucinations in lieu of a dedicated SMQ for hallucinations. The existing HLT Perception disturbances currently groups hallucination terms together with other disturbances in perception such as PT Deja vu and PT Time perception altered. These changes will group the specific terms for hallucinations together while separating out the other miscellaneous perception disturbances. Sleep-related hallucination concepts are not included in new HLT Hallucinations (excl sleep-related); PT Hypnagogic hallucination and PT Hypnopompic hallucination remain in HLT Narcolepsy and associated conditions.

Supplemental Update Report

CR Number: 2018260013 **Implementation Date:** 10-Oct-18 Related CR: 2018260013

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hallucinations, mixed*	Approved as Requested	Proposed PT	
From HLT	*Perception disturbances*		*Hallucinations, mixed*	10019079
To HLT	*Hallucinations (excl sleep-related)*		From HLT	
			Perception disturbances	
			To HLT	
			Hallucinations (excl sleep-related)	10082212

MSSO Comment: The proposal to move the PT Hallucinations, mixed from HLT Perception disturbances to HLT Hallucinations (excl sleep-related) is approved as requested. These changes were recommended by the CIOMS SMQ Implementation Working Group to facilitate the retrieval of potential cases of hallucinations in lieu of a dedicated SMQ for hallucinations. The existing HLT Perception disturbances currently groups hallucination terms together with other disturbances in perception such as PT Deja vu and PT Time perception altered. These changes will group the specific terms for hallucinations together while separating out the other miscellaneous perception disturbances. Sleep-related hallucination concepts are not included in new HLT Hallucinations (excl sleep-related); PT Hypnagogic hallucination and PT Hypnopompic hallucination remain in HLT Narcolepsy and associated conditions.

CR Number: 2018260014 **Implementation Date:** 10-Oct-18 Related CR: 2018260014

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Formication*	Approved as Requested	Proposed PT	
From HLT	*Perception disturbances*		*Formication*	10017062
To HLT	*Hallucinations (excl sleep-related)*		From HLT	
			Perception disturbances	
			To HLT	
			Hallucinations (excl sleep-related)	10082212

MSSO Comment: The proposal to move the PT Formication from HLT Perception disturbances to HLT Hallucinations (excl sleep-related) is approved as requested. These changes were recommended by the CIOMS SMQ Implementation Working Group to facilitate the retrieval of potential cases of hallucinations in lieu of a dedicated SMQ for hallucinations. The existing HLT Perception disturbances currently groups hallucination terms together with other disturbances in perception such as PT Deja vu and PT Time perception altered. These changes will group the specific terms for hallucinations together while separating out the other miscellaneous perception disturbances. Sleep-related hallucination concepts are not included in new HLT Hallucinations (excl sleep-related); PT Hypnagogic hallucination and PT Hypnopompic hallucination remain in HLT Narcolepsy and associated conditions.

Supplemental Update Report

CR Number: 2018260015 **Implementation Date:** 10-Oct-18 Related CR: 2018260015

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Paroxysmal perceptual alteration*	Approved as Requested	Proposed PT	
From HLT	*Perception disturbances*		*Paroxysmal perceptual alteration*	10063117
To HLT	*Hallucinations (excl sleep-related)*		From HLT	
			Perception disturbances	
			To HLT	
			Hallucinations (excl sleep-related)	10082212

MSSO Comment: The proposal to move the PT Paroxysmal perceptual alteration from HLT Perception disturbances to HLT Hallucinations (excl sleep-related) is approved as requested. These changes were recommended by the CIOMS SMQ Implementation Working Group to facilitate the retrieval of potential cases of hallucinations in lieu of a dedicated SMQ for hallucinations. The existing HLT Perception disturbances currently groups hallucination terms together with other disturbances in perception such as PT Deja vu and PT Time perception altered. These changes will group the specific terms for hallucinations together while separating out the other miscellaneous perception disturbances. Sleep-related hallucination concepts are not included in new HLT Hallucinations (excl sleep-related); PT Hypnagogic hallucination and PT Hypnopompic hallucination remain in HLT Narcolepsy and associated conditions.

CR Number: 2018260016 **Implementation Date:** 10-Oct-18 Related CR: 2018260016

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Somatic hallucination*	Approved as Requested	Proposed PT	
From HLT	*Perception disturbances*		*Somatic hallucination*	10062684
To HLT	*Hallucinations (excl sleep-related)*		From HLT	
			Perception disturbances	
			To HLT	
			Hallucinations (excl sleep-related)	10082212

MSSO Comment: The proposal to move the PT Somatic hallucination from HLT Perception disturbances to HLT Hallucinations (excl sleep-related) is approved as requested. These changes were recommended by the CIOMS SMQ Implementation Working Group to facilitate the retrieval of potential cases of hallucinations in lieu of a dedicated SMQ for hallucinations. The existing HLT Perception disturbances currently groups hallucination terms together with other disturbances in perception such as PT Deja vu and PT Time perception altered. These changes will group the specific terms for hallucinations together while separating out the other miscellaneous perception disturbances. Sleep-related hallucination concepts are not included in new HLT Hallucinations (excl sleep-related); PT Hypnagogic hallucination and PT Hypnopompic hallucination remain in HLT Narcolepsy and associated conditions.

Supplemental Update Report

CR Number: 2018260017 **Implementation Date:** 10-Oct-18 Related CR: 2018260017

Change Requested	Add a New HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed HLT	*Perception disturbances NEC*	Approved as Requested	Proposed HLT	
To HLGT	*Disturbances in thinking and perception*		*Perception disturbances NEC*	10082213
			To HLGT	
			Disturbances in thinking and perception	10013511

MSSO Comment: The proposal to add a new HLT Perception disturbances NEC to HLGT Disturbances in thinking and perception is approved as requested. These changes were recommended by the CIOMS SMQ Implementation Working Group to facilitate the retrieval of potential cases of hallucinations in lieu of a dedicated SMQ for hallucinations. The existing HLT Perception disturbances currently groups hallucination terms together with other disturbances in perception such as PT Deja vu and PT Time perception altered. These changes will group the specific terms for hallucinations together while separating out the other miscellaneous perception disturbances. Sleep-related hallucination concepts are not included in new HLT Hallucinations (excl sleep-related); PT Hypnagogic hallucination and PT Hypnopompic hallucination remain in HLT Narcolepsy and associated conditions.

CR Number: 2018260018 **Implementation Date:** 10-Oct-18 Related CR: 2018260018

Change Requested	Merge HLT	Final Disposition	Final Placement	MedDRA Code #
HLT to merge	*Perception disturbances*	Approved as Requested	HLT to merge	
To HLT	*Perception disturbances NEC*		*Perception disturbances*	
			To HLT	
			Perception disturbances NEC	10082213

MSSO Comment: The proposal to merge HLT Perception disturbances to HLT Perception disturbances NEC is approved as requested. These changes were recommended by the CIOMS SMQ Implementation Working Group to facilitate the retrieval of potential cases of hallucinations in lieu of a dedicated SMQ for hallucinations. The existing HLT Perception disturbances currently groups hallucination terms together with other disturbances in perception such as PT Deja vu and PT Time perception altered. These changes will group the specific terms for hallucinations together while separating out the other miscellaneous perception disturbances. Sleep-related hallucination concepts are not included in new HLT Hallucinations (excl sleep-related); PT Hypnagogic hallucination and PT Hypnopompic hallucination remain in HLT Narcolepsy and associated conditions.

Supplemental Update Report

CR Number: 2018260019 **Implementation Date:** 25-Sep-18 Related CR: 2018260019

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Brain cyst haemorrhage*	Approved Not as Requested	Proposed PT	
			Cerebral cyst haemorrhage	10082099
			HLT primary	
			Nervous system cysts and polyps	10068205
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Nervous system haemorrhagic disorders	10008206
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new PT Brain cyst haemorrhage is approved but not as requested. Intracranial cysts, for example congenital arachnoid cysts, may become haemorrhagic, either spontaneously, or following trauma. Brain cyst haemorrhage will be modified consistent with similar concepts and added as a PT Cerebral cyst haemorrhage to primary HLT Nervous system cysts and polyps (bi-axial at the HLGT level to primary SOC Nervous system disorders and secondary SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps)), and to secondary HLT Nervous system haemorrhagic disorders. In addition American English spelling LLT Cerebral cyst hemorrhage will be added to PT Cerebral cyst haemorrhage.

CR Number: 2018267017 **Implementation Date:** 25-Sep-18 Related CR: 2018260019

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cerebral cyst hemorrhage*	Approved as Requested	Proposed LLT	
To PT	*Cerebral cyst haemorrhage*		*Cerebral cyst hemorrhage*	10082105 Current
			To PT	
			Cerebral cyst haemorrhage	10082099

MSSO Comment:

CR Number: 2018260020 **Implementation Date:** 25-Sep-18 Related CR: 2018260020

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Benign prostate syndrome*	Rejected		

MSSO Comment: The proposal to add a new term Benign prostate syndrome is not approved. Benign prostate syndrome is not internationally accepted coined expression and can be represented by split coding with LLT Benign prostatic hyperplasia plus LLT Lower urinary tract symptoms or more specific symptoms such as weak urinary stream, frequent urination, nocturia, acute urge to urinate or acute urinary retention.

Supplemental Update Report

CR Number: 2018260021 **Implementation Date:** 25-Sep-18 Related CR: 2018260021

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Metallic smell*	Approved as Requested	Proposed LLT	
To PT	*Parosmia*		*Metallic smell*	10082103 Current
			To PT	
			Parosmia	10034018

MSSO Comment: The proposal to add a new LLT Metallic smell to PT Parosmia is approved as requested. Metallic smell is one of the possible manifestations of Parosmia, which is defined as an olfactory dysfunction characterized by the inability of the brain to properly identify an odor's "natural" smell.

CR Number: 2018260022 **Implementation Date:** 25-Sep-18 Related CR: 2018260022

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Autoimmune gastritis*	Approved as Requested	Proposed LLT	
			Autoimmune gastritis	10082104 Current
			To PT	
			Chronic gastritis	10008882

MSSO Comment: The proposal to add a new LLT Autoimmune gastritis is approved as requested. Autoimmune gastritis is a chronic inflammatory disease of the stomach, resulting in atrophy of the mucosa. It is a specific type of chronic gastritis in that it is an autoimmune reaction which targets parietal cells of the corpus and fundus of the stomach. Autoimmune gastritis will be added as an LLT to PT Chronic gastritis.

CR Number: 2018260023 **Implementation Date:** 25-Sep-18 Related CR: 2018260023

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gastric electrical stimulation implant*	Approved Not as Requested	Proposed PT	
			Gastric electrical stimulation	10082102
			HLT primary	
			Gastric therapeutic procedures	10017813
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT Gastric electrical stimulation implant is approved but not as requested. Gastric electrical stimulation uses a device implanted in the abdomen to send mild electrical pulses to the nerves and smooth muscle of the lower stomach. This helps decrease nausea and vomiting in some patients with gastroparesis. The proposed term, Gastric electrical stimulation implant, will be expressed as Gastric electrical stimulation, the more commonly used term in the medical literature, and will be added as a new PT to HLT Gastric therapeutic procedures.

Supplemental Update Report

CR Number: 2018260024 **Implementation Date:** 25-Sep-18 Related CR: 2018260024

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Oligoarthritis*	Approved as Requested	Proposed PT	
			Oligoarthritis	10082100
			HLT primary	
			Arthropathies NEC	10003284
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new PT Oligoarthritis is approved as requested. Oligoarthritis, is defined as arthritis affecting a small number of joints, often stated as fewer than five joints. The joints most commonly affected are the knee, ankle, and wrist. Oligoarthritis will be added as a PT to HLT Arthropathies NEC.

CR Number: 2018260025 **Implementation Date:** 25-Sep-18 Related CR: 2018260025

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hematoma muscle*	Approved Not as Requested	Proposed LLT	
From PT	*Muscle haemorrhage*		*Haematoma muscle*	10055890
			From PT	
			Muscle haemorrhage	10028309
			HLT primary	
			Muscle related signs and symptoms NEC	10028326
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395
			HLT secondary	
			Muscle, tendon and ligament injuries	10028288
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to promote the LLT Hematoma muscle from PT Muscle haemorrhage is approved but not as requested. In MedDRA, site specific haematoma concepts are normally represented at the PT level. Accordingly, LLT Haematoma muscle will be promoted from PT Muscle haemorrhage to primary HLT Muscle related signs and symptoms NEC, to secondary HLT Muscle, tendon and ligament injuries, and to secondary HLT Haemorrhages NEC. In a related change, LLT Hematoma muscle will be moved from PT Muscle haemorrhage to PT Haematoma muscle.

Supplemental Update Report

CR Number: 2018267015 **Implementation Date:** 25-Sep-18 Related CR: 2018260025

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hematoma muscle*	Approved as Requested	Proposed LLT	
From PT	*Muscle haemorrhage*		*Hematoma muscle*	10019433 Current
To PT	*Haematoma muscle*		From PT	
			Muscle haemorrhage	10028309
			To PT	
			Haematoma muscle	10055890

MSSO Comment:

CR Number: 2018267018 **Implementation Date:** 25-Sep-18 Related CR: 2018260025

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Haematoma muscle*	Approved as Requested	Proposed PT	
To HLT	*Haemorrhages NEC*		*Haematoma muscle*	10055890
			To HLT	
			Haemorrhages NEC	10018987

MSSO Comment:

CR Number: 2018260026 **Implementation Date:** 25-Sep-18 Related CR: 2018260026

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Pleural mass*	Approved as Requested	Proposed PT	
			Pleural mass	10082101
			HLT primary	
			Musculoskeletal and connective tissue conditions NEC	10080711
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new term Pleural mass is approved as requested. Pleural mass is often used to describe a diagnostic image finding of potential clinical significance. Pleural mass will be added as a PT to HLT Musculoskeletal and connective tissue conditions NEC.

Supplemental Update Report

CR Number: 2018260027 **Implementation Date:** 25-Sep-18 Related CR: 2018260027

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Chronic polyarthritis*	Rejected		
Status	*non-current*			

MSSO Comment: The proposal to change status of LLT Chronic polyarthritis to non-current is not approved. Chronic arthritis represents a descriptive clinical term, which does not have diagnostic implications such as referring to rheumatoid arthritis or osteoarthritis and is best placed as a sub-concept LLT under PT Polyarthritis aligned with LLT Acute polyarthritis.

CR Number: 2018260028 **Implementation Date:** 19-Oct-18 Related CR: 2018260028

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Non-inflammatory chronic polyarthritis*	Rejected After Suspension		

MSSO Comment: The proposal to add a new term Non-inflammatory chronic polyarthritis is not approved after suspension. The broadest classification of chronic polyarthritis is non-inflammatory vs inflammatory arthritis. The prototype non-inflammatory polyarthritis is osteoarthritis whereas the prototype inflammatory polyarthritis is rheumatoid arthritis. Adding the requested LLT Non-inflammatory chronic polyarthritis would cause confusion as most often used as synonym for osteoarthitis but not exclusively.

CR Number: 2018260029 **Implementation Date:** 19-Oct-18 Related CR: 2018260029

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Inflammatory chronic polyarthritis*	Rejected After Suspension		

MSSO Comment: The proposal to add a new term Inflammatory chronic polyarthritis is not approved after suspension. MedDRA cannot accomodate this double qualified LLT. The broadest classification of chronic polyarthritis is non-inflammatory vs inflammatory arthritis and the prototype inflammatory polyarthritis is rheumatoid arthritis but not exclusively so that the requested term as LLT under PT Polyarthritis or PT Rheumatoid arthritis could cause conflicts.

Supplemental Update Report

CR Number: 2018260030 **Implementation Date:** 25-Sep-18 Related CR: 2018260030

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Candida foot infection*	Rejected		

MSSO Comment: The proposal to add a new term Candida foot infection is not approved. MedDRA cannot accommodate a unique term for a candida infection of every potential anatomical location. The requested term may be represented by split coding with more than one LLT, for example, LLT Fungal foot infection and LLT Candida infection or LLT Skin candida.

CR Number: 2018261001 **Implementation Date:** 25-Sep-18 Related CR: 2018261001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Human anti-hamster antibody test*	Approved as Requested	Proposed PT	
			Human anti-hamster antibody test	10082106
HLT primary	*Immunology analyses NEC*		HLT primary	
			Immunology analyses NEC	10021504
SOC primary	*Investigations*		SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Human anti-hamster antibody test to primary HLT Immunology analyses NEC in SOC Investigations is approved as requested. A number of biologics are produced in Chinese hamster ovary cells. All these products bear the important potential risk of residual hamster protein provoking an immunological response in the patient resulting in Human anti-hamster antibody formation. Human anti-hamster antibody testing is an important test to differentiate a hamster specific reaction from reactions to the product.

CR Number: 2018261002 **Implementation Date:** 25-Sep-18 Related CR: 2018261002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Human anti-hamster antibody positive*	Approved as Requested	Proposed PT	
			Human anti-hamster antibody positive	10082109
HLT primary	*Immunology analyses NEC*		HLT primary	
			Immunology analyses NEC	10021504
SOC primary	*Investigations*		SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Human anti-hamster antibody positive to primary HLT Immunology analyses NEC in SOC Investigations is approved as requested. A number of biologics are produced in Chinese hamster ovary cells. All these products bear the important potential risk of residual hamster protein provoking an immunological response in the patient resulting in Human anti-hamster antibody formation. Human anti-hamster antibody testing is an important test to differentiate a hamster specific reaction from reactions to the product.

Supplemental Update Report

CR Number: 2018261003 **Implementation Date:** 25-Sep-18 Related CR: 2018261003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Human anti-hamster antibody increased*	Approved as Requested	Proposed PT	
HLT primary	*Immunology analyses NEC*		*Human anti-hamster antibody increased*	10082107
SOC primary	*Investigations*		HLT primary	
			Immunology analyses NEC	10021504
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Human anti-hamster antibody increased to primary HLT Immunology analyses NEC in SOC Investigations is approved as requested. A number of biologics are produced in Chinese hamster ovary cells. All these products bear the important potential risk of residual hamster protein provoking an immunological response in the patient resulting in Human anti-hamster antibody formation. Human anti-hamster antibody testing is an important test to differentiate a hamster specific reaction from reactions to the product.

CR Number: 2018261004 **Implementation Date:** 25-Sep-18 Related CR: 2018261004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Human anti-hamster antibody negative*	Approved as Requested	Proposed PT	
HLT primary	*Immunology analyses NEC*		*Human anti-hamster antibody negative*	10082108
SOC primary	*Investigations*		HLT primary	
			Immunology analyses NEC	10021504
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Human anti-hamster antibody negative to primary HLT Immunology analyses NEC in SOC Investigations is approved as requested. A number of biologics are produced in Chinese hamster ovary cells. All these products bear the important potential risk of residual hamster protein provoking an immunological response in the patient resulting in Human anti-hamster antibody formation. Human anti-hamster antibody testing is an important test to differentiate a hamster specific reaction from reactions to the product.

Supplemental Update Report

CR Number: 2018262001 **Implementation Date:** 27-Sep-18 Related CR: 2018262001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Heart rate variability increased*	Approved as Requested	Proposed PT	
			Heart rate variability increased	10082110
			HLT primary	
			Heart rate and pulse investigations	10053103
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Heart rate variability increased is approved as requested. Heart rate variability is a noninvasive, practical and reproducible measure of autonomic nervous system function. A heart rate that is variable and responsive to demands is believed to bestow a survival advantage, whereas reduced heart rate variability may be associated with poorer cardiovascular health and outcomes. Heart rate variability increased will be added as PT to HLT Heart rate and pulse investigations. In a related change, PT Heart rate variability decreased and non-qualified PT Heart rate variability test will also be added to HLT Heart rate and pulse investigations.

CR Number: 2018270004 **Implementation Date:** 27-Sep-18 Related CR: 2018262001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Heart rate variability decreased*	Approved as Requested	Proposed PT	
HLT primary	*Heart rate and pulse investigations*		*Heart rate variability decreased*	10082111
SOC primary	*Investigations*		HLT primary	
			Heart rate and pulse investigations	10053103
			SOC primary	
			Investigations	10022891

MSSO Comment:

Supplemental Update Report

CR Number: 2018270005 **Implementation Date:** 27-Sep-18 Related CR: 2018262001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Heart rate variability test*	Approved as Requested	Proposed PT	
			Heart rate variability test	10082112
HLT primary	*Heart rate and pulse investigations*		HLT primary	
			Heart rate and pulse investigations	10053103
SOC primary	*Investigations*		SOC primary	
			Investigations	10022891

MSSO Comment:

CR Number: 2018263001 **Implementation Date:** 27-Sep-18 Related CR: 2018263001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Malaria relapse*	Approved as Requested	Proposed PT	
			Malaria relapse	10082114
			HLT primary	
			Plasmodia infections	10035499
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Anaemias NEC	10002067
			SOC secondary	
			Blood and lymphatic system disorders	10005329

MSSO Comment: The proposal to add a new PT Malaria relapse is approved as requested. Both Plasmodium vivax and P. ovale have persistent liver stages (hypnozoites) which may lead to a relapse within a period of 8 or 9 years after initial infection. This is a feature of these parasites, that enables their survival during periods when mosquito vectors are absent (cold winters) and enables the transport of the parasite to new regions, establishing new foci of transmission. Malaria relapse will be added as PT with primary link to HLT Plasmodia infections and secondary link to HLT Anaemias NEC.

Supplemental Update Report

CR Number: 2018263002 **Implementation Date:** 27-Sep-18 Related CR: 2018263002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Plasmodium vivax relapse*	Approved as Requested	Proposed LLT	
To PT	*Malaria relapse*		*Plasmodium vivax relapse*	10082116 Current
			To PT	
			Malaria relapse	10082114

MSSO Comment: The proposal to add a new LLT Plasmodium vivax relapse to PT Malaria relapse is approved as requested. Plasmodium vivax has persistent liver stages (hypnozoites) which may lead to a relapse within a period of 8 or 9 years after initial infection. The intervals between relapses display a remarkable periodicity which has not been explained. Evidence is presented that the proportion of patients who have successive relapses is relatively constant and that the factor which activates hypnozoites and leads to regular interval relapse in vivax malaria is the systemic febrile illness itself. Plasmodium vivax relapse will be added as a sub-element LLT of the new PT Malaria relapse, added in change request 2018263001.

CR Number: 2018263003 **Implementation Date:** 27-Sep-18 Related CR: 2018263003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Plasmodium ovale relapse*	Approved as Requested	Proposed LLT	
To PT	*Malaria relapse*		*Plasmodium ovale relapse*	10082118 Current
			To PT	
			Malaria relapse	10082114

MSSO Comment: The proposal to add a new LLT Plasmodium ovale relapse to PT Malaria relapse is approved as requested. P. ovale has persistent liver stages (hypnozoites) which may lead to a relapse within a period of 8 or 9 years after initial infection. If, following re-activation of a latent hypnozoite in the liver, a relapse occurred, then that individual would, potentially, be able to spread the infection to mosquitoes. Plasmodium ovale relapse will be added as a sub-element LLT to PT Malaria relapse, added in change request 2018263001.

Supplemental Update Report

CR Number: 2018263004 **Implementation Date:** 27-Sep-18 Related CR: 2018263004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Malaria recrudescence*	Approved as Requested	Proposed PT	
			Malaria recrudescence	10082115
			HLT primary	
			Plasmodia infections	10035499
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Anaemias NEC	10002067
			SOC secondary	
			Blood and lymphatic system disorders	10005329

MSSO Comment: The proposal to add a new PT Malaria recrudescence is approved as requested. In the case of the persistence of drug resistant parasites, there would be no clearance of parasitaemia even though it might be reduced to sub-patent levels for a time. In this instance, recurrence would be termed "recrudescence' not "relapse'. Malaria recrudescence will be added as a PT with primary link to HLT Plasmodia infections and secondary link to HLT Anaemias NEC.

CR Number: 2018263005 **Implementation Date:** 27-Sep-18 Related CR: 2018263005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Plasmodium falciparum recrudescence*	Approved as Requested	Proposed LLT	
To PT	*Malaria recrudescence*		*Plasmodium falciparum recrudescence*	10082121 Current
			To PT	
			Malaria recrudescence	10082115

MSSO Comment: The proposal to add a new LLT Plasmodium falciparum recrudescence to PT Malaria recrudescence is approved as requested. In the case of the persistence of drug resistant Plasmodium falciparum parasites, there would be no clearance of parasitaemia even though it might be reduced to sub-patent levels for a time. This would be the same case but, in this instance, recurrence would be termed "recrudescence' not "relapse'. Plasmodium falciparum recrudescence will be added as a sub-element LLT to PT Malaria recrudescence, added in change request 2018263004.

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CR Number: 2018263006 **Implementation Date:** 27-Sep-18 Related CR: 2018263006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Plasmodium malariae recrudescence*	Approved as Requested	Proposed LLT	
To PT	*Malaria recrudescence*		*Plasmodium malariae recrudescence*	10082122 Current
			To PT	
			Malaria recrudescence	10082115

MSSO Comment: The proposal to add a new LLT Plasmodium malariae recrudescence to PT Malaria recrudescence is approved as requested. In the case of the persistence of drug resistant Plasmodium malariae parasites, there would be no clearance of parasitaemia even though it might be reduced to sub-patent levels for a time. This would be the same case but, in this instance, recurrence would be termed "recrudescence' not "relapse'. Plasmodium malariae recrudescence will be added as sub-element LLT to PT Malaria recrudescence, added in change request 2018263004.

CR Number: 2018263007 **Implementation Date:** 27-Sep-18 Related CR: 2018263007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Plasmodium knowlesi recrudescence*	Approved as Requested	Proposed LLT	
To PT	*Malaria recrudescence*		*Plasmodium knowlesi recrudescence*	10082120 Current
			To PT	
			Malaria recrudescence	10082115

MSSO Comment: The proposal to add a new LLT Plasmodium knowlesi recrudescence to PT Malaria recrudescence is approved as requested. In the case of the persistence of drug resistant Plasmodium knowlesi parasites, there would be no clearance of parasitaemia even though it might be reduced to sub-patent levels for a time. This would be the same case but, in this instance, recurrence would be termed "recrudescence' not "relapse'. Plasmodium knowlesi recrudescence will be added as sub-element LLT to PT Malaria recrudescence, added in change request 2018263004.

CR Number: 2018263008 **Implementation Date:** 27-Sep-18 Related CR: 2018263008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Plasmodium vivax recrudescence*	Approved as Requested	Proposed LLT	
To PT	*Malaria recrudescence*		*Plasmodium vivax recrudescence*	10082119 Current
			To PT	
			Malaria recrudescence	10082115

MSSO Comment: The proposal to add a new LLT Plasmodium vivax recrudescence to PT Malaria recrudescence is approved as requested. In the case of the persistence of drug resistant parasites, there would be no clearance of parasitaemia even though it might be reduced to sub-patent levels for a time. This would be the same case but, in this instance, recurrence would be termed "recrudescence' not "relapse'. The period of 8 weeks used to exclude recrudescence as the cause of recurrences of chloroquine resistant P. vivax is somewhat arbitrary, but it does extend beyond the period during which there would be sufficient drug present to suppress the resistant parasites below patency. Plasmodium vivax recrudescence will be added as an LLT to PT Malaria recrudescence, added in change request 2018263004.

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CR Number: 2018263009 **Implementation Date:** 27-Sep-18 Related CR: 2018263009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Plasmodium ovale recrudescence*	Approved as Requested	Proposed LLT	
To PT	*Malaria recrudescence*		*Plasmodium ovale recrudescence*	10082117 Current
			To PT	
			Malaria recrudescence	10082115

MSSO Comment: The proposal to add a new LLT Plasmodium ovale recrudescence to PT Malaria recrudescence is approved as requested. In the case of the persistence of drug resistant parasites, there would be no clearance of parasitaemia even though it might be reduced to sub-patent levels for a time. This would be the same case but, in this instance, recurrence would be termed "recrudescence' not "relapse'. The period used to exclude recrudescence as the cause of recurrences of chloroquine resistant P. Ovale is somewhat arbitrary, but it does extend beyond the period during which there would be sufficient drug present to suppress the resistant parasites below patency. Plasmodium ovale recrudescence will be added as an LLT to PT Malaria recrudescence, added in change request 2018263004.

CR Number: 2018263010 **Implementation Date:** 27-Sep-18 Related CR: 2018263010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Acquired Blaschkoid dermatitis*	Approved Not as Requested	Proposed PT	
			Acquired blaschkoid dermatitis	10082113
			HLT primary	
			Dermatitis and eczema	10012435
			SOC primary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment: The proposal to add a new term Acquired Blaschkoid dermatitis is approved but not as requested. Acquired blaschkoid dermatitis is a rare skin condition of unknown cause. This condition is an inflammatory skin condition resembling dermatitis or eczema and presents with dry, red irritable skin lesions. Typical lesions are following lines generally longitudinally oriented on the limbs and circumferential on the trunk, which resolve spontaneously but that have a tendency to relapse over time, especially at times of stress. Some authors consider it may represent the adult form of lichen striatus. The term will be modified in accordance with MedDRA capitalization rules and added as PT Acquired blaschkoid dermatitis to HLT Dermatitis and eczema.

CR Number: 2018263011 **Implementation Date:** 27-Sep-18 Related CR: 2018263011

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Herpes simplex labialis*	Approved as Requested	Proposed LLT	
To PT	*Oral herpes*		*Herpes simplex labialis*	10082141 Current
			To PT	
			Oral herpes	10067152

MSSO Comment: The proposal to add a new LLT Herpes simplex labialis to PT Oral herpes is approved as requested. Nongenital herpes simplex virus type 1 is a common infection usually transmitted during childhood via nonsexual contact. Most of these infections involve the oral mucosa or lips, known synonymously as herpes labialis, herpes simplex labialis, or oral herpes.

Supplemental Update Report

CR Number: 2018263012 **Implementation Date:** 27-Sep-18 Related CR: 2018263012

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Adrenal gland insufficiency*	Approved as Requested	Proposed LLT	
To PT	*Adrenal insufficiency*		*Adrenal gland insufficiency*	10082130 Current
			To PT	
			Adrenal insufficiency	10001367

MSSO Comment: The proposal to add a new LLT Adrenal gland insufficiency to PT Adrenal insufficiency is approved as requested. LLT Adrenal gland insufficiency is a sub-element of PT Adrenal insufficiency.

CR Number: 2018263013 **Implementation Date:** 27-Sep-18 Related CR: 2018263013

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Lung embolism*	Approved as Requested	Proposed LLT	
To PT	*Pulmonary embolism*		*Lung embolism*	10082134 Current
			To PT	
			Pulmonary embolism	10037377

MSSO Comment: The proposal to add a new LLT Lung embolism to PT Pulmonary embolism is approved as requested. Lung embolism will be added as a LLT to PT Pulmonary embolism which are synonymous, and to help facilitate auto encoding despite the fact that LLT Embolism lung is already present.

CR Number: 2018263014 **Implementation Date:** 27-Sep-18 Related CR: 2018263014

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Tumor resection*	Approved Not as Requested	Proposed LLT	
HLT primary	*Therapeutic procedures NEC*		*Tumor resection*	10082131 Current
SOC primary	*Surgical and medical procedures*		To PT	
			Tumour excision	10061392

MSSO Comment: The proposal to add a new PT Tumor resection to primary HLT Therapeutic procedures NEC in SOC Surgical and medical procedures is approved but not as requested. Tumor resection is the surgical removal of all or part of a tumor. The tumor, along with a margin of normal tissue around it, is removed when possible. Tumor resection will be added as a sub-concept LLT to PT Tumour excision. In a related change, the British English spelling of the term will also be added as LLT Tumour resection to PT Tumour excision.

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CR Number: 2018270008 **Implementation Date:** 27-Sep-18 Related CR: 2018263014

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Tumour resection*	Approved as Requested	Proposed LLT	
To PT	*Tumour excision*		*Tumour resection*	10082145 Current
			To PT	
			Tumour excision	10061392

MSSO Comment:

CR Number: 2018263015 **Implementation Date:** 27-Sep-18 Related CR: 2018263015

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Port insertion*	Approved as Requested	Proposed LLT	
To PT	*Central venous catheterisation*		*Port insertion*	10082138 Current
			To PT	
			Central venous catheterisation	10053377

MSSO Comment: The proposal to add a new LLT Port insertion to PT Central venous catheterisation is approved as requested. An implanted port is a device that is surgically inserted and positioned under the skin to provide intravenous access for chemotherapy, medications, and transfusions. It consists of a small reservoir and a catheter that provides access to larger veins.

CR Number: 2018263016 **Implementation Date:** 27-Sep-18 Related CR: 2018263016

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Port removal*	Approved as Requested	Proposed LLT	
To PT	*Central venous catheter removal*		*Port removal*	10082139 Current
			To PT	
			Central venous catheter removal	10067098

MSSO Comment: The proposal to add a new LLT Port removal to PT Central venous catheter removal is approved as requested. An implanted port is a device that is surgically inserted and positioned under the skin to provide intravenous access for chemotherapy, medications, and transfusions. It is made up of a small reservoir and a catheter that provides access to larger veins.

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CR Number: 2018263017 **Implementation Date:** 27-Sep-18 Related CR: 2018263017

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Groin hernia*	Approved as Requested	Proposed LLT	
To PT	*Inguinal hernia*		*Groin hernia*	10082132 Current
			To PT	
			Inguinal hernia	10022016

MSSO Comment: The proposal to add a new LLT Groin hernia to PT Inguinal hernia is approved as requested. An inguinal hernia, a herniation of a loop of intestine into the inguinal canal, is also commonly known as a groin hernia.

CR Number: 2018263018 **Implementation Date:** 27-Sep-18 Related CR: 2018263018

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Swollen cheek*	Rejected		
To PT	*Swelling face*			

MSSO Comment: The proposal to add a new LLT Swollen cheek to PT Swelling face is not approved. The proposed concept can be represented by LLT Cheek swelling.

CR Number: 2018263019 **Implementation Date:** 27-Sep-18 Related CR: 2018263019

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Thick cheek*	Rejected		
To PT	*Swelling face*			

MSSO Comment: The proposal to add a new LLT Thick cheek to PT Swelling face is not approved. The proposed concept is vague. Although "thick or thickened" in the context of an anatomical structure or region is sometimes used in a similar manner as "swollen or swelling," the terms are not always used in a synonymous manner. Thick often relates to a tissue which is increased in density or indurated, whereas swelling frequently relates to edema or engorgement of a tissue.

Supplemental Update Report

CR Number: 2018263020 **Implementation Date:** 27-Sep-18 Related CR: 2018263020

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Necrosectomy*	Approved as Requested	Proposed LLT	
			Necrosectomy	10082137 Current
			To PT	
			Debridement	10067806

MSSO Comment: The proposal to add a new LLT Necrosectomy is approved as requested. Necrosectomy, the surgical excision of necrotic tissue, is essentially a synonym of debridement, and will thus be added as a synonym LLT to PT Debridement.

CR Number: 2018263021 **Implementation Date:** 27-Sep-18 Related CR: 2018263021

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Intestinal miscolonization*	Approved as Requested	Proposed LLT	
			Intestinal miscolonization	10082140 Current
			To PT	
			Dysbiosis	10082129

MSSO Comment: The proposal to add a new LLT Intestinal miscolonization is approved as requested. To encompass all microflora, the LLT Intestinal miscolonization will be added to a new PT Dysbiosis which is defined as imbalance in your gut flora caused by too few beneficial bacteria and an overgrowth of bad bacteria, yeast, and/or parasites. In a related change, PT Dysbiosis will be added to primary HLT Gastrointestinal disorders NEC and secondary HLT Non-site specific procedural complications. Furthermore, the British English spelled LLT Intestinal miscolonisation will be added to PT Dysbiosis. Additionally, PT Dysbacteriosis will be merged under the broader PT Dysbiosis.

Supplemental Update Report

CR Number: 2018270009 **Implementation Date:** 27-Sep-18 Related CR: 2018263021

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Dysbiosis*	Approved as Requested	Proposed PT	
HLT primary	*Gastrointestinal disorders NEC*		*Dysbiosis*	10082129
SOC primary	*Gastrointestinal disorders*		HLT primary	
			Gastrointestinal disorders NEC	10017948
			SOC primary	
			Gastrointestinal disorders	10017947
			HLT secondary	
			Non-site specific procedural complications	10029559
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment:

CR Number: 2018270010 **Implementation Date:** 27-Sep-18 Related CR: 2018263021

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Intestinal miscolonisation*	Approved as Requested	Proposed LLT	
To PT	*Dysbiosis*		*Intestinal miscolonisation*	10082147 Current
			To PT	
			Dysbiosis	10082129

MSSO Comment:

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CR Number: 2018270011 **Implementation Date:** 27-Sep-18 Related CR: 2018263021

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Dysbacteriosis*	Approved as Requested	PT to merge	
To PT	*Dysbiosis*		*Dysbacteriosis*	10064389 Current
			To PT	
			Dysbiosis	10082129

MSSO Comment:

CR Number: 2018263022 **Implementation Date:** 27-Sep-18 Related CR: 2018263022

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Miscolonization of small intestine*	Approved as Requested	Proposed LLT	
			Miscolonization of small intestine	10082133 Current
			To PT	
			Dysbiosis	10082129

MSSO Comment: The proposal to add a new LLT Miscolonization of small intestine is approved as requested. Miscolonization of small intestine will be added a sub-concept LLT to new PT Dysbiosis added in change request 2018263021. In a related change, the British spelled counterpart LLT Miscolonisation of small intestine will be added to PT Dysbiosis.

CR Number: 2018270012 **Implementation Date:** 27-Sep-18 Related CR: 2018263022

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Miscolonisation of small intestine*	Approved as Requested	Proposed LLT	
To PT	*Dysbiosis*		*Miscolonisation of small intestine*	10082148 Current
			To PT	
			Dysbiosis	10082129

MSSO Comment:

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CR Number: 2018263023 **Implementation Date:** 27-Sep-18 Related CR: 2018263023

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Colonic miscolonization*	Approved as Requested	Proposed LLT *Colonic miscolonization* To PT *Dysbiosis*	10082142 Current 10082129

MSSO Comment: The proposal to add a new LLT Colonic miscolonization is approved as requested. Colonic miscolonization will be added as an sub-concept LLT to PT Dysbiosis, added in change request 2018263021. In a related change, the British English spelled counterpart LLT Colonic miscolonisation will be added to PT Dysbiosis.

CR Number: 2018270013 **Implementation Date:** 27-Sep-18 Related CR: 2018263023

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Colonic miscolonisation*	Approved as Requested	Proposed LLT *Colonic miscolonisation* To PT *Dysbiosis*	10082146 Current 10082129
To PT	*Dysbiosis*			

MSSO Comment:

CR Number: 2018263024 **Implementation Date:** 27-Sep-18 Related CR: 2018263024

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Polyneuropathy limb*	Rejected		
To PT	*Polyneuropathy*			

MSSO Comment: The proposal to add a new LLT Polyneuropathy limb to PT Polyneuropathy is not approved. Polyneuropathy is defined as a neuropathy of several peripheral nerves simultaneously, usually involving limbs, called also multiple or peripheral neuropathy. Please consider also LLT Peripheral neuropathy for your coding needs.

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CR Number: 2018263025 **Implementation Date:** 27-Sep-18 Related CR: 2018263025

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Oral dysbiosis*	Approved as Requested	Proposed LLT *Oral dysbiosis*	10082143 Current
			To PT *Dysbiosis*	10082129

MSSO Comment: The proposal to add a new LLT Oral dysbiosis is approved as requested. Oral dysbiosis will be added as a sub-concept LLT to PT Dysbiosis, added in change request 2018263021.

CR Number: 2018263026 **Implementation Date:** 27-Sep-18 Related CR: 2018263026

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Intestinal dysbiosis*	Approved as Requested	Proposed LLT *Intestinal dysbiosis*	10082144 Current
			To PT *Dysbiosis*	10082129

MSSO Comment: The proposal to add a new LLT Intestinal dysbiosis is approved as requested. Intestinal dysbiosis will be added as a sub-concept LLT to PT Dysbiosis, added in change request 2018263021.

CR Number: 2018263027 **Implementation Date:** 27-Sep-18 Related CR: 2018263027

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Allergy to antibiotic*	Rejected		
To PT	*Drug hypersensitivity*			

MSSO Comment: The proposal to add a new LLT Allergy to antibiotic to PT Drug hypersensitivity is not approved. The proposed concept can be represented by LLT Allergic reaction to antibiotics.

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CR Number: 2018263028 **Implementation Date:** 27-Sep-18 Related CR: 2018263028

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Allergic reaction to drug*	Approved Not as Requested	Proposed LLT	
HLT primary	*Allergies to foods, food additives, drugs and other chemicals*		*Allergic reaction to drug*	10082135 Current
SOC primary	*Immune system disorders*		To PT	
			Drug hypersensitivity	10013700

MSSO Comment: The proposal to add a new PT Allergic reaction to drug to primary HLT Allergies to foods, food additives, drugs and other chemicals in SOC Immune system disorders is approved but not as requested. Allergic reaction to drug will be added as a sub-concept LLT to PT Drug hypersensitivity.

CR Number: 2018263029 **Implementation Date:** 27-Sep-18 Related CR: 2018263029

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Intestinal mucositis*	Approved as Requested	Proposed LLT	
To PT	*Gastrointestinal inflammation*		*Intestinal mucositis*	10082136 Current
			To PT	
			Gastrointestinal inflammation	10064147

MSSO Comment: The proposal to add a new LLT Intestinal mucositis to PT Gastrointestinal inflammation is approved as requested. The concept of mucositis is represented with anatomic specificity under multiple existing MedDRA PTs under the HLGT Gastrointestinal inflammatory conditions, including LLT Small intestine mucositis and LLT Large intestine mucositis. In a related change, LLT Large intestinal mucositis will be moved from PT Gastrointestinal inflammation to PT Colitis for consistency with the placement of LLT Small intestinal mucositis under PT Enteritis.

CR Number: 2018270014 **Implementation Date:** 27-Sep-18 Related CR: 2018263029

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Large intestinal mucositis*	Approved as Requested	Proposed LLT	
From PT	*Gastrointestinal inflammation*		*Large intestinal mucositis*	10065733 Current
To PT	*Colitis*		From PT	
			Gastrointestinal inflammation	10064147
			To PT	
			Colitis	10009887

MSSO Comment:

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CR Number: 2018263031 **Implementation Date:** 27-Sep-18 Related CR: 2018263031

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Genital dysaesthesia*	Approved as Requested	Proposed PT	
HLT primary	*Reproductive tract disorders NEC (excl neoplasms)*		*Genital dysaesthesia*	10082123
SOC primary	*Reproductive system and breast disorders*		HLT primary	
			Reproductive tract disorders NEC (excl neoplasms)	10027696
			SOC primary	
			Reproductive system and breast disorders	10038604
			HLT secondary	
			Paraesthesias and dysaesthesias	10033788
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new PT Genital dysaesthesia to primary HLT Reproductive tract disorders NEC (excl neoplasms) in SOC Reproductive system and breast disorders and secondary HLT Paraesthesias and dysaesthesias in SOC Nervous system disorders is approved as requested. Distortion of genital sensitivity produced by normal stimuli, often associated to an unpleasant abnormal sensation such as burning, heat, irritation, discomfort, etc. Genital dysaesthesia will be added as PT with a primary link to HLT Reproductive tract disorders NEC (excl neoplasms) and a secondary link to HLT Paraesthesias and dysaesthesias. In a related change, the American English spelled counterpart LLT Genital dysesthesia will be added to new PT Genital dysaesthesia.

CR Number: 2018270006 **Implementation Date:** 27-Sep-18 Related CR: 2018263031

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Genital dysesthesia*	Approved as Requested	Proposed LLT	
To PT	*Genital dysaesthesia*		*Genital dysesthesia*	10082128 Current
			To PT	
			Genital dysaesthesia	10082123

MSSO Comment:

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CR Number: 2018263032 **Implementation Date:** 27-Sep-18 Related CR: 2018263032

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Unintentional weight gain*	Approved as Requested	Proposed LLT	
To PT	*Abnormal weight gain*		*Unintentional weight gain*	10082126 Current
			To PT	
			Abnormal weight gain	10000188

MSSO Comment: The proposal to add a new LLT Unintentional weight gain to PT Abnormal weight gain is approved as requested. Unintentional weight gain occurs when putting on weight without increasing food or liquid consumption, and without decreasing daily activity. It could be due different causes, such as fluid retention, abnormal growths, constipation, pregnancy, etc. Unintentional weight gain will be added as an LLT to PT Abnormal weight gain, as a counterpart of current LLT Unintentional weight loss.

CR Number: 2018263033 **Implementation Date:** 27-Sep-18 Related CR: 2018263033

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Muscle discomfort*	Approved Not as Requested	Proposed LLT	
From PT	*Musculoskeletal discomfort*		*Muscle discomfort*	10028299
To PT	*Myalgia*		From PT	
			Musculoskeletal discomfort	10053156
			HLT primary	
			Muscle related signs and symptoms NEC	10028326
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to move the LLT Muscle discomfort from PT Musculoskeletal discomfort to PT Myalgia is approved but not as requested. Muscle discomfort represents a sensation of uneasiness, hardship, or mild pain in muscles. Discomfort sensations are usually represented at the PT level in MedDRA. Consequently, PT Muscle discomfort will be promoted from PT Musculoskeletal discomfort to the PT level, linked to HLT Muscle related signs and symptoms NEC.

CR Number: 2018263034 **Implementation Date:** 27-Sep-18 Related CR: 2018263034

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Chemical sensitivity*	Approved as Requested	Proposed LLT	
To PT	*Allergy to chemicals*		*Chemical sensitivity*	10082124 Current
			To PT	
			Allergy to chemicals	10061626

MSSO Comment: The proposal to add a new LLT Chemical sensitivity to PT Allergy to chemicals is approved as requested. Chemical sensitivity is usually understood as a synonym expression of allergy to chemicals, and will be added as an LLT under such PT to differentiate the concept from the syndrome of Multiple chemical sensitivity (a MedDRA PT), which is defined as an “environmental illness” characterized by recurrent, often nonspecific symptoms involving multiple organ systems as a response to exposure to a multitude of unrelated chemical compounds at doses below those generally regarded as safe in the general population.

Supplemental Update Report

CR Number: 2018263035 **Implementation Date:** 27-Sep-18 Related CR: 2018263035

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Genital irritation*	Rejected		
From PT	*Genital discomfort*			

MSSO Comment: The proposal to promote the LLT Genital irritation from PT Genital discomfort is not approved. Mucosal irritations of the anogenital region are adequately represented under the anatomically related discomfort terms, since irritation is one of the clinical manifestations of discomfort in this anatomical location, as it is also assumed in the following PT-LLT associations: Anorectal discomfort with Anal irritation; Vulvovaginal discomfort with Vaginal irritation; and Vulvovaginal discomfort with Vulval irritation.

CR Number: 2018263036 **Implementation Date:** 10-Oct-18 Related CR: 2018263036

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Therapeutic product effect decreased*	Approved After Suspension	Proposed PT	
HLT primary	*Therapeutic and nontherapeutic responses*		*Therapeutic product effect decreased*	10082201
SOC primary	*General disorders and administration site conditions*		HLT primary	
			Therapeutic and nontherapeutic responses	10043409
			SOC primary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Therapeutic product effect decreased to primary HLT Therapeutic and nontherapeutic responses in SOC General disorders and administration site conditions is approved as requested after suspension. The proposed term will be added as a coding alternative when the implicated product is not a drug or device (e.g., a biologic) or when its exact nature is not specified. In a related change, PT Drug effect decreased will be merged under the new PT Therapeutic product effect decreased as a sub-concept.

CR Number: 2018282002 **Implementation Date:** 10-Oct-18 Related CR: 2018263036

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Drug effect decreased*	Approved as Requested	PT to merge	
To PT	*Therapeutic product effect decreased*		*Drug effect decreased*	10013678 Current
			To PT	
			Therapeutic product effect decreased	10082201

MSSO Comment:

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CR Number: 2018263037 **Implementation Date:** 10-Oct-18 Related CR: 2018263037

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Therapeutic product effect delayed*	Approved After Suspension	Proposed PT	
			Therapeutic product effect delayed	10082202
HLT primary	*Therapeutic and nontherapeutic responses*		HLT primary	
			Therapeutic and nontherapeutic responses	10043409
SOC primary	*General disorders and administration site conditions*		SOC primary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Therapeutic product effect delayed to primary HLT Therapeutic and nontherapeutic responses in SOC General disorders and administration site conditions is approved as requested after suspension. The proposed term will be added as a coding alternative when the implicated product is not a drug or device (e.g., a biologic) or when its exact nature is not specified. In a related change, PT Drug effect delayed will be demoted under new PT Therapeutic product effect delayed.

CR Number: 2018282003 **Implementation Date:** 10-Oct-18 Related CR: 2018263037

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Drug effect delayed*	Approved as Requested	PT to merge	
			Drug effect delayed	10068303 Current
To PT	*Therapeutic product effect delayed*		To PT	
			Therapeutic product effect delayed	10082202

MSSO Comment:

CR Number: 2018263038 **Implementation Date:** 10-Oct-18 Related CR: 2018263038

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Therapeutic product effect incomplete*	Approved After Suspension	Proposed PT	
			Therapeutic product effect incomplete	10082200
HLT primary	*Therapeutic and nontherapeutic responses*		HLT primary	
			Therapeutic and nontherapeutic responses	10043409
SOC primary	*General disorders and administration site conditions*		SOC primary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Therapeutic product effect incomplete to primary HLT Therapeutic and nontherapeutic responses in SOC General disorders and administration site conditions is approved as requested after suspension. The proposed term will be added as a coding alternative when the implicated product is not a drug or device (e.g., a biologic) or when its exact nature is not specified. In a related change, PT Drug effect incomplete will be demoted under new PT Therapeutic product effect incomplete.

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CR Number: 2018282004 **Implementation Date:** 10-Oct-18 Related CR: 2018263038

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Drug effect incomplete*	Approved as Requested	PT to merge	
To PT	*Therapeutic product effect incomplete*		*Drug effect incomplete*	10013682 Current
			To PT	
			Therapeutic product effect incomplete	10082200

MSSO Comment:

CR Number: 2018263039 **Implementation Date:** 10-Oct-18 Related CR: 2018263039

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Therapeutic product effect increased*	Approved After Suspension	Proposed PT	
HLT primary	*Therapeutic and nontherapeutic responses*		*Therapeutic product effect increased*	10082203
SOC primary	*General disorders and administration site conditions*		HLT primary	
			Therapeutic and nontherapeutic responses	10043409
			SOC primary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Therapeutic product effect increased to primary HLT Therapeutic and nontherapeutic responses in SOC General disorders and administration site conditions is approved as requested after suspension. The proposed term will be added as a coding alternative when the implicated product is not a drug or device (e.g., a biologic) or when its exact nature is not specified. In a related change, PT Drug effect increased will be demoted under new PT Therapeutic product effect increased.

CR Number: 2018282005 **Implementation Date:** 10-Oct-18 Related CR: 2018263039

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Drug effect increased*	Approved as Requested	PT to merge	
To PT	*Therapeutic product effect increased*		*Drug effect increased*	10013683 Current
			To PT	
			Therapeutic product effect increased	10082203

MSSO Comment:

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CR Number: 2018263040 **Implementation Date:** 10-Oct-18 Related CR: 2018263040

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Therapeutic product effect prolonged*	Approved After Suspension	Proposed PT	
			Therapeutic product effect prolonged	10082205
HLT primary	*Therapeutic and nontherapeutic responses*		HLT primary	
			Therapeutic and nontherapeutic responses	10043409
SOC primary	*General disorders and administration site conditions*		SOC primary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Therapeutic product effect prolonged to primary HLT Therapeutic and nontherapeutic responses in SOC General disorders and administration site conditions is approved as requested after suspension. The proposed term will be added as a coding alternative when the implicated product is not a drug or device (e.g., a biologic) or when its exact nature is not specified. In a related change, PT Drug effect prolonged will be demoted under PT Therapeutic product effect prolonged.

CR Number: 2018282006 **Implementation Date:** 10-Oct-18 Related CR: 2018263040

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Drug effect prolonged*	Approved as Requested	PT to merge	
			Drug effect prolonged	10013685 Current
To PT	*Therapeutic product effect prolonged*		To PT	
			Therapeutic product effect prolonged	10082205

MSSO Comment:

CR Number: 2018263041 **Implementation Date:** 10-Oct-18 Related CR: 2018263041

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Therapeutic product effect variable*	Approved After Suspension	Proposed PT	
			Therapeutic product effect variable	10082204
HLT primary	*Therapeutic and nontherapeutic responses*		HLT primary	
			Therapeutic and nontherapeutic responses	10043409
SOC primary	*General disorders and administration site conditions*		SOC primary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Therapeutic product effect variable to primary HLT Therapeutic and nontherapeutic responses in SOC General disorders and administration site conditions is approved as requested after suspension. The proposed term will be added as a coding alternative when the implicated product is not a drug or device (e.g., a biologic) or when its exact nature is not specified. In a related change, PT Drug effect variable will be demoted under new PT Therapeutic product effect variable.

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CR Number: 2018282007 **Implementation Date:** 10-Oct-18 Related CR: 2018263041

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Drug effect variable*	Approved as Requested	PT to merge	
To PT	*Therapeutic product effect variable*		*Drug effect variable*	10074541 Current
			To PT	
			Therapeutic product effect variable	10082204

MSSO Comment:

CR Number: 2018263042 **Implementation Date:** 27-Sep-18 Related CR: 2018263042

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Eye damage*	Approved as Requested	Proposed LLT	
To PT	*Eye injury*		*Eye damage*	10082127 Current
			To PT	
			Eye injury	10061128

MSSO Comment: The proposal to add a new LLT Eye damage to PT Eye injury is approved as requested. Because damage is defined as injury or harm resulting in impairment or loss of function, Eye damage will be added essentially as a synonym LLT to PT Eye injury.

CR Number: 2018263043 **Implementation Date:** 27-Sep-18 Related CR: 2018263043

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Chemical eye damage*	Approved as Requested	Proposed LLT	
To PT	*Chemical eye injury*		*Chemical eye damage*	10082125 Current
			To PT	
			Chemical eye injury	10055116 Current

MSSO Comment: The proposal to add a new LLT Chemical eye damage to PT Chemical eye injury is approved as requested. Because damage is defined as injury or harm resulting in impairment or loss of function, Chemical eye damage will be added as a synonym LLT to PT Chemical eye injury.

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CR Number: 2018263044 **Implementation Date:** 19-Oct-18 Related CR: 2018263044

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Transient partial visual loss*	Approved After Suspension	Proposed LLT	
From PT	*Blindness transient*		*Transient partial visual loss*	10065557 Current
To PT	*Visual impairment*		From PT	
			Blindness transient	10005184
			To PT	
			Visual impairment	10047571

MSSO Comment: The proposal to move the LLT Transient partial visual loss from PT Blindness transient to PT Visual impairment is approved as requested after suspension for better alignment of concepts.

CR Number: 2018263045 **Implementation Date:** 27-Sep-18 Related CR: 2018263045

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Visual impairment*	Approved as Requested	Proposed PT	
From HLT	*Visual disorders NEC*		*Visual impairment*	10047571
To HLT	*Visual impairment and blindness (excl colour blindness)*		From HLT	
			Visual disorders NEC	10047541
			To HLT	
			Visual impairment and blindness (excl colour blindness)	10080708

MSSO Comment: The proposal to move the PT Visual impairment from HLT Visual disorders NEC to HLT Visual impairment and blindness (excl colour blindness) is approved as requested. The hierarchical placement of PT Visual impairment is more appropriately aligned with HLT Visual impairment and blindness (excl colour blindness), than with the current link to HLT Visual disorders NEC, by virtue of the wording "Visual impairment."

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CR Number: 2018263046 **Implementation Date:** 27-Sep-18 Related CR: 2018263046

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Throat discomfort*	Approved as Requested	Proposed LLT	
From PT	*Throat irritation*		*Throat discomfort*	10081115 Current
To PT	*Oropharyngeal discomfort*		From PT	
			Throat irritation	10043521
			To PT	
			Oropharyngeal discomfort	10068318

MSSO Comment: The proposal to move the LLT Throat discomfort from PT Throat irritation to PT Oropharyngeal discomfort is approved as requested. LLT Throat discomfort is better aligned under PT Oropharyngeal discomfort than its current placement under PT Throat irritation. Oropharynx is generally synonymous with throat; also, in MedDRA, most LLTs incorporating discomfort are subordinate to a corresponding discomfort PT concept. In a related change, PT Throat irritation will be moved from HLT Oral soft tissue pain and paraesthesia to HLT Oral soft tissue signs and symptoms for better grouping.

CR Number: 2018270007 **Implementation Date:** 27-Sep-18 Related CR: 2018263046

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Throat irritation*	Approved as Requested	Proposed PT	
From HLT	*Oral soft tissue pain and paraesthesia*		*Throat irritation*	10043521
To HLT	*Oral soft tissue signs and symptoms*		From HLT	
			Oral soft tissue pain and paraesthesia	10031019
			To HLT	
			Oral soft tissue signs and symptoms	10031021

MSSO Comment:

CR Number: 2018263047 **Implementation Date:** 28-Sep-18 Related CR: 2018263047

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pharynx strange sensation of*	Rejected		
From PT	*Oropharyngeal discomfort*			
To PT	*Pharyngeal disorder*			

MSSO Comment: The proposal to move the LLT Pharynx strange sensation of from PT Oropharyngeal discomfort to PT Pharyngeal disorder is not approved. The current placement of LLT Pharynx strange sensation of is appropriate since a "strange" sensation, although not necessarily painful, can be pronounced enough to cause awareness and a pervasive lack of comfort in the sufferer. The proposal to move Pharynx strange sensation under a "disorder" concept incorrectly presumes a structural or functional issue with the pharynx itself.

Supplemental Update Report

CR Number: 2018263048 **Implementation Date:** 28-Sep-18 Related CR: 2018263048

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Shoulder soreness*	Approved Not as Requested	Proposed LLT	
To PT	*Musculoskeletal discomfort*		*Shoulder soreness*	10082149 Current
			To PT	
			Musculoskeletal pain	10028391

MSSO Comment: The proposal to add a new LLT Shoulder soreness to PT Musculoskeletal discomfort is approved but not as requested. As per the Introductory Guide, for purposes of MedDRA, “sore” and “soreness” terms are used for pain. Shoulder soreness will be added as an LLT to PT Musculoskeletal pain.

CR Number: 2018263049 **Implementation Date:** 28-Sep-18 Related CR: 2018263049

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Soreness of joint*	Approved Not as Requested	Proposed LLT	
To PT	*Discomfort in joints*		*Soreness of joint*	10082150 Current
			To PT	
			Arthralgia	10003239

MSSO Comment: The proposal to add a new LLT Soreness of joint to PT Discomfort in joints is approved but not as requested. As per the Introductory Guide, for purposes of MedDRA, “sore” and “soreness” terms are used for pain. Soreness of joint will be added as an LLT to PT Arthralgia.

Supplemental Update Report

CR Number: 2018264001 **Implementation Date:** 28-Sep-18 Related CR: 2018264001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Meatitis*	Approved Not as Requested	Proposed PT	
			Urinary meatitis	10082153
			HLT primary	
			Urinary tract infections	10046577
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Urethral infections and inflammations	10046453
			SOC secondary	
			Renal and urinary disorders	10038359

MSSO Comment: The proposal to add a new term Meatitis is approved but not as requested. The term Urinary meatitis represents inflammation of the external urethral orifice, usually due to infection, particularly these associated to sexual transmitted diseases. The proposed term will be renamed to Urinary meatitis for differentiation with inflammation of other anatomical meatus, and will be added as PT primarily linked to HLT Urinary tract infections, with a secondary link to HLT Urethral infections and inflammations. In an associated change, a new PT Noninfectious urinary meatitis will also be added to represent cases of urinary meatus inflammation caused by noninfective causes, such as chemical irritation. The PT Noninfectious urinary meatitis will be added solely to HLT Urethral infections and inflammations.

CR Number: 2018271001 **Implementation Date:** 28-Sep-18 Related CR: 2018264001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Noninfectious urinary meatitis*	Approved as Requested	Proposed PT	
HLT primary	*Urethral infections and inflammations*		*Noninfectious urinary meatitis*	10082151
SOC primary	*Renal and urinary disorders*		HLT primary	
			Urethral infections and inflammations	10046453
			SOC primary	
			Renal and urinary disorders	10038359

MSSO Comment:

Supplemental Update Report

CR Number: 2018264002 **Implementation Date:** 28-Sep-18 Related CR: 2018264002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Narrowband ultraviolet B phototherapy*	Approved as Requested	Proposed LLT	
			Narrowband ultraviolet B phototherapy	10082154 Current
			To PT	
			UV light therapy	10046850

MSSO Comment: The proposal to add a new LLT Narrowband ultraviolet B phototherapy is approved as requested. While UVB (type B ultravioletphototherapy) was formerly provided as a broadband source (290 to 320 nm), the new narrowband UVB, with shorter wavelength of ultraviolet radiation of 311 to 312 nm, has become the most common form of phototherapy used to treat several skin diseases. The narrowband range of UV radiation has proved to be the most beneficial component of natural sunlight principally for psoriasis, but also in the treatment of many other skin conditions including atopic eczema, vitiligo, pruritus, lichen planus, polymorphous light eruption, early cutaneous T-cell lymphoma and dermographism. Narrowband ultraviolet B phototherapy will be added as an sub-concept LLT to PT UV light therapy.

CR Number: 2018264003 **Implementation Date:** 28-Sep-18 Related CR: 2018264003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Paraneoplastic hypoglycemia*	Approved as Requested	Proposed LLT	
			Paraneoplastic hypoglycemia	10082155 Current
			To PT	
			Paraneoplastic hypoglycaemia	10082152

MSSO Comment: The proposal to add a new term Paraneoplastic hypoglycemia is approved as requested. Hypoglycemia may result from production of insulin-like growth factors or insulin production by pancreatic islet cell tumors. It can also be the associated to large retroperitoneal tumors (nonislet tumors), in which the most common cause is tumoral overproduction of incompletely processed insulin-like growth factor-2 (IGF-2), which results in stimulation of the insulin receptors and increased glucose utilization. Other potential but less common causes include the production of autoantibodies against insulin or the insulin receptor and extensive tumor burden resulting in destruction of the liver or adrenal glands. Paraneoplastic hypoglycemia will be added as an LLT under the British spelled PT Paraneoplastic hypoglycaemia, to comply with MedDRA rules. In a related change, Paraneoplastic hypoglycaemia will be added as a PT to primary bi-axial HLT Hypoglycaemic conditions NEC (primary SOC Metabolism and nutrition disorders, secondary SOC Endocrine disorders), with a secondary link to HLT Paraneoplastic syndromes NEC.

Supplemental Update Report

CR Number: 2018271002 **Implementation Date:** 28-Sep-18 Related CR: 2018264003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Paraneoplastic hypoglycaemia*	Approved as Requested	Proposed PT	
HLT primary	*Hypoglycaemic conditions NEC*		*Paraneoplastic hypoglycaemia*	10082152
SOC primary	*Metabolism and nutrition disorders*		HLT primary	
			Hypoglycaemic conditions NEC	10021001
			SOC primary	
			Metabolism and nutrition disorders	10027433
			HLT secondary	
			Paraneoplastic syndromes NEC	10067229
			SOC secondary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104

MSSO Comment:

CR Number: 2018264004 **Implementation Date:** 28-Sep-18 Related CR: 2018264004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Traumatic catheterisation*	Rejected		

MSSO Comment: The proposal to add a new term Traumatic catheterisation is not approved. The proposed term could be represented by existing LLT/PT Catheter site injury. Catheter site injury represents any traumatic procedure for any of the wide variety of catheters used in different anatomic sites.

CR Number: 2018264005 **Implementation Date:** 28-Sep-18 Related CR: 2018264005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Taste stale*	Rejected		
To PT	*Dysgeusia*			

MSSO Comment: The proposal to add a new LLT Taste stale to PT Dysgeusia is not approved. MedDRA can not accommodate every description of an abnormal product taste. Please consider existing LLT Product taste abnormal for your coding needs.

Supplemental Update Report

CR Number: **2018264006** **Implementation Date:** 28-Sep-18 Related CR: 2018264006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Taste burnt*	Rejected		
To PT	*Dysgeusia*			

MSSO Comment: The proposal to add a new LLT Taste burnt to PT Dysgeusia is not approved. MedDRA can not accommodate every description of an abnormal product taste. Please consider existing LLT Product taste abnormal for your coding needs.

CR Number: **2018264007** **Implementation Date:** 28-Sep-18 Related CR: 2018264007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Taste chemical*	Rejected		
To PT	*Dysgeusia*			

MSSO Comment: The proposal to add a new LLT Taste chemical to PT Dysgeusia is not approved. MedDRA can not accommodate every description of an abnormal product taste. Please consider existing LLT Product taste abnormal for your coding needs.

CR Number: **2018264008** **Implementation Date:** 28-Sep-18 Related CR: 2018264008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Burn of unspecified degree of two or more digits of hand*	Approved Not as Requested	Proposed LLT *Burn unspecified degree*	10082156 Current
To PT	*Thermal burn*		To PT *Thermal burn*	10053615

MSSO Comment: The proposal to add a new LLT Burn of unspecified degree of two or more digits of hand to PT Thermal burn is approved but not as requested. The MSSO generally refrains from adding combination terms comprised of multiple concepts unless such a term represents an internationally recognized, distinct and robust medical concept. Also, MedDRA cannot accommodate all possible terms that are plural versions of, or specific multiple quantities of existing singular term concepts. The proposed term will thus be modified to Burn unspecified degree and added as a sub-concept LLT to PT Thermal burn.

Supplemental Update Report

CR Number: 2018264009 **Implementation Date:** 28-Sep-18 Related CR: 2018264009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Burn of unspecified degree of single digit of hand*	Rejected		
To PT	*Thermal burn*			

MSSO Comment: The proposal to add a new LLT Burn of unspecified degree of single digit of hand to PT Thermal burn is not approved. The MSSO generally refrains from adding combination terms comprised of multiple concepts unless such a term represents an internationally recognized, distinct and robust medical concept. Also, MedDRA cannot accommodate all possible terms that are plural versions of, or specific multiple quantities of existing singular term concepts. Please consider using LLT Burn unspecified degree for our coding needs added in change request 2018264008.

CR Number: 2018264010 **Implementation Date:** 28-Sep-18 Related CR: 2018264010

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cut(s) on Lip – more specific location*	Rejected		
To PT	*Lip injury*			

MSSO Comment: The proposal to add a new LLT Cut(s) on Lip – more specific location to PT Lip injury is not approved. The requested term can be represented by existing LLT Lip laceration or LLT Split lip. In general, the MSSO does not add new terms as separate singular and plural term versions of a concept, or terms with a combined singular/plural parenthetical expression such as cut(s).

CR Number: 2018264011 **Implementation Date:** 28-Sep-18 Related CR: 2018264011

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Poikilothermia*	Approved as Requested	Proposed PT	
HLT primary	*Body temperature altered*		*Poikilothermia*	10082157
SOC primary	*General disorders and administration site conditions*		HLT primary	
			Body temperature altered	10005907
			SOC primary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Poikilothermia to primary HLT Body temperature altered in SOC General disorders and administration site conditions is approved as requested. Poikilothermia, the inability to maintain a constant core temperature independent of ambient temperature, which can influence both the mental and physical function of affected patients.

Supplemental Update Report

CR Number: 2018267001 **Implementation Date:** 01-Oct-18 Related CR: 2018267001

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Postoperative hypotension*	Approved as Requested	Proposed LLT	
From PT	*Procedural hypotension*		*Postoperative hypotension*	10050632
HLT primary	*Non-site specific procedural complications*		From PT	
			Procedural hypotension	10062300
			HLT primary	
			Non-site specific procedural complications	10029559
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Vascular hypotensive disorders	10057181
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to promote the LLT Postoperative hypotension from PT Procedural hypotension to primary HLT Non-site specific procedural complications in SOC Injury, poisoning and procedural complications and secondary HLT Vascular hypotensive disorders in SOC Vascular disorders is approved as requested. Arterial hypotension in the postoperative period has been defined either as systolic pressure below 90 mm Hg in an initially normotensive patient, or as systolic pressure more than 40 mm Hg below the preoperative readings in a hypertensive patient. Postoperative hypotension has been associated with factors related to cardiovascular, respiratory, pharmacological, neurogenic, hematologic, and humoral etiologies. LLT Postoperative hypotension warrants promotion from PT Procedural hypotension to represent hypotension that specifically occurs during the period following a procedure.

Supplemental Update Report

CR Number: 2018267002 **Implementation Date:** 01-Oct-18 Related CR: 2018267002

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Postoperative hypertension*	Approved as Requested	Proposed LLT	
From PT	*Procedural hypertension*		*Postoperative hypertension*	10050631
HLT primary	*Non-site specific procedural complications*		From PT	
			Procedural hypertension	10062886
			HLT primary	
			Non-site specific procedural complications	10029559
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Vascular hypertensive disorders NEC	10020774
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to promote the LLT Postoperative hypertension from PT Procedural hypertension to primary HLT Non-site specific procedural complications in SOC Injury, poisoning and procedural complications and secondary HLT Vascular hypertensive disorders NEC in SOC Vascular disorders is approved as requested. Postoperative hypertension is an acute, transient increase in blood pressure that develops within 30 to 90 minutes following a surgical procedure. Potential etiologic factors include: pain, anxiety, hypercarbia, hypercapnia, hypothermia, volume overload, and bladder distension. Postoperative hypertension warrants promotion from PT Procedural hypertension to represent hypertension that occurs during the immediate period following a procedure.

CR Number: 2018267003 **Implementation Date:** 01-Oct-18 Related CR: 2018267003

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Post procedural pain*	Rejected		
From PT	*Procedural pain*			
HLT primary	*Non-site specific procedural complications*			

MSSO Comment: The proposal to promote the LLT Post procedural pain from PT Procedural pain to primary HLT Non-site specific procedural complications in SOC Injury, poisoning and procedural complications and secondary HLT Pain and discomfort NEC in SOC General disorders and administration site conditions is not approved. Pain is a symptom frequently associated to the procedural intervention and the post-procedural period in a continuum, having in any time similar treatment and prognostic value.

Supplemental Update Report

CR Number: 2018267004 **Implementation Date:** 01-Oct-18 Related CR: 2018267004

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Gastrointestinal stromal cancer*	Approved as Requested	PT to merge	
To PT	*Gastrointestinal stromal tumour*		*Gastrointestinal stromal cancer*	10071653 Current
			To PT	
			Gastrointestinal stromal tumour	10051066

MSSO Comment: The proposal to demote the PT Gastrointestinal stromal cancer under PT Gastrointestinal stromal tumour is approved as requested. Gastrointestinal stromal tumors are mesenchymal gut tumors that differ dramatically from other histologically similar neoplasms, such as leimomyomas, leiomyosarcomas, and neural tumors. Complete surgical removal remains the best current therapy of this lesion which characteristically undergoes malignant transformation. The understanding of GIST biology changed significantly with identification of their molecular basis, which has led to a reclassification of the group, in which all GIST tumors are now considered to have malignant potential, and no GIST tumor can be definitively classified as "benign".

CR Number: 2018267005 **Implementation Date:** 01-Oct-18 Related CR: 2018267005

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gastrointestinal stromal tumour*	Approved as Requested	Proposed PT	
From HLT	*Gastrointestinal neoplasms malignancy unspecified NEC*		*Gastrointestinal stromal tumour*	10051066
To HLT	*Gastrointestinal neoplasms malignant NEC*		From HLT	
			Gastrointestinal neoplasms malignancy unspecified NEC	10017994
			To HLT	
			Gastrointestinal neoplasms malignant NEC	10017992

MSSO Comment: The proposal to move the PT Gastrointestinal stromal tumour from HLT Gastrointestinal neoplasms malignancy unspecified NEC to HLT Gastrointestinal neoplasms malignant NEC is approved as requested. Gastrointestinal stromal tumours are considered to be of malignant potential, as the natural history of this neoplasm usually undergoes malignant transformation, necessitating resection and chemotherapy in advanced cases.

CR Number: 2018267006 **Implementation Date:** 01-Oct-18 Related CR: 2018267006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Injection site vascular injury*	Rejected		

MSSO Comment: The proposal to add a new PT Injection site vascular injury is not approved. MedDRA can not accommodate combinations of all sort of injures or conditions associated to an injection site or any other administration site. Please consider split coding with LLT Injection site injury and LLT Vascular injury.

Supplemental Update Report

CR Number: 2018267007 **Implementation Date:** 01-Oct-18 Related CR: 2018267007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Uroplasmal cervicitis*	Approved Not as Requested	Proposed PT	
HLT primary	*Ureaplasma infections*		*Ureaplasma cervicitis*	10082162
SOC primary	*Infections and infestations*		HLT primary	
			Ureaplasma infections	10046367
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Cervix infections and inflammations	10008275
			SOC secondary	
			Reproductive system and breast disorders	10038604

MSSO Comment: The proposal to add a new PT Uroplasmal cervicitis to primary HLT Ureaplasma infections in SOC Infections and infestations is approved but not as requested. Ureaplasma parvum and Ureaplasma urealyticum are commonly found in the cervix of women with non-chlamydial and non-gonococcal cervicitis or non-specific cervicitis. The proposed term will be added with corrected spelling as Ureaplasma cervicitis as a new PT to primary HLT Ureaplasma infections and to secondary HLT Cervix infections and inflammations.

CR Number: 2018267008 **Implementation Date:** 01-Oct-18 Related CR: 2018267008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Supra-aortic trunk sclerosis*	Approved as Requested	Proposed PT	
			Supra-aortic trunk sclerosis	10082160
			HLT primary	
			Site specific necrosis and vascular insufficiency NEC	10052781
			SOC primary	
			Vascular disorders	10047065
			HLT secondary	
			Cardiac and vascular procedural complications	10007602
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new term Supra-aortic trunk sclerosis is approved as requested. Supra-aortic trunk sclerosis, affecting vessels such as the common carotid artery, the subclavian artery, and the innominate artery, has been etiologically associated with factors that include previous radiotherapy, arteritis, and diabetes mellitus. Supra-aortic trunk sclerosis will thus be added as a new PT to primary HLT Site specific necrosis and vascular insufficiency NEC and secondary HLT Cardiac and vascular procedural complications.

Supplemental Update Report

CR Number: 2018267009 **Implementation Date:** 01-Oct-18 Related CR: 2018267009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Acquired perforating dermatosis*	Approved as Requested	Proposed PT	
			Acquired perforating dermatosis	10082163
			HLT primary	
			Dermal and epidermal conditions NEC	10012424
			SOC primary	
			Skin and subcutaneous tissue disorders	10040785
			HLT secondary	
			Diabetic complications dermal	10062911
			SOC secondary	
			Endocrine disorders	10014698

MSSO Comment: The proposal to add a new term Acquired perforating dermatosis is approved as requested. Acquired perforating dermatosis is a skin disorder occurring in patients with chronic renal failure, diabetes mellitus or both. The lesions are characterized by eruption of generally pruritic keratotic papules and nodules, primarily on the extensor surface of the extremities and the trunk. Histopathological examination of lesional skin demonstrates invagination of the epidermis with extrusion of dermal material (collagen, elastin, and/or fibrin) through the cup-shaped epidermal depression. Acquired perforating dermatosis will be added as a new PT to primary HLT Dermal and epidermal conditions NEC, to secondary HLT Diabetic complications dermal, and to secondary HLT Renal failure complications.

CR Number: 2018274009 **Implementation Date:** 01-Oct-18 Related CR: 2018267009

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Acquired perforating dermatosis*	Approved as Requested	Proposed PT	
To HLT	*Renal failure complications*		*Acquired perforating dermatosis*	10082163
			To HLT	
			Renal failure complications	10010180

MSSO Comment:

Supplemental Update Report

CR Number: 2018267010 **Implementation Date:** 01-Oct-18 Related CR: 2018267010

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Carotid vascular resistance increased*	Approved as Requested	Proposed PT	
			Carotid vascular resistance increased	10082161
			HLT primary	
			Vascular tests NEC (incl blood pressure)	10047110
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Carotid vascular resistance increased is approved as requested. Vascular resistance is the resistance that must be overcome to push blood through the circulatory system and create flow. In contrast to systemic vascular resistance which is used in calculations of blood pressure, blood flow, and cardiac function, vascular resistance can be determined for specific blood vessels such as the carotid arteries, and is related to factors such as the radius of the vessel lumen, and the viscosity of the blood. Carotid vascular resistance increased will be added as a new PT to HLT Vascular tests NEC (incl blood pressure).

CR Number: 2018268001 **Implementation Date:** 28-Sep-18 Related CR: 2018268001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Peroneal tendonitis*	Approved as Requested	Proposed LLT	
			Peroneal tendonitis	10082159 Current
			To PT	
			Tendonitis	10043255

MSSO Comment: The proposal to add a new LLT Peroneal tendonitis is approved as requested. Peroneal tendonitis is a inflammation of the peroneal tendons usually caused by an increased load and overuse of the tendons, and the subsequent friction on the bone. Peroneal tendonitis will be added as an anatomical sub-concept LLT to PT Tendonitis.

CR Number: 2018268002 **Implementation Date:** 28-Sep-18 Related CR: 2018268002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Posterior tibial tendonitis*	Approved as Requested	Proposed LLT	
			Posterior tibial tendonitis	10082158 Current
			To PT	
			Tendonitis	10043255

MSSO Comment: The proposal to add a new LLT Posterior tibial tendonitis is approved as requested. Posterior tibial tendonitis results from overuse of the tendon or from a specific incident such as a fall, causing the tendon to become inflamed or even torn. Sudden injuries are found in athletes associated to a distinct injury, whereas progressive dysfunction usually occurs in older people, particularly women. Posterior tibial tendonitis will be added as an anatomical sub-concept LLT to PT Tendonitis.

Supplemental Update Report

CR Number: 2018269001 **Implementation Date:** 01-Oct-18 Related CR: 2018269001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Short stature homeobox gene mutation*	Approved as Requested	Proposed PT	
HLT primary	*Acquired gene mutations and other alterations*		*Short stature homeobox gene mutation*	10082164
SOC primary	*General disorders and administration site conditions*		HLT primary	
			Acquired gene mutations and other alterations	10071951
			SOC primary	
			General disorders and administration site conditions	10018065
			HLT secondary	
			Musculoskeletal and connective tissue conditions NEC	10080711
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new PT Short stature homeobox gene mutation to primary HLT Acquired gene mutations and other alterations in SOC General disorders and administration site conditions is approved as requested. Short stature homeobox gene is responsible for the normal growth of bones, and a mutation of this gene has been described in over 4 per cent of children with idiopathic short stature. Short stature homeobox gene is located on each of the sex chromosomes, and is responsible for growth in the epiphyseal plates, where the long bones of the arms and legs grow in length.`Short stature homeobox gene mutation will be added as a new PT to primary HLT Acquired gene mutations and other alterations, and to secondary HLT Musculoskeletal and connective tissue conditions NEC.

CR Number: 2018269002 **Implementation Date:** 01-Oct-18 Related CR: 2018269002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Penile tingling*	Approved as Requested	Proposed LLT	
To PT	*Genital paraesthesia*		*Penile tingling*	10082168 Current
			To PT	
			Genital paraesthesia	10073420

MSSO Comment: The proposal to add a new LLT Penile tingling to PT Genital paraesthesia is approved as requested. Tingling is a descriptive term that is frequently used in the context of, or synonymously with, paraesthesia.

Supplemental Update Report

CR Number: 2018269003 **Implementation Date:** 01-Oct-18 Related CR: 2018269003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Penile throbbing*	Approved Not as Requested	Proposed LLT	
To PT	*Penile Pain*		*Penile throbbing*	10082167 Current
			To PT	
			Penile pain	10034310

MSSO Comment: The proposal to add a new LLT Penile throbbing to PT Penile Pain is approved but not as requested. Throbbing pain is described as continuous severe pain, pulsates like heart beat. Throbbing pain is perception of pulsatile pain produced by rapid intermittent transmission pain impulses from disease tissue to pain centers in brain. Penile throbbing will be added as an LLT to PT Penile pain, with corrected capitalization of pain, in accordance with MedDRA capitalization rules.

CR Number: 2018269004 **Implementation Date:** 01-Oct-18 Related CR: 2018269004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Penile numbness*	Approved as Requested	Proposed LLT	
To PT	*Genital hypoaesthesia*		*Penile numbness*	10082165 Current
			To PT	
			Genital hypoaesthesia	10068912

MSSO Comment: The proposal to add a new LLT Penile numbness to PT Genital hypoaesthesia is approved as requested. Numbness describes a reduction of, or loss of sensation or feeling in a part of one's body, and is synonymously used with hypoaesthesia.

CR Number: 2018269005 **Implementation Date:** 01-Oct-18 Related CR: 2018269005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Penile Itching*	Approved Not as Requested	Proposed LLT	
To PT	*Pruritus genital*		*Penile itching*	10082166 Current
			To PT	
			Pruritus genital	10037093

MSSO Comment: The proposal to add a new LLT Penile Itching to PT Pruritus genital is approved but not as requested. Itching and itchiness are common expressions for pruritus. The proposed term will be modified to Penile itching in accordance with MedDRA capitalization rules and added as an LLT to PT Pruritus genital.

Supplemental Update Report

CR Number: 2018269006 **Implementation Date:** 01-Oct-18 Related CR: 2018269006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Drug level abnormal*	Approved as Requested	Proposed PT	
HLT primary	*Therapeutic drug monitoring analyses*		*Drug level abnormal*	10082169
SOC primary	*Investigations*		HLT primary	
			Therapeutic drug monitoring analyses	10043411
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Drug level abnormal to primary HLT Therapeutic drug monitoring analyses in SOC Investigations is approved as requested. The proposed medical concept will facilitate coding when the exact nature of an abnormal drug level is not specified (i.e. whether it is increased, decreased, etc.). Abnormal drug level terms already exist in MedDRA for several specific drug classes (e.g., anticonvulsants, benzodiazepines and anticoagulants).

CR Number: 2018269007 **Implementation Date:** 01-Oct-18 Related CR: 2018269007

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cold symptoms*	Rejected		
From PT	*Nasopharyngitis*			

MSSO Comment: The proposal to promote the LLT Cold symptoms from PT Nasopharyngitis is not approved. Due to concerns about the negative impact on legacy data, LLT Cold symptoms, along with synonymous terms for the common cold, were moved back under PT Nasopharyngitis in MedDRA version 20.1. This had been the original placement of such terms since MedDRA version 2.1. Because the diagnosis of the common cold is typically based on the simple presence of hallmark signs and symptoms (without the need for confirmatory cultures) and the characteristic benign clinical course, the placement of LLT Cold symptoms under the medical concept of nasopharyngitis is considered appropriate.

CR Number: 2018269008 **Implementation Date:** 01-Oct-18 Related CR: 2018269008

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Retrospondylolisthesis*	Approved as Requested	Proposed LLT	
From PT	*Spondylolisthesis*		*Retrospondylolisthesis*	10052493 Current
To PT	*Spinal retrolisthesis*		From PT	
			Spondylolisthesis	10063550
			To PT	
			Spinal retrolisthesis	10081602

MSSO Comment: The proposal to move the LLT Retrospondylolisthesis from PT Spondylolisthesis to PT Spinal retrolisthesis is approved as requested. Spinal retrolisthesis (synonym: retrospondylolisthesis) is the posterior displacement of one vertebral body on the subjacent vertebral body. In contrast, spondylolisthesis is the forward displacement of one vertebra over another. Accordingly, moving LLT Retrospondylolisthesis from PT Spondylolisthesis to PT Spinal retrolisthesis is proposed to improve the conceptual alignment of these terms.

Supplemental Update Report

CR Number: 2018269009 **Implementation Date:** 01-Oct-18 Related CR: 2018269009

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Retrospondylolisthesis NOS*	Approved as Requested	Proposed LLT	
From PT	*Spondylolisthesis*		*Retrospondylolisthesis NOS*	10052054 Current
To PT	*Spinal retrolisthesis*		From PT	
			Spondylolisthesis	10063550
			To PT	
			Spinal retrolisthesis	10081602

MSSO Comment: The proposal to move the LLT Retrospondylolisthesis NOS from PT Spondylolisthesis to PT Spinal retrolisthesis is approved as requested. Spinal retrolisthesis (synonym: retrospondylolisthesis) is the posterior displacement of one vertebral body on the subjacent vertebral body. In contrast, spondylolisthesis is the forward displacement of one vertebra over another. Accordingly, moving LLT Retrospondylolisthesis NOS from PT Spondylolisthesis to PT Spinal retrolisthesis is proposed to improve the conceptual alignment of these terms.

CR Number: 2018269010 **Implementation Date:** 01-Oct-18 Related CR: 2018269010

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Acquired retrospondylolisthesis*	Approved as Requested	Proposed LLT	
From PT	*Spondylolisthesis*		*Acquired retrospondylolisthesis*	10048986 Current
To PT	*Spinal retrolisthesis*		From PT	
			Spondylolisthesis	10063550
			To PT	
			Spinal retrolisthesis	10081602

MSSO Comment: The proposal to move the LLT Acquired retrospondylolisthesis from PT Spondylolisthesis to PT Spinal retrolisthesis is approved as requested. Spinal retrolisthesis (synonym: retrospondylolisthesis) is the posterior displacement of one vertebral body on the subjacent vertebral body. In contrast, spondylolisthesis is the forward displacement of one vertebra over another. Accordingly, moving LLT Acquired retrospondylolisthesis from PT Spondylolisthesis to PT Spinal retrolisthesis is proposed to improve the hierarchical alignment of these concepts.

CR Number: 2018270001 **Implementation Date:** 01-Oct-18 Related CR: 2018270001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Syringitis*	Approved as Requested	Proposed LLT	
			Syringitis	10082170 Current
			To PT	
			Otosalpingitis	10033102

MSSO Comment: The proposal to add a new term Syringitis is approved as requested. Syringitis is an inflammation of the eustachian tube, which may be etiologically associated with an infection. Syringitis will be added as a sub-concept LLT to PT Otosalpingitis. In a related change, LLT Eustachian catarrh will be moved from PT Eustachian tube disorder to PT Otosalpingitis for better placement.

Supplemental Update Report

CR Number: 2018274010 **Implementation Date:** 01-Oct-18 Related CR: 2018270001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Eustachian catarrh*	Approved as Requested	Proposed LLT	
From PT	*Eustachian tube disorder*		*Eustachian catarrh*	10015537 Current
To PT	*Otosalpingitis*		From PT	
			Eustachian tube disorder	10061462
			To PT	
			Otosalpingitis	10033102

MSSO Comment:

CR Number: 2018270002 **Implementation Date:** 01-Oct-18 Related CR: 2018270002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Parapneumonic effusion*	Approved as Requested	Proposed LLT	
			Parapneumonic effusion	10082171 Current
			To PT	
			Infectious pleural effusion	10071699

MSSO Comment: The proposal to add a new term Parapneumonic effusion is approved as requested. A parapneumonic effusion is a pleural effusion that occurs as a complication of pneumonia, commonly bacterial in nature. Parapneumonic effusion will be added as a sub-concept LLT to PT Infectious pleural effusion.

CR Number: 2018270003 **Implementation Date:** 02-Oct-18 Related CR: 2018270003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Glycopenia*	Approved as Requested	Proposed PT	
			Glycopenia	10082172
			HLT primary	
			Hypoglycaemic conditions NEC	10021001
			SOC primary	
			Metabolism and nutrition disorders	10027433

MSSO Comment: The proposal to add a new term Glycopenia is approved as requested. Glycopenia is a deficiency of sugar in the tissues, usually resulting from hypoglycemia. Glycopenia affects the function of neurons, and alters brain function and behavior. Prolonged or recurrent glycopenia of the brain can result in loss of consciousness, damage to the brain, and eventual death. Glycopenia will be added as a new PT to HLT Hypoglycaemic conditions NEC which under HLGT Glucose metabolism disorders (incl diabetes mellitus), which is bi-axial to primary SOC Metabolism and nutrition disorders, and to secondary SOC Endocrine disorders.

Supplemental Update Report

CR Number: 2018274001 **Implementation Date:** 04-Oct-18 Related CR: 2018274001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Trachelorrhaphy*	Approved Not as Requested	Proposed LLT	
To PT	*Cervix cerclage procedure*		*Trachelorrhaphy*	10082177 Current
			To PT	
			Tracheloplasty	10077464

MSSO Comment: The proposal to add a new LLT Trachelorrhaphy to PT Cervix cerclage procedure is approved but not as requested. Trachelorrhaphy is the name for an specific cerclage technique of sewing up a laceration of the neck of the uterus. Trachelorrhaphy will be placed as a sub-concept LLT to the newly promoted PT Tracheloplasty to represent trachelorrhaphy under a more specific technique. In a related change, LLT Tracheloplasty will be promoted from under PT Cervix cerclage procedure and linked to HLT Cervix therapeutic procedures.

CR Number: 2018277001 **Implementation Date:** 04-Oct-18 Related CR: 2018274001

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Tracheloplasty*	Approved as Requested	Proposed LLT	
From PT	*Cervix cerclage procedure*		*Tracheloplasty*	10077464
HLT primary	*Cervix therapeutic procedures*		From PT	
			Cervix cerclage procedure	10054992
			HLT primary	
			Cervix therapeutic procedures	10008294
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment:

CR Number: 2018274002 **Implementation Date:** 04-Oct-18 Related CR: 2018274002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Emmet operation*	Approved Not as Requested	Proposed LLT	
To PT	*Cervix cerclage procedure*		*Emmet operation*	10082176 Current
			To PT	
			Tracheloplasty	10077464

MSSO Comment: The proposal to add a new LLT Emmet operation to PT Cervix cerclage procedure is approved but not as requested. Emmet operation and trachelorrhaphy are synonymously used for sewing a laceration of the cervix uteri. Therefore, Emmet operation will be added as an LLT under the newly promoted PT Tracheloplasty. See change request 2018274001 for the promotion of Tracheloplasty.

Supplemental Update Report

CR Number: 2018274003 **Implementation Date:** 04-Oct-18 Related CR: 2018274003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Placenta duplex*	Approved as Requested	Proposed PT	
HLT primary	*Placental abnormalities (excl neoplasms)*		*Placenta duplex*	10082173
SOC primary	*Pregnancy, puerperium and perinatal conditions*		HLT primary	
			Placental abnormalities (excl neoplasms)	10035130
			SOC primary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new PT Placenta duplex to primary HLT Placental abnormalities (excl neoplasms) in SOC Pregnancy, puerperium and perinatal conditions is approved as requested. A bilobed placenta, also referred as bipartite placenta or placenta duplex, is a variation in placental morphology and refers to a placenta separated into two near equal-sized lobes.

CR Number: 2018274004 **Implementation Date:** 04-Oct-18 Related CR: 2018274004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Placenta bipartita*	Approved as Requested	Proposed LLT	
			Placenta bipartita	10082175 Current
			To PT	
			Placenta duplex	10082173

MSSO Comment: The proposal to add a new LLT Placenta bipartita is approved as requested. Placenta bipartita is a synonym for Placenta duplex and will be added as an LLT to the new PT Placenta duplex. Please see change request 2018274003.

CR Number: 2018274005 **Implementation Date:** 04-Oct-18 Related CR: 2018274005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Velamentous cord insertion*	Approved as Requested	Proposed PT	
			Velamentous cord insertion	10082174
			HLT primary	
			Umbilical cord complications	10045448
			SOC primary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new PT Velamentous cord insertion is approved as requested. A velamentous cord insertion is a pregnancy complication in which the umbilical cord is abnormally inserted into the placenta. Velamentous cord insertion will be added as a PT to HLT Umbilical cord complications.

Supplemental Update Report

CR Number: 2018274006 **Implementation Date:** 08-Oct-18 Related CR: 2018274006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Misleading serological testing by passive antibody transfer*	Approved Not as Requested	Proposed LLT	
			Misleading serological test result by passive antibody transfer	10082183 Current
			To PT	
			Misleading laboratory test result	10082181

MSSO Comment: The proposal to add a new LLT Misleading serological testing by passive antibody transfer is approved but not as requested. Intravenous immunoglobulin is used to treat a wide range of disorders, and preparations are extracted from pools of greater than 10,000 donors. Depending on the manufacturer, blood collection may be obtained from donors with different selection criteria that will translate into different immunoglobulin composition. Intravenous immunoglobulin administration complicates serological profile interpretation at the laboratory level, as the biologist is most often unaware of such treatment, but also misleads the clinician who may falsely interpret the laboratory results. Misleading serological testing by passive antibody transfer will be modified to Misleading serological test result by passive antibody transfer and added as a sub-element LLT to PT Misleading laboratory test result, newly added in change request 2018274008.

CR Number: 2018274007 **Implementation Date:** 08-Oct-18 Related CR: 2018274007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Misleading serological testing by vaccination*	Approved Not as Requested	Proposed LLT	
			Misleading serological test result by vaccination	10082182 Current
			To PT	
			Misleading laboratory test result	10082181

MSSO Comment: The proposal to add a new LLT Misleading serological testing by vaccination is approved but not as requested. Some vaccines have been reported to cause transitory false positives in serological tests, to the point that it has been suggested that blood donors be temporarily deferred from blood donation for intravenous immunoglobulin preparations. Misleading serological testing by vaccination will be modified to Misleading serological test result by vaccination and added as a sub-element LLT to PT Misleading laboratory test result, added in change request 2018274008.

Supplemental Update Report

CR Number: 2018274008 **Implementation Date:** 08-Oct-18 Related CR: 2018274008

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Misleading laboratory test interpretation*	Approved Not as Requested	Proposed PT	
HLT primary	*Investigations NEC*		*Misleading laboratory test result*	10082181
SOC primary	*Investigations*		HLT primary	
			Investigations NEC	10022892
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Misleading laboratory test interpretation to primary HLT Investigations NEC in SOC Investigations is approved but not as requested. Despite laboratory tests being analytically robust and trusted, some common tests performed by certain techniques, such as immunoassays, are inherently more prone to analytical interference, giving rise to incorrect results. This form of interference often cannot be predicted a priori and cannot be detected even by most stringent laboratory quality control assurance schemes because it is unique to an individual sample. Misleading laboratory test interpretation will be modified to Misleading laboratory test result and added as a new PT to HLT Investigations NEC. "Interpretation" in the proposed term may imply a human error and therefore will replaced by the neutral "result".

CR Number: 2018275001 **Implementation Date:** 08-Oct-18 Related CR: 2018275001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cholecystits Perforated*	Rejected		

MSSO Comment: The proposal to add a new PT Cholecystits Perforated is not approved. The proposed term is a combination of two concepts, cholecystitis and gallbladder perforation. MedDRA cannot accommodate a specific term for every possible combination of anatomical site and condition. This concept may be represented in MedDRA by coding with more than one term, for example, LLT Cholecystitis plus LLT Gallbladder perforation. Please review the MedDRA Term Selection: Points to Consider document, Section 3.5.

CR Number: 2018275002 **Implementation Date:** 08-Oct-18 Related CR: 2018275002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Squamous Cell Carcinoma Of Head And Neck metastatic*	Approved Not as Requested	Proposed LLT	
			Squamous cell carcinoma of head and neck metastatic	10082179 Current
			To PT	
			Squamous cell carcinoma of head and neck	10060121

MSSO Comment: The proposal to add a new PT Squamous Cell Carcinoma Of Head And Neck metastatic is approved but not as requested. Squamous Cell Carcinoma Of Head And Neck metastatic will be modified in accordance with MedDRA capitalization rules and added as a sub-concept LLT Squamous cell carcinoma of head and neck metastatic to PT Squamous cell carcinoma of head and neck.

Supplemental Update Report

CR Number: 2018275003 **Implementation Date:** 08-Oct-18 Related CR: 2018275003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Philadelphia positive chronic myeloid leukemia*	Approved Not as Requested	Proposed LLT	
To PT	*Chronic myeloid leukemia*		*Philadelphia positive chronic myeloid leukemia*	10082178 Current
			To PT	
			Chronic myeloid leukaemia	10009013

MSSO Comment: The proposal to add a new LLT Philadelphia positive chronic myeloid leukemia to PT Chronic myeloid leukemia is approved but not as requested. It has been shown that chronic myeloid leukemia is associated with an abnormal chromosome known as the Philadelphia chromosome (Ph chromosome). The Ph chromosome is an abnormality that occurs when a piece of chromosome 22 breaks off and attaches to the end of chromosome 9, which also breaks off and attaches to chromosome 22. Philadelphia positive chronic myeloid leukemia and its British English spelled counterpart Philadelphia positive chronic myeloid leukaemia will be added as LLTs to British spelled PT Chronic myeloid leukaemia.

CR Number: 2018281006 **Implementation Date:** 08-Oct-18 Related CR: 2018275003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Philadelphia positive chronic myeloid leukaemia*	Approved as Requested	Proposed LLT	
To PT	*Chronic myeloid leukaemia*		*Philadelphia positive chronic myeloid leukaemia*	10082180 Current
			To PT	
			Chronic myeloid leukaemia	10009013

MSSO Comment:

CR Number: 2018275004 **Implementation Date:** 08-Oct-18 Related CR: 2018275004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Immunosuppressant nephrotoxicity*	Rejected		
To PT	*Nephropathy toxic*			

MSSO Comment: The proposal to add a new LLT Immunosuppressant nephrotoxicity to PT Nephropathy toxic is not approved. The proposed term is a combination of two concepts, immunosuppressant therapy and nephrotoxicity. The MSSO considers this term to be of a “due to” nature. Terms that state or imply a “due to” concept are generally not added to MedDRA because causality is not inherent in the coded term, but is instead determined by the reporter/investigator or by the sponsor. This concept may be represented in MedDRA by coding with more than one term, for example, LLT Immunosuppressant drug therapy plus LLT Nephrotoxicity. Please review the MedDRA Term Selection: Points to Consider document, Section 3.5.

Supplemental Update Report

CR Number: 2018276001 **Implementation Date:** 08-Oct-18 Related CR: 2018276001

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Colpomycosis*	Approved as Requested	Proposed LLT	
To PT	*Vulvovaginal mycotic infection*		*Colpomycosis*	10082184 Current
			To PT	
			Vulvovaginal mycotic infection	10064899

MSSO Comment: The proposal to add a new LLT Colpomycosis to PT Vulvovaginal mycotic infection is approved as requested. Colpomycosis and existing LLT Vaginal mycosis under PT Vulvovaginal mycotic infection, are synonymously used.

CR Number: 2018276002 **Implementation Date:** 08-Oct-18 Related CR: 2018276002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Dyspnoea aggravated*	Rejected		
To PT	*Dyspnoea*			

MSSO Comment: The proposal to add a new LLT Dyspnoea aggravated to PT Dyspnoea is not approved. The requested term can be coded with LLT Dyspnoea exacerbated - exacerbated, worsened and aggravated are synonymously used. Alternatively, if the submitter needs to capture "aggravated" in term selection, they can split code using LLT Dyspnoea, plus LLT Condition aggravated.

Supplemental Update Report

CR Number: 2018276003 **Implementation Date:** 10-Oct-18 Related CR: 2018276003

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Neonatal epileptic seizure*	Approved as Requested	Proposed LLT	
From PT	*Neonatal seizure*		*Neonatal epileptic seizure*	10082068
HLT primary	*Seizures and seizure disorders NEC*		From PT	
			Neonatal seizure	10082067
			HLT primary	
			Seizures and seizure disorders NEC	10039912
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Neonatal neurological system disorders NEC	10028964
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to promote the LLT Neonatal epileptic seizure from PT Neonatal seizure to primary HLT Seizures and seizure disorders NEC in SOC Nervous system disorders and secondary HLT Neonatal neurological system disorders NEC in SOC Pregnancy, puerperium and perinatal conditions is approved as requested. This change request is part of a neonatal adverse event terminology mapping initiative. There is agreement after consulting a specialist from this initiative, that neonatal epileptic seizure (EEG confirmed epilepsy per the International Neonatal Consortium (INC) definition) is a distinct medical concept.

Supplemental Update Report

CR Number: 2018276004 **Implementation Date:** 10-Oct-18 Related CR: 2018276004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pulmonary haemorrhage neonatal*	Approved as Requested	Proposed PT	
HLT primary	*Newborn respiratory disorders NEC*		*Pulmonary haemorrhage neonatal*	10082194
SOC primary	*Respiratory, thoracic and mediastinal disorders*		HLT primary	
			Newborn respiratory disorders NEC	10027689
			SOC primary	
			Respiratory, thoracic and mediastinal disorders	10038738
			HLT secondary	
			Neonatal respiratory disorders NEC	10028972
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new PT Pulmonary haemorrhage neonatal to primary HLT Newborn respiratory disorders NEC in SOC Respiratory, thoracic and mediastinal disorders and secondary HLT Neonatal respiratory disorders NEC in SOC Pregnancy, puerperium and perinatal conditions is approved as requested. Furthermore, PT Pulmonary haemorrhage neonatal will be linked to HLT Haemorrhages NEC, as well. In related changes, the American English counterpart LLT Pulmonary hemorrhage neonatal will be added to new PT Pulmonary haemorrhage neonatal. In addition, to match International Neonatal Consortium (INC) terms and in the natural word order, LLT Neonatal pulmonary hemorrhage and LLT Neonatal pulmonary haemorrhage will be added to new PT Pulmonary haemorrhage neonatal. Also, non-current LLTs Pulmonary hemorrhage of fetus or newborn and Pulmonary haemorrhage of fetus or newborn will be moved from PT Respiratory tract haemorrhage neonatal to new PT Pulmonary haemorrhage neonatal. This change request is made in the context of a wider effort to standardize adverse event severity terminology for neonates from the INC and part of a mapping initiative to MedDRA.

CR Number: 2018281007 **Implementation Date:** 10-Oct-18 Related CR: 2018276004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pulmonary hemorrhage neonatal*	Approved as Requested	Proposed LLT	
To PT	*Pulmonary haemorrhage neonatal*		*Pulmonary hemorrhage neonatal*	10082197 Current
			To PT	
			Pulmonary haemorrhage neonatal	10082194

MSSO Comment:

Supplemental Update Report

CR Number: 2018281008 **Implementation Date:** 10-Oct-18 Related CR: 2018276004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Neonatal pulmonary haemorrhage*	Approved as Requested	Proposed LLT		
To PT	*Pulmonary haemorrhage neonatal*		*Neonatal pulmonary haemorrhage*	10082198	Current
			To PT		
			Pulmonary haemorrhage neonatal	10082194	

MSSO Comment:

CR Number: 2018281009 **Implementation Date:** 10-Oct-18 Related CR: 2018276004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Neonatal pulmonary hemorrhage*	Approved as Requested	Proposed LLT		
To PT	*Pulmonary haemorrhage neonatal*		*Neonatal pulmonary hemorrhage*	10082199	Current
			To PT		
			Pulmonary haemorrhage neonatal	10082194	

MSSO Comment:

CR Number: 2018281010 **Implementation Date:** 10-Oct-18 Related CR: 2018276004

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Pulmonary hemorrhage of fetus or newborn*	Approved as Requested	Proposed LLT		
From PT	*Respiratory tract haemorrhage neonatal*		*Pulmonary hemorrhage of fetus or newborn*	10037398	Non-Current
To PT	*Pulmonary haemorrhage neonatal*		From PT		
			Respiratory tract haemorrhage neonatal	10038728	
			To PT		
			Pulmonary haemorrhage neonatal	10082194	

MSSO Comment:

Supplemental Update Report

CR Number: 2018281011 **Implementation Date:** 10-Oct-18 Related CR: 2018276004

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Pulmonary haemorrhage of fetus or newborn*	Approved as Requested	Proposed LLT		
From PT	*Respiratory tract haemorrhage neonatal*		*Pulmonary haemorrhage of fetus or newborn*	10037395	Non-Current
To PT	*Pulmonary haemorrhage neonatal*		From PT		
			Respiratory tract haemorrhage neonatal	10038728	
			To PT		
			Pulmonary haemorrhage neonatal	10082194	

MSSO Comment:

CR Number: 2018281014 **Implementation Date:** 10-Oct-18 Related CR: 2018276004

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pulmonary haemorrhage neonatal*	Approved as Requested	Proposed PT	
To HLT	*Haemorrhages NEC*		*Pulmonary haemorrhage neonatal*	10082194
			To HLT	
			Haemorrhages NEC	10018987

MSSO Comment:

CR Number: 2018276005 **Implementation Date:** 10-Oct-18 Related CR: 2018276005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Persistent pulmonary hypertension of the newborn*	Approved as Requested	Proposed LLT		
To PT	*Newborn persistent pulmonary hypertension*		*Persistent pulmonary hypertension of the newborn*	10082195	Current
			To PT		
			Newborn persistent pulmonary hypertension	10053592	

MSSO Comment: The proposal to add a new LLT Persistent pulmonary hypertension of the newborn to PT Newborn persistent pulmonary hypertension is approved as requested. This change request is made in the context of a wider effort to standardize adverse event severity terminology for neonates from the International Neonatal Consortium (INC) and part of a mapping initiative to MedDRA. Persistent pulmonary hypertension of the newborn represents the natural word order for the INC concept.

Supplemental Update Report

CR Number: 2018276006 **Implementation Date:** 10-Oct-18 Related CR: 2018276006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*PPHN*	Rejected		
To PT	*Newborn persistent pulmonary hypertension*			

MSSO Comment: The proposal to add a new LLT PPHN to PT Newborn persistent pulmonary hypertension is not approved. PPHN is not a unique acronym for the recently added LLT Persistent pulmonary hypertension of the newborn. It is also used, e.g., for Progressive Passive Heymann Nephritis, or Postoperative Pulmonary Hypertension.

CR Number: 2018276007 **Implementation Date:** 10-Oct-18 Related CR: 2018276007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Spontaneous neonatal intestinal perforation*	Approved as Requested	Proposed LLT	
To PT	*Neonatal intestinal perforation*		*Spontaneous neonatal intestinal perforation*	
			To PT	
			Neonatal intestinal perforation	10074160

MSSO Comment: The proposal to add a new LLT Spontaneous neonatal intestinal perforation to PT Neonatal intestinal perforation is approved as requested. This change request is made in the context of a wider effort to standardize adverse event severity terminology for neonates from the International Neonatal Consortium (INC) and part of a mapping initiative to MedDRA. Spontaneous neonatal intestinal perforation is a perforation in the gastrointestinal tract of a newborn with no demonstrable cause.

Supplemental Update Report

CR Number: 2018276008 **Implementation Date:** 10-Oct-18 Related CR: 2018276008

Change Requested	Add a New PT
Proposed PT	*Administration site reaction neonatal*
HLT primary	*Administration site reactions NEC*
SOC primary	*General disorders and administration site conditions*

Final Disposition
Approved as Requested

Final Placement	MedDRA Code #
Proposed PT	
Administration site reaction neonatal	10082193
HLT primary	
Administration site reactions NEC	10057196
SOC primary	
General disorders and administration site conditions	10018065
HLT secondary	
Newborn complications NEC	10010168
SOC secondary	
Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new PT Administration site reaction neonatal to primary HLT Administration site reactions NEC in primary SOC General disorders and administration site conditions and secondary HLT Newborn complications NEC in secondary SOC Pregnancy, puerperium and perinatal conditions is approved as requested. Please note HLT Administration site reactions NEC is biaxial at the HLGT level to primary SOC General disorders and administration site conditions and secondary SOC Injury, poisoning and procedural complications. This change request refers to recently rejected CR 2018241010 to add PT Administration site complication neonatal from the International Neonatal Consortium (INC) adverse event terminology. The following rationale was provided by the submitter - "We lack an umbrella term under which many local administration reactions and complications can be captured for different forms of administration (IV, local e.g.). Can either remain generic, or preferably a neonatal term." Following a meeting with the members of that initiative it was reconsidered and agreed to provide such an umbrella term named Administration site reaction neonatal.

Supplemental Update Report

CR Number: 2018276009 **Implementation Date:** 10-Oct-18 Related CR: 2018276009

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*High-pitched crying*	Approved as Requested	Proposed LLT	
From PT	*Crying*		*High-pitched crying*	10052286
HLT primary	*General signs and symptoms NEC*		From PT	
			Crying	10011469
			HLT primary	
			General signs and symptoms NEC	10018072
			SOC primary	
			General disorders and administration site conditions	10018065
			HLT secondary	
			Neurological signs and symptoms NEC	10029306
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to promote the LLT High-pitched crying from PT Crying to primary HLT General signs and symptoms NEC in SOC General disorders and administration site conditions and secondary HLTs Neurological signs and symptoms NEC and Vaccination related complications is approved as requested. High-pitched crying most often applies to vaccination and is specific to infants/neonates. Furthermore, non-current LLT Crying DPT vaccine related will be moved from PT Crying to the promoted PT High-pitched crying. This change request is made in the context of a wider effort to standardize adverse event severity terminology for neonates from the International Neonatal Consortium (INC) and part of a mapping initiative to MedDRA.

CR Number: 2018281012 **Implementation Date:** 10-Oct-18 Related CR: 2018276009

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Crying DPT vaccine related*	Approved as Requested	Proposed LLT	
From PT	*Crying*		*Crying DPT vaccine related*	10011471 Non-Current
To PT	*High-pitched crying*		From PT	
			Crying	10011469
			To PT	
			High-pitched crying	10052286

MSSO Comment:

Supplemental Update Report

CR Number: 2018283009 **Implementation Date:** 10-Oct-18 Related CR: 2018276009

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*High-pitched crying*	Approved as Requested	Proposed PT	
To HLT	*Vaccination related complications*		*High-pitched crying*	10052286
			To HLT	
			Vaccination related complications	10068755

MSSO Comment:

CR Number: 2018276010 **Implementation Date:** 10-Oct-18 Related CR: 2018276010

Change Requested	Reassign Primary SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Agitation neonatal*	Approved as Requested	Proposed PT	
Old Primary SOC	*Psychiatric disorders*		*Agitation neonatal*	10001500
New Primary SOC	*Nervous system disorders*		Old Primary SOC	
			Psychiatric disorders	10037175
			New Primary SOC	
			Nervous system disorders	10029205

MSSO Comment: The proposal to reassign the primary SOC of PT Agitation neonatal from current SOC Psychiatric disorders to SOC Nervous system disorders is approved as requested. This change request is made in the context of a wider effort to standardize adverse event severity terminology for neonates from the International Neonatal Consortium (INC) and part of a mapping initiative to MedDRA. Similar to irritation in infants or neonates the event should not be classified as psychiatric of origin. Therefore, in a related change, the link from PT Agitation neonatal to HLT Anxiety symptoms will be removed.

CR Number: 2018281013 **Implementation Date:** 10-Oct-18 Related CR: 2018276010

Change Requested	Unlink a PT from a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Agitation neonatal*	Approved as Requested	Proposed PT	
From HLT	*Anxiety symptoms*		*Agitation neonatal*	10001500
			From HLT	
			Anxiety symptoms	10002869

MSSO Comment:

Supplemental Update Report

CR Number: 2018276011 **Implementation Date:** 08-Oct-18 Related CR: 2018276011

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Reaction to fragrance*	Approved as Requested	Proposed LLT	
To PT	*Perfume sensitivity*		*Reaction to fragrance*	10082186 Current
			To PT	
			Perfume sensitivity	10034434

MSSO Comment: The proposal to add a new LLT Reaction to fragrance to PT Perfume sensitivity is approved as requested. Reaction to fragrance represents a nonspecific phenomenon caused by the action of a chemical agent in a perfume or a scented cosmetic product that has not necessarily been confirmed as an allergic or hypersensitivity response. As with other existing "reaction" term concepts, LLT Reaction to fragrance provides a coding option for such a verbatim report.

CR Number: 2018276012 **Implementation Date:** 08-Oct-18 Related CR: 2018276012

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Nasal mucosal blistering*	Approved as Requested	Proposed PT	
HLT primary	*Nasal disorders NEC*		*Nasal mucosal blistering*	10082185
SOC primary	*Respiratory, thoracic and mediastinal disorders*		HLT primary	
			Nasal disorders NEC	10028731
			SOC primary	
			Respiratory, thoracic and mediastinal disorders	10038738

MSSO Comment: The proposal to add a new PT Nasal mucosal blistering to primary HLT Nasal disorders NEC in SOC Respiratory, thoracic and mediastinal disorders is approved as requested. Blistering in the nasal mucosa may be associated with etiologies that include infections such as herpes simplex virus, autoimmunological disorders such as pemphigus, exposure to drugs and chemicals, etc.

CR Number: 2018276013 **Implementation Date:** 08-Oct-18 Related CR: 2018276013

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Akinaesthesia*	Rejected		
From HLT	*Sensory abnormalities NEC*			
To HLT	*Paraesthesias and dysaesthesias*			

MSSO Comment: The proposal to move the PT Akinaesthesia from HLT Sensory abnormalities NEC to HLT Paraesthesias and dysaesthesias is not approved. Because Akinaesthesia is defined as the absence or loss of the sense of movement, rather than a paraesthesia or dysaesthesia, the current placement of PT Akinaesthesia under HLT Sensory abnormalities NEC seems appropriate.

Supplemental Update Report

CR Number: 2018276014 **Implementation Date:** 08-Oct-18 Related CR: 2018276014

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Anaesthesia dolorosa*	Approved as Requested	Proposed PT	
From HLT	*Sensory abnormalities NEC*		*Anaesthesia dolorosa*	10054878
To HLT	*Paraesthesias and dysaesthesias*		From HLT	
			Sensory abnormalities NEC	10040021
			To HLT	
			Paraesthesias and dysaesthesias	10033788

MSSO Comment: The proposal to move the PT Anaesthesia dolorosa from HLT Sensory abnormalities NEC to HLT Paraesthesias and dysaesthesias is approved as requested. This request is based on a proactivity proposal to review the placement of anaesthesia terms.

CR Number: 2018276015 **Implementation Date:** 08-Oct-18 Related CR: 2018276015

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Anaesthesia*	Approved as Requested	Proposed PT	
From HLT	*Sensory abnormalities NEC*		*Anaesthesia*	10002091
To HLT	*Paraesthesias and dysaesthesias*		From HLT	
			Sensory abnormalities NEC	10040021
			To HLT	
			Paraesthesias and dysaesthesias	10033788

MSSO Comment: The proposal to move the PT Anaesthesia from HLT Sensory abnormalities NEC to HLT Paraesthesias and dysaesthesias is approved as requested. This request is based on a proactivity proposal to review the placement of anaesthesia terms.

CR Number: 2018276016 **Implementation Date:** 08-Oct-18 Related CR: 2018276016

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hemianaesthesia*	Approved as Requested	Proposed PT	
From HLT	*Sensory abnormalities NEC*		*Hemianaesthesia*	10077170
To HLT	*Paraesthesias and dysaesthesias*		From HLT	
			Sensory abnormalities NEC	10040021
			To HLT	
			Paraesthesias and dysaesthesias	10033788

MSSO Comment: The proposal to move the PT Hemianaesthesia from HLT Sensory abnormalities NEC to HLT Paraesthesias and dysaesthesias is approved as requested. This request is based on a proactivity proposal to review the placement of anaesthesia terms.

Supplemental Update Report

CR Number: 2018276017 **Implementation Date:** 08-Oct-18 Related CR: 2018276017

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Thermoanaesthesia*	Approved as Requested	Proposed PT	
From HLT	*Sensory abnormalities NEC*		*Thermoanaesthesia*	10068010
To HLT	*Paraesthesias and dysaesthesias*		From HLT	
			Sensory abnormalities NEC	10040021
			To HLT	
			Paraesthesias and dysaesthesias	10033788

MSSO Comment: The proposal to move the PT Thermoanaesthesia from HLT Sensory abnormalities NEC to HLT Paraesthesias and dysaesthesias is approved as requested. This request is based on a proactivity proposal to review the placement of anaesthesia terms.

CR Number: 2018278001 **Implementation Date:** 11-Oct-18 Related CR: 2018278001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Product foaming*	Approved as Requested	Proposed LLT	
To PT	*Liquid product physical issue*		*Product foaming*	10082215 Current
			To PT	
			Liquid product physical issue	10069224

MSSO Comment: The proposal to add a new LLT Product foaming to PT Liquid product physical issue is approved as requested. Foam is a substance formed by trapping pockets of gas in a liquid or solid. Shaking of blood products such as immunoglobulins during reconstitution can cause foaming and may inactivate the immune globulin in solution.

CR Number: 2018278002 **Implementation Date:** 11-Oct-18 Related CR: 2018278002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Spinal canal stenosis*	Approved as Requested	Proposed LLT	
			Spinal canal stenosis	10082216 Current
			To PT	
			Spinal stenosis	10082214

MSSO Comment: The proposal to add a new LLT Spinal canal stenosis is approved as requested. Spinal stenosis is an abnormal narrowing of the spinal canal or neural foramen that results in pressure on the spinal cord or nerve roots. Spinal canal stenosis will be added as an LLT to new PT Spinal stenosis, the more prevalent expression. In a related change, new PT Spinal stenosis will be added to primary HLT Spine and neck deformities and secondary HLT Spinal cord and nerve root disorders NEC. Furthermore, PT Spinal column stenosis will be merged under the new PT Spinal stenosis. Spinal column is a misnomer for the concept and used to be an LLT under PT Spinal stenosis NOS starting in MedDRA version 2.1 and swapped with Spinal column stenosis in version 6.1.

Supplemental Update Report

CR Number: 2018284001 **Implementation Date:** 11-Oct-18 Related CR: 2018278002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Spinal stenosis*	Approved as Requested	Proposed PT	
HLT primary	*Spine and neck deformities*		*Spinal stenosis*	10082214
SOC primary	*Musculoskeletal and connective tissue disorders*		HLT primary	
			Spine and neck deformities	10012140
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395
			HLT secondary	
			Spinal cord and nerve root disorders NEC	10041544
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment:

CR Number: 2018284002 **Implementation Date:** 11-Oct-18 Related CR: 2018278002

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Spinal column stenosis*	Approved as Requested	PT to merge	
To PT	*Spinal stenosis*		*Spinal column stenosis*	10041540 Current
			To PT	
			Spinal stenosis	10082214

MSSO Comment:

Supplemental Update Report

CR Number: 2018278003 **Implementation Date:** 11-Oct-18 Related CR: 2018278003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Medical device site fistula*	Approved as Requested	Proposed PT	
			Medical device site fistula	10082217
HLT primary	*Complications associated with device NEC*		HLT primary	
			Complications associated with device NEC	10069785
SOC primary	*General disorders and administration site conditions*		SOC primary	
			General disorders and administration site conditions	10018065
			HLT secondary	
			Soft tissue disorders NEC	10041288
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new PT Medical device site fistula to primary HLT Complications associated with device NEC in SOC General disorders and administration site conditions is approved as requested. A fistula that develops at the site of a medical device that is situated in or on the body can be considered to be a complication of a medical device. Medical device site fistula will be added as a new PT to primary HLT Complications associated with device NEC, to secondary HLT Soft tissue disorders NEC and to secondary HLT Device site reactions.

CR Number: 2018284003 **Implementation Date:** 11-Oct-18 Related CR: 2018278003

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Medical device site fistula*	Approved as Requested	Proposed PT	
			Medical device site fistula	10082217
To HLT	*Device site reactions*		To HLT	
			Device site reactions	10077527

MSSO Comment:

Supplemental Update Report

CR Number: 2018278004 **Implementation Date:** 11-Oct-18 Related CR: 2018278004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gap junction protein beta 2 gene mutation*	Approved Not as Requested	Proposed PT	
HLT primary	*Chromosomal abnormalities NEC*		*Gap junction protein beta 2 gene mutation*	10082218
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Abnormal gene carriers	10052636
			SOC primary	
			Congenital, familial and genetic disorders	10010331

MSSO Comment: The proposal to add a new PT Gap junction protein beta 2 gene mutation to primary HLT Chromosomal abnormalities NEC in SOC Congenital, familial and genetic disorders is approved but not as requested. The gap junction protein beta 2 gene encodes the gap junction beta-2 protein, also known as Connexin 26, a member of the gap junction protein family. Mutations in this gene are responsible for as much as 50% of pre-lingual, recessive deafness. In addition, Connexin 26 also plays a role in tumor suppression through mediation of the cell cycle Gap junction protein beta 2 gene mutation will be added as a new PT to HLT Abnormal gene carriers. Please note that the MSSO will review current hierarchy for better representation of gene defects. In a related change, LLT GJB2 gene mutation will be added to new PT Gap junction protein beta 2 gene mutation.

CR Number: 2018284004 **Implementation Date:** 11-Oct-18 Related CR: 2018278004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*GJB2 gene mutation*	Approved as Requested	Proposed LLT	
To PT	*Gap junction protein beta 2 gene mutation*		*GJB2 gene mutation*	10082219 Current
			To PT	
			Gap junction protein beta 2 gene mutation	10082218

MSSO Comment:

CR Number: 2018281001 **Implementation Date:** 11-Oct-18 Related CR: 2018281001

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Chemical iritis*	Approved as Requested	PT to merge	
To PT	*Chemical burns of eye*		*Chemical iritis*	10073680 Current
			To PT	
			Chemical burns of eye	10008422

MSSO Comment: The proposal to demote the PT Chemical iritis under PT Chemical burns of eye is approved as requested. This change request is related to proactivity initiative 70; review the placement of chemical burns vs corrosive injuries. Merging PT Chemical iritis will reduce over-granulation at PT level of anatomically close related concepts.

Supplemental Update Report

CR Number: 2018281002 **Implementation Date:** 11-Oct-18 Related CR: 2018281002

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Chemical phlebitis*	Approved as Requested	Proposed LLT	
From PT	*Phlebitis*		*Chemical phlebitis*	10067560
HLT primary	*Chemical injuries*		From PT	
			Phlebitis	10034879
			HLT primary	
			Chemical injuries	10008424
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Phlebitis NEC	10052780
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to promote the LLT Chemical phlebitis from PT Phlebitis to primary HLT Chemical injuries in SOC Injury, poisoning and procedural complications and secondary HLT Phlebitis NEC in SOC Vascular disorders is approved as requested. This change request is related to the proactivity initiative 70; review the placement of chemical burns vs corrosive injuries. All "chemical" burns/injuries/-itis concepts need to have a consistent representation in MedDRA with primary HLT Chemical injuries.

CR Number: 2018281003 **Implementation Date:** 11-Oct-18 Related CR: 2018281003

Change Requested	Swap a PT with an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Corrosive oropharyngeal injury*	Approved as Requested	Proposed PT	
With LLT	*Chemical burn of oral cavity*		*Corrosive oropharyngeal injury*	10070816 Current
			With LLT	
			Chemical burn of oral cavity	10070782

MSSO Comment: The proposal to swap the PT Corrosive oropharyngeal injury with the LLT Chemical burn of oral cavity is approved as requested. This change request is related to pro-activity initiative 70; review the placement of chemical burns vs corrosive injuries. Chemical burn is broader than corrosive injury.

Supplemental Update Report

CR Number: **2018281004** **Implementation Date:** 11-Oct-18 Related CR: 2018281004

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Reactive gastropathy*	Approved as Requested	Proposed PT	
To HLT	*Chemical injuries*		*Reactive gastropathy*	10075425
			To HLT	
			Chemical injuries	10008424

MSSO Comment: The proposal to link the PT Reactive gastropathy to the HLT Chemical injuries is approved as requested. This change request is related to pro-activity initiative 70; review the placement of chemical burns vs corrosive injuries. Reactive gastropathy, also called chemical gastropathy, is an abnormality in the stomach caused by chemicals, e.g. bile, alcohol, Nonsteroidal anti-inflammatory drugs (NSAIDs) and characteristically has minimal inflammation. In a related change, the primary SOC for PT Reactive gastropathy will be reassigned from SOC Gastrointestinal disorders to SOC Injury, poisoning and procedural complications.

CR Number: **2018284005** **Implementation Date:** 11-Oct-18 Related CR: 2018281004

Change Requested	Reassign Primary SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Reactive gastropathy*	Approved as Requested	Proposed PT	
Old Primary SOC	*Gastrointestinal disorders*		*Reactive gastropathy*	10075425
			Old Primary SOC	
New Primary SOC	*Injury, poisoning and procedural complications*		*Gastrointestinal disorders*	10017947
			New Primary SOC	
			Injury, poisoning and procedural complications	10022117

MSSO Comment:

CR Number: **2018281005** **Implementation Date:** 11-Oct-18 Related CR: 2018281005

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Chemical eye injury*	Approved as Requested	PT to merge	
To PT	*Chemical burns of eye*		*Chemical eye injury*	10055116 Current
			To PT	
			Chemical burns of eye	10008422

MSSO Comment: The proposal to demote the PT Chemical eye injury under PT Chemical burns of eye is approved as requested. This change request is related to proactivity initiative 70; review the placement of chemical burns vs corrosive injuries. Chemical injury and chemical burn are synonymously used.

Supplemental Update Report

CR Number: 2018284006 **Implementation Date:** 19-Oct-18 Related CR: 2018284006

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Spontaneous neonatal intestinal perforation*	Approved as Requested	Term to modify	
Replacement term	*Neonatal spontaneous intestinal perforation*		*Spontaneous neonatal intestinal perforation*	
			Replacement term	
			Neonatal spontaneous intestinal perforation	10082196 Current

MSSO Comment: The proposal to rename PT/LLT Spontaneous neonatal intestinal perforation to Neonatal spontaneous intestinal perforation is approved as requested. This change request is made in the context of a wider effort to standardize adverse event severity terminology for neonates from INC (International Neonatal Consortium)and part of a mapping initiative to MedDRA. The term will be renamed to match the word order of the term in the INC terminology.

CR Number: 2018284007 **Implementation Date:** 19-Oct-18 Related CR: 2018284007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Brain dislocation syndrome*	Approved as Requested	Proposed PT	
			Brain dislocation syndrome	10082220
			HLT primary	
			Increased intracranial pressure disorders	10062912
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Cerebral injuries NEC	10052638
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new PT Brain dislocation syndrome is approved as requested. Dislocation syndrome occurs at elevated intracranial pressure and has several potential etiologic pathologies such stroke, severe head injury with herniation of structures or tumors. The clinical symptomatology depends on the extent of the intracranial pressure and increase of volume of cranial Contents. Dislocation syndrome manifests as intense headache, vomiting, dizziness, gaze palsy, decreased pupillary light reaction etc. followed by loss of consciousness and coma. Brain dislocation syndrome will be placed as PT to primary HLT Increased intracranial pressure disorders and secondary HLT Cerebral injuries NEC.

Supplemental Update Report

CR Number: 2018285001 **Implementation Date:** 19-Oct-18 Related CR: 2018285001

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Arteriovenous fistula access site rupture*	Approved as Requested	Term to modify *Arteriovenous fistula access site rupture*	
Replacement term	*Arteriovenous fistula site rupture*		Replacement term *Arteriovenous fistula site rupture*	10082098 Current

MSSO Comment: The proposal to rename PT/LLT Arteriovenous fistula access site rupture to Arteriovenous fistula site rupture is approved as requested. Arteriovenous fistula access and arteriovenous fistula site indeed are synonymously used and redundant to represent both in one concept.

CR Number: 2018285002 **Implementation Date:** 19-Oct-18 Related CR: 2018285002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Automatic positive airway pressure*	Approved as Requested	Proposed PT *Automatic positive airway pressure*	10082223
			HLT primary *Respiratory tract therapeutic procedures NEC*	10052727
			SOC primary *Surgical and medical procedures*	10042613

MSSO Comment: The proposal to add a new term Automatic positive airway pressure is approved as requested. In contrast to Continuous Positive Airway Pressure therapy, which is set to deliver one continuous pressure, automatic positive airway pressure is set within a high and low pressure range for the purpose of providing specific inhalation needs for individual patients, as the machine is able to detect how much inhalation pressure is needed with each breath. Automatic positive airway pressure will be added as a new PT to HLT Respiratory tract therapeutic procedures NEC.

Supplemental Update Report

CR Number: 2018285003 **Implementation Date:** 19-Oct-18 Related CR: 2018285003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Enzymatic activity assay*	Approved Not as Requested	Proposed PT	
			Enzyme activity assay	10082222
			HLT primary	
			Tissue enzyme analyses NEC	10043891
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new term Enzymatic activity assay is approved but not as requested. The vast majority of catalyzing biological processes is performed by enzymes which provide a wide variety of functions inside living organisms. They are indispensable for metabolic processes, cellular signaling and regulation and can generate movement and active transport of molecules. Enzymatic reactions specifically convert substrate molecules into chemically modified products. These modifications include proteolytic or glycolytic degradation, chemical modifications such as phosphorylation, acylation, glycosylation or oxidative and reductive processes. Dysregulated enzyme activity can lead to disease states. As a result enzymes are considered to be attractive targets for pharmacological intervention in drug therapy. The proposed term, Enzymatic activity assay, will be modified to Enzyme activity assay to conform with existing qualified terms such as PT Enzyme activity increased, and added as a new PT to HLT Tissue enzyme analyses NEC.

CR Number: 2018285004 **Implementation Date:** 19-Oct-18 Related CR: 2018285004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Congenital nasal septum deviation*	Approved as Requested	Proposed PT	
			Congenital nasal septum deviation	10082221
			HLT primary	
			Nasal disorders congenital	10028739
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Nasal disorders NEC	10028731
			SOC secondary	
			Respiratory, thoracic and mediastinal disorders	10038738

MSSO Comment: The proposal to add a new term Congenital nasal septum deviation is approved as requested. A deviated septum is a condition in which the nasal septum -- the bone and cartilage that divide the nasal cavity of the nose in half -- is significantly off center, and may result in impaired breathing through the nose. Congenital nasal septal anomalies are rare and tend to have fairly typical imaging features. Congenital nasal septum deviation will be added as a new PT to primary HLT Nasal disorders congenital, and to secondary HLT Nasal disorders NEC.

Supplemental Update Report

CR Number: 2018285005 **Implementation Date:** 19-Oct-18 Related CR: 2018285005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #	
Proposed Term	*Therapeutic tumor infiltrating lymphocytes*	Approved as Requested	Proposed LLT		
			Therapeutic tumor infiltrating lymphocytes	10082224	Current
			To PT		
			Lymphocyte adoptive therapy	10025250	

MSSO Comment: The proposal to add a new term Therapeutic tumor infiltrating lymphocytes is approved as requested. Therapeutic tumor infiltrating lymphocytes is a preparation of cells consisting of autologous tumor infiltrating lymphocytes, that are manipulated in vitro and, upon administration in vivo, re-infiltrate the tumor to initiate tumor cell lysis. In vitro, therapeutic tumor-infiltrating lymphocytes are isolated from tumor tissue and cultured with lymphokines such as interleukin-2; the therapeutic tumor infiltrating lymphocytes are then infused into the patient, where, after re-infiltration of the tumor, they may induce lysis of tumor cells and tumor regression. The use of therapeutic TILs is considered a form of adoptive immunotherapy. Therapeutic tumor infiltrating lymphocytes will be added as a sub-concept LLT to PT Lymphocyte adoptive therapy. In a related change, the British spelled counterpart LLT Therapeutic tumour infiltrating lymphocytes will also be added to PT Lymphocyte adoptive therapy.

CR Number: 2018292035 **Implementation Date:** 19-Oct-18 Related CR: 2018285005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Therapeutic tumour infiltrating lymphocytes*	Approved as Requested	Proposed LLT		
To PT	*Lymphocyte adoptive therapy*		*Therapeutic tumour infiltrating lymphocytes*	10082225	Current
			To PT		
			Lymphocyte adoptive therapy	10025250	

MSSO Comment:

Supplemental Update Report

CR Number: 2018285006 **Implementation Date:** 19-Oct-18 Related CR: 2018285006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Infant dyschezia*	Approved as Requested	Proposed PT	
			Infant dyschezia	10082228
			HLT primary	
			Gastrointestinal dyskinetic disorders	10017950
			SOC primary	
			Gastrointestinal disorders	10017947
			HLT secondary	
			Neonatal gastrointestinal disorders	10028940
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new PT Infant dyschezia is approved as requested. Infant dyschezia is a functional condition characterized by excessive straining and crying before successful or unsuccessful passage of soft stools in an otherwise healthy infant less than six months of age. Defecation requires two coordinated events: Pelvic floor relaxation, and an increase in intra-abdominal pressure (bearing down to have a bowel movement). Children with infant dyschezia have not yet developed this coordination so they are unable to enjoy easy defecation. Infant dyschezia will be added as a new PT to primary HLT Gastrointestinal dyskinetic disorders, and to secondary HLT Neonatal gastrointestinal disorders.

CR Number: 2018285007 **Implementation Date:** 19-Oct-18 Related CR: 2018285007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Biliary pancreatitis*	Approved as Requested	Proposed LLT	
			Biliary pancreatitis	10082229 Current
			To PT	
			Obstructive pancreatitis	10079822

MSSO Comment: The proposal to add a new LLT Biliary pancreatitis is approved as requested. Biliary pancreatitis (also known as obstructive pancreatitis) refers to pancreatitis caused by gallstones, specifically distal choledocholithiasis. Gallstones are a leading cause of pancreatitis worldwide, which can develop into significant sequelae, including an overall mortality of 2-7%. The exact pathophysiology of gallstone pancreatitis remains unclear, as there are a number of theories which include: distal gallstone obstruction results in pancreatic duct obstruction, and progressed to increased pancreatic duct pressure and unregulated pancreatic enzyme activity; acinar cell hyperstimulation has been implicated; infected bile reflux inducing pancreatic enzyme action. Biliary pancreatitis is a set expression and will be added as a sub-concept LLT to PT Obstructive pancreatitis.

Supplemental Update Report

CR Number: 2018285008 **Implementation Date:** 19-Oct-18 Related CR: 2018285008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Anti-MuSK Antibody Myasthenia Gravis*	Approved Not as Requested	Proposed LLT	
			MuSK myasthenia gravis	10082226 Current
			To PT	
			Myasthenia gravis	10028417

MSSO Comment: The proposal to add a new LLT Anti-MuSK Antibody Myasthenia Gravis is approved but not as requested. Approximately 5-8 % of myasthenia gravis (MG) patients test positive for antibodies against muscle- specific tyrosine kinase (MuSK) receptors. Except in extremely rare reports, all are acetylcholine receptor (AChR) antibody-negative. The requested term will be rephrased to MuSK myasthenia gravis and added as an LLT to PT Myasthenia gravis. In a related change, Anti-MuSK antibody positive will be added as an LLT to PT Anti-muscle specific kinase antibody positive to facilitate coding.

CR Number: 2018292036 **Implementation Date:** 19-Oct-18 Related CR: 2018285008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Anti-MuSK antibody positive*	Approved as Requested	Proposed LLT	
To PT	*Anti-muscle specific kinase antibody positive*		*Anti-MuSK antibody positive*	10082227 Current
			To PT	
			Anti-muscle specific kinase antibody positive	10072522

MSSO Comment:

Supplemental Update Report

CR Number: 2018286001 **Implementation Date:** 19-Oct-18 Related CR: 2018286001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Squamous cell carcinoma of the parotid gland*	Approved Not as Requested	Proposed PT	
			Squamous cell carcinoma of the parotid gland	10082230
			HLT primary	
			Salivary gland neoplasms malignant	10039396
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Malignant oral cavity neoplasms	10026660
			SOC secondary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new LLT Squamous cell carcinoma of the parotid gland is approved but not as requested. Primary squamous cell carcinoma of the parotid gland is a rare aggressive malignancy. It is a rapidly advancing lesion which, if not recognised and treated early, results in high morbidity and mortality. Despite radical surgery and adjuvant radiotherapy, prognosis of this cancer continues to be poor. The squamous cell carcinoma of salivary gland is a malignant epithelial tumor of major salivary glands composed of epidermoid cells. Squamous cell carcinoma of the parotid gland will be added as a PT to primary HLT Salivary gland neoplasms malignant and secondary HLT Malignant oral cavity neoplasms.

CR Number: 2018286002 **Implementation Date:** 19-Oct-18 Related CR: 2018286002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Disseminated mantle cell lymphoma*	Approved as Requested	Proposed LLT	
			Disseminated mantle cell lymphoma	10082231 Current
			To PT	
			Mantle cell lymphoma stage IV	10026805

MSSO Comment: The proposal to add a new LLT Disseminated mantle cell lymphoma is approved as requested. is a rare form of non-Hodgkin lymphoma that arises from cells originating in the “mantle zone.” It is an aggressive high-grade type of lymphoma that is fast growing and generally need to be treated immediately, although is frequently diagnosed at a late stage, in most cases involves the gastrointestinal tract and bone marrow. Disseminated mantle cell lymphoma will be placed as LLT to PT Mantle cell lymphoma stage IV.

Supplemental Update Report

CR Number: **2018286003** **Implementation Date:** 19-Oct-18 Related CR: 2018286003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Infected pimple*	Rejected		

MSSO Comment: The proposal to add a new LLT Infected pimple is not approved. The proposed concept is colloquial term and can be represented by spit coding, for example with LLT Pimple and LLT Skin infection.

CR Number: **2018286004** **Implementation Date:** 19-Oct-18 Related CR: 2018286004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pubic symphysis separation*	Approved as Requested	Proposed LLT	
			Pubic symphysis separation	10082232 Current
			To PT	
			Symphysiolysis	10042747

MSSO Comment: The proposal to add a new LLT Pubic symphysis separation is approved as requested. The diagnosis of pubic symphysis diastasis or separation is based on the persistence of symptoms and a symphysis pubis separation of more than 10 to 13 mm on imaging. Treatment is conservative, with bed rest and gradual mobilization if the diastasis is less than 25 mm, but extreme cases may require surgery. Pubic symphysis separation will be placed as an LLT to PT Symphysiolysis.

CR Number: **2018288001** **Implementation Date:** 25-Oct-18 Related CR: 2018288001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Subretinal hyperreflective exudation*	Approved Not as Requested	Proposed PT	
			Subretinal hyperreflective exudation	10082240
			HLT primary	
			Retinal structural change, deposit and degeneration	10038896
			SOC primary	
			Eye disorders	10015919

MSSO Comment: The proposal to add a new LLT Subretinal hyperreflective exudation is approved but not as requested. Subretinal hyperreflective exudation differs from other types of subretinal hyperreflective material (SHM) based on the findings from multimodal imaging. This novel type of SHM likely represents a sign of active neovascular age-related macular degeneration distinct from subretinal fluid, hemorrhage, neovascular tissue, lipid, pigment hyperplasia, subretinal fibrosis, and the SHM observed with acquired vitelliform lesions. Subretinal hyperreflective exudation will be added as PT to HLT Retinal structural change, deposit and degeneration.

Supplemental Update Report

CR Number: 2018288002 **Implementation Date:** 25-Oct-18 Related CR: 2018288002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pachydermodactyly*	Approved Not as Requested	Proposed PT	
			Pachydermodactyly	10082245
			HLT primary	
			Soft tissue neoplasms benign NEC	10041295
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Benign musculoskeletal and connective tissue neoplasms	10004297
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new LLT Pachydermodactyly is approved but not as requested. Pachydermodactyly is a superficial dermal fibromatosis that presents as a poorly circumscribed symmetric, infiltrative, asymptomatic soft-tissue hypertrophy of the proximal fingers, typically sparing the thumbs and fifth fingers and rarely extending proximally to the wrists or occurring distally. Pachydermodactyly predominantly affects adolescent males who usually have no family history, and may be associated with repetitive mechanical stimulations, and can be confused with joint disorders or rheumatologic diseases. Pachydermodactyly will be added as PT to primary HLT Soft tissue neoplasms benign NEC and secondary HLT Benign musculoskeletal and connective tissue neoplasms.

CR Number: 2018288003 **Implementation Date:** 25-Oct-18 Related CR: 2018288003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Sensitivity from specific antibiotic (Levaquin)*	Rejected		

MSSO Comment: The proposal to add a new LLT Sensitivity from specific antibiotic (Levaquin) is not approved. MedDRA cannot provide such high specifity regarding allergic reactions/sensitivity to particular antibiotics. The requested term can be represented by the broader LLT Allergic reaction to antibiotics.

Supplemental Update Report

CR Number: **2018288004** **Implementation Date:** 25-Oct-18 Related CR: 2018288004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*The Ex-PRESS Mini Glaucoma Shunt Excessive Pressure REgulation Shunt System*	Rejected		

MSSO Comment: The proposal to add a new LLT The Ex-PRESS Mini Glaucoma Shunt Excessive Pressure REgulation Shunt System is not approved. A newer glaucoma treatment is called the Ex-PRESS mini glaucoma shunt (excessive pressure regulating shunt system). The Ex-PRESS is a simple method of filtration for open-angle glaucoma and can be implanted following cataract surgery. The requested term represents a combination between a brand name and the explanation what "Ex-PRESS" stands for. Terms including trade names are out of scope of MedDRA. However, please see the broad LLT Glaucoma drainage device placement for your coding needs.

CR Number: **2018288005** **Implementation Date:** 25-Oct-18 Related CR: 2018288005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Interstim implant*	Rejected		

MSSO Comment: The proposal to add a new LLT Interstim implant is not approved. InterStim is a brand name of a device for bladder control. MedDRA does not represent brand names. Please review the broader LLT Urinary control neurostimulator implantation for your coding needs.

CR Number: **2018288006** **Implementation Date:** 25-Oct-18 Related CR: 2018288006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Sternoclavicular dislocation*	Approved as Requested	Proposed LLT *Sternoclavicular dislocation* To PT *Dislocation of sternum*	 10082251 Current 10054892

MSSO Comment: The proposal to add a new LLT Sternoclavicular dislocation is approved as requested. Dislocations of the sternoclavicular joint (SCJ) occur with relative infrequency and can be classified into anterior and posterior dislocation, with the former being more common. Sternoclavicular dislocation will be added as sub-concept LLT to PT Dislocation of sternum.

Supplemental Update Report

CR Number: **2018288007** **Implementation Date:** 25-Oct-18 Related CR: 2018288007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Partial edentulism*	Approved as Requested	Proposed LLT *Partial edentulism*	10082252 Current
			To PT *Tooth loss*	10044044

MSSO Comment: The proposal to add a new LLT Partial edentulism is approved as requested. Edentulism or toothlessness is the condition of being toothless to at least some degree; in organisms (such as humans) that naturally have teeth (dentition), it is the result of tooth loss. Loss of some teeth is called partial edentulism, whereas loss of all teeth is called complete edentulism. Partial edentulism will be placed as sub-concept LLT to PT Tooth loss.

CR Number: **2018288008** **Implementation Date:** 25-Oct-18 Related CR: 2018288008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Refractory benign esophageal stricture*	Approved as Requested	Proposed LLT *Refractory benign esophageal stricture*	10082257 Current
			To PT *Oesophageal stenosis*	10030194

MSSO Comment: The proposal to add a new LLT Refractory benign esophageal stricture is approved as requested. Benign esophageal strictures are seen frequently and are caused by a variety of esophageal injuries, such as gastroesophageal reflux, radiotherapy, corrosive substance ingestion, eosinophilic esophagitis, after esophageal resection, and as an adverse event of ablation. Refractory benign esophageal stricture will be added as an LLT to PT Oesophageal stenosis. In a related change, the British English counterpart spelled LLT Refractory benign oesophageal stricture will also be added to PT Oesophageal stenosis.

CR Number: **2018298005** **Implementation Date:** 25-Oct-18 Related CR: 2018288008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Refractory benign oesophageal stricture*	Approved as Requested	Proposed LLT	
To PT	*Oesophageal stenosis*		*Refractory benign oesophageal stricture*	10082266 Current
			To PT *Oesophageal stenosis*	10030194

MSSO Comment:

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CR Number: 2018288009 **Implementation Date:** 25-Oct-18 Related CR: 2018288009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Chemo therapy fatigue*	Approved Not as Requested	Proposed LLT	
			Chemotherapy fatigue	10082262 Current
			To PT	
			Cancer fatigue	10082239

MSSO Comment: The proposal to add a new LLT Chemo therapy fatigue is approved but not as requested. Fatigue, usually described as feeling tired, weak or exhausted, affects most people during cancer treatment. Cancer fatigue can result from the side effects of treatment or the cancer itself. Chemotherapy, radiation therapy, surgery, bone marrow transplantation and biological therapy may all may cause fatigue. The proposed term LLT Chemo therapy fatigue, will be rephrased to Chemotherapy fatigue and added as a sub-concept LLT to a new PT Cancer fatigue. In a related change, PT Cancer fatigue will be added to primary HLT Oncologic complications and emergencies, and to secondary HLT Asthenic conditions.

CR Number: 2018298006 **Implementation Date:** 25-Oct-18 Related CR: 2018288009

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cancer fatigue*	Approved as Requested	Proposed PT	
HLT primary	*Oncologic complications and emergencies*		*Cancer fatigue*	10082239
SOC primary	*Neoplasms benign, malignant and unspecified (incl cysts and polyps)*		HLT primary	
			Oncologic complications and emergencies	10030315
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Asthenic conditions	10003550
			SOC secondary	
			General disorders and administration site conditions	10018065

MSSO Comment:

Supplemental Update Report

CR Number: 2018288010 **Implementation Date:** 25-Oct-18 Related CR: 2018288010

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vaginal mesh removal surgery*	Approved Not as Requested	Proposed PT	
			Vaginal mesh removal surgery	10082241
			HLT primary	
			Vaginal therapeutic procedures	10046936
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT Vaginal mesh removal surgery is approved but not as requested. Transvaginal mesh implantation, performed most frequently for vaginal prolapse, may develop subsequent complications such as chronic pain, infection, bleeding, pain during intercourse, urinary disorders, and exposure of the mesh through the vagina. To alleviate such complications, complete transvaginal mesh removal is possible for some women, while only part of the mesh can be removed in other women due to complicated issues from the type of mesh that was originally used. PT Vaginal mesh removal surgery will be added to HLT Vaginal therapeutic procedures.

CR Number: 2018288011 **Implementation Date:** 25-Oct-18 Related CR: 2018288011

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Blephex procedure*	Approved Not as Requested	Proposed PT	
			Microblepharoexfoliation procedure	10082246
			HLT primary	
			Eyelid therapeutic procedures	10015994
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT Blephex procedure is approved but not as requested. Eyelid margin desquamation is a therapeutic procedure used in clinical ophthalmology and optometry to treat blepharitis and dry eye disease. The procedure entails removal of accumulated biofilm, eliminating the source of inflammation which leads to healthier, more comfortable eyelids and an increase in natural tear production. Because MedDRA does not include product trade names such as Blephex in the scope of the terminology, the proposed term will instead be added as new PT Microblepharoexfoliation procedure to HLT Eyelid therapeutic procedures. In a related change, sub-concept LLT Eyelid margin desquamation procedure will be added to PT Microblepharoexfoliation procedure as another descriptive term for this procedure.

CR Number: 2018298007 **Implementation Date:** 25-Oct-18 Related CR: 2018288011

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Eyelid margin desquamation procedure*	Approved as Requested	Proposed LLT	
To PT	*Microblepharoexfoliation procedure*		*Eyelid margin desquamation procedure*	10082267 Current
			To PT	
			Microblepharoexfoliation procedure	10082246

MSSO Comment:

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CR Number: 2018288012 **Implementation Date:** 25-Oct-18 Related CR: 2018288012

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*CT enterography*	Approved as Requested	Proposed LLT	
			CT enterography	10082258 Current
			To PT	
			Computerised tomogram intestine	10077359

MSSO Comment: The proposal to add a new LLT CT enterography is approved as requested. Computed tomographic enterography is an emerging alternative to traditional fluoroscopy for the assessment of disorders of the small bowel. The greatly improved spatial and temporal resolution provided by multidetector CT scanners, combined with good luminal distention provided by negative oral contrast agents and with good bowel wall and luminal visualization, have made CT enterography the main imaging modality not only for investigating proved or suspected inflammatory bowel disease but also for detecting occult gastrointestinal tract bleeding, small bowel neoplasms, and mesenteric ischemia. CT enterography will be added as a synonym LLT to PT Computerised tomogram intestine.

CR Number: 2018288013 **Implementation Date:** 25-Oct-18 Related CR: 2018288013

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Duplex ultrasound*	Approved as Requested	Proposed LLT	
			Duplex ultrasound	10082260 Current
			To PT	
			Ultrasound Doppler	10045412

MSSO Comment: The proposal to add a new LLT Duplex ultrasound is approved as requested. Duplex ultrasound is a specialized interpretation of ultrasound waves, and an integral tool in medical diagnosis and therapy today. Duplex ultrasonography combines the principles of anatomic and flow ultrasonography to deliver diagnostic information to the interpreter. Doppler ultrasonography refers to the utilization and application of the Doppler effect to sound wave information to interpret movement or flow within tissues in vascular pathology. Duplex ultrasound will be added as an a synonym LLT to PT Ultrasound Doppler.

CR Number: 2018288014 **Implementation Date:** 25-Oct-18 Related CR: 2018288014

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Geriatric assessment*	Approved Not as Requested	Proposed PT	
			Geriatric assessment	10082242
			HLT primary	
			Investigations NEC	10022892
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new LLT Geriatric assessment is approved but not as requested. Comprehensive geriatric assessment, or geriatric assessment, is a process which is used to manage frail or vulnerable older people. It is interdisciplinary taking into account inputs not only from doctors but also nurses and allied health professionals, and multidimensional, not only including medical diagnoses, but also functional impairments and the environmental and social issues which affect patient wellbeing. It produces problem lists and develops goal-driven interventions to coordinate an integrated plan for treatment, rehabilitation, support and long-term care. Geriatric assessment will be added as a new PT to HLT Investigations NEC.

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CR Number: 2018288015 **Implementation Date:** 25-Oct-18 Related CR: 2018288015

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Phoniatric Rehabilitation*	Approved Not as Requested	Proposed PT	
			Phoniatric rehabilitation	10082248
			HLT primary	
			Laryngeal therapeutic procedures	10023847
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT Phoniatric Rehabilitation is approved but not as requested. Phoniatrics focuses on the diagnosis and treatment of voice disorders, laryngeal dysfunctions, swallowing disorders difficulties, dysfluent and unclear speech and specific language impairment, and the consequent difficulties in communicating and learning. The new term represents a well defined relevant concept which warrants PT level, and will be added as PT Phoniatric rehabilitation, in accordance with MedDRA capitalization conventions, as PT under HLT Laryngeal therapeutic procedures.

CR Number: 2018288016 **Implementation Date:** 25-Oct-18 Related CR: 2018288016

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Photorejuvenation*	Approved Not as Requested	Proposed PT	
			Photorejuvenation	10082247
			HLT primary	
			Phototherapies	10034976
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT Photorejuvenation is approved but not as requested. Photorejuvenation is a skin treatment that uses lasers, intense pulsed light, or photodynamic therapy to treat skin conditions and remove effects of photoaging such as wrinkles, spots, and textures. Photorejuvenation will be added a PT to HLT Phototherapies.

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CR Number: 2018288017 **Implementation Date:** 25-Oct-18 Related CR: 2018288017

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Nonalcoholic fatty liver disease*	Approved Not as Requested	Proposed PT	
			Nonalcoholic fatty liver disease	10082249
			HLT primary	
			Hepatocellular damage and hepatitis NEC	10019833
			SOC primary	
			Hepatobiliary disorders	10019805
			HLT secondary	
			Lipid metabolism and deposit disorders NEC	10024581
			SOC secondary	
			Metabolism and nutrition disorders	10027433

MSSO Comment: The proposal to add a new LLT Nonalcoholic fatty liver disease is approved but not as requested. Nonalcoholic fatty liver disease (the most common chronic liver disease in many parts of the world) is strongly associated with overweight/obesity and insulin resistance. It encompasses a spectrum of liver pathology with different clinical prognoses, from the simple accumulation of triglyceride within hepatocytes (hepatic steatosis) on the most clinically benign extreme, to frank cirrhosis, with nonalcoholic steatohepatitis (NASH) as an intermediate stage. Nonalcoholic fatty liver disease will be added as a PT with a primary link to HLT Hepatocellular damage and hepatitis NEC, and a secondary link to HLT Lipid metabolism and deposit disorders NEC. In a related change, the less frequently used existing synonym PT Non-alcoholic fatty liver will be demoted under the new PT Nonalcoholic fatty liver disease.

CR Number: 2018298008 **Implementation Date:** 25-Oct-18 Related CR: 2018288017

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Non-alcoholic fatty liver*	Approved as Requested	PT to merge	
			Non-alcoholic fatty liver	10029530 Current
To PT	*Nonalcoholic fatty liver disease*		To PT	
			Nonalcoholic fatty liver disease	10082249

MSSO Comment:

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CR Number: 2018288018 **Implementation Date:** 25-Oct-18 Related CR: 2018288018

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Elective abortion*	Approved as Requested	Proposed LLT	
			Elective abortion	10082264 Current
			To PT	
			Abortion induced	10000220

MSSO Comment: The proposal to add a new LLT Elective abortion is approved as requested. An abortion is referred to as an elective or voluntary abortion when it is performed at the request of the woman for non-medical reasons. Elective abortion represents a circumstance of special relevance, both in its sociological and personal perspectives, which usually comports an important psychological stress, and thus will be added as an LLT to PT Abortion induced.

CR Number: 2018288019 **Implementation Date:** 25-Oct-18 Related CR: 2018288019

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Eyelid lesions*	Rejected		

MSSO Comment: The proposal to add a new LLT Eyelid lesions is not approved. To avoid the overpopulation of MedDRA, the MSSO refrains form adding lesion terms indiscriminately. Lesion terms are usually considered for inclusion in MedDRA when the word “lesion” is part of the wording of a medical concept e.g., PT Glomerulonephritis minimal lesion or is itself a well documented medical concept (e.g., LLT Bankart lesion). Generally, a broad “lesion” term only adds an additional imprecise term to existing “disorder” concepts. Please, consider existing PTs Eyelid disorder and/or Eyelid injury for your coding needs.

CR Number: 2018288020 **Implementation Date:** 25-Oct-18 Related CR: 2018288020

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Dextrostix*	Approved Not as Requested	Proposed LLT	
			Glucose strip test	10082253 Current
			To PT	
			Blood glucose	10005553

MSSO Comment: The proposal to add a new LLT Dextrostix is approved but not as requested. MedDRA refrains from adding trademark names. In order to represent the proposed concept, a new equivalent generic term named Glucose strip test will be added as an LLT under the PT Blood glucose.

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CR Number: 2018288021 **Implementation Date:** 25-Oct-18 Related CR: 2018288021

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Abdominal fat deposition*	Rejected		

MSSO Comment: The proposal to add a new LLT Abdominal fat deposition is not approved. The proposed concept can be represented by LLT Abdominal obesity under PT Central obesity.

CR Number: 2018288022 **Implementation Date:** 25-Oct-18 Related CR: 2018288022

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Smoke allergy*	Rejected		

MSSO Comment: The proposal to add a new LLT Smoke allergy is not approved. The existing LLT Smoke sensitivity, which mirrors the phrase used in the title of the provided reference, can be used for coding purposes. The literature reference also specifically rejects the demonstration of an allergic mechanism for the observed smoke sensitivity, making the proposed "smoke allergy" term inaccurate.

CR Number: 2018288023 **Implementation Date:** 25-Oct-18 Related CR: 2018288023

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Subcision*	Approved Not as Requested	Proposed PT	
			Subcision	10082250
			HLT primary	
			Skin and subcutaneous tissue therapeutic procedures NEC	10040794
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT Subcision is approved but not as requested. Subcision is a minor surgical procedure used for treating depressed cutaneous scars, cellulite and wrinkles. It is also called subcutaneous incisional surgery. Subcision is performed using a special hypodermic needle inserted through a puncture in the skin surface. The sharp edge of the needle is used to break fibrotic strands that are tethering the scar to the underlying tissue. The release of the fibrotic strands and new collagen deposition caused by wound healing leads to cosmetic improvement of the scar. The proposed term will be added as PT under HLT Skin and subcutaneous tissue therapeutic procedures NEC.

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CR Number: 2018288024 **Implementation Date:** 25-Oct-18 Related CR: 2018288024

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Intramuscular injection*	Approved as Requested	Proposed LLT	
			Intramuscular injection	10082261 Current
			To PT	
			Injection	10052995

MSSO Comment: The proposal to add a new LLT Intramuscular injection is approved as requested. Intramuscular injection will be added as a sub-concept LLT under the existing PT Injection.

CR Number: 2018288025 **Implementation Date:** 25-Oct-18 Related CR: 2018288025

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Percutaneous correction*	Rejected		

MSSO Comment: The proposal to add a new LLT Percutaneous correction is not approved. The proposed term is too vague to be valuable for MedDRA coding purposes. Although the proposed term describes a percutaneous technique, the term "correction" is too vague to be interpreted (i.e., what is being corrected? - a condition, a lesion, an anomaly, etc.).

CR Number: 2018288026 **Implementation Date:** 25-Oct-18 Related CR: 2018288026

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Dorsally adducted fifth toe*	Approved as Requested	Proposed LLT	
			Dorsally adducted fifth toe	10082259 Current
			To PT	
			Congenital foot malformation	10062332

MSSO Comment: The proposal to add a new LLT Dorsally adducted fifth toe is approved as requested. The overriding fifth toe is a congenital triplane deformity that may cause aesthetic and functional concerns in children and adolescents. Dorsally adducted fifth toe will be added as an LLT to PT Congenital foot malformation. In a related change, the more commonly cited term in literature, Overriding fifth toe, will be added as an LLT to PT Congenital foot malformation.

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CR Number: 2018298009 **Implementation Date:** 25-Oct-18 Related CR: 2018288026

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Overriding fifth toe*	Approved as Requested	Proposed LLT	
To PT	*Congenital foot malformation*		*Overriding fifth toe*	10082265 Current
			To PT	
			Congenital foot malformation	10062332

MSSO Comment:

CR Number: 2018288027 **Implementation Date:** 25-Oct-18 Related CR: 2018288027

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hypokinetic dysarthria*	Approved Not as Requested	Proposed PT	
			Hypokinetic dysarthria	10082243
			HLT primary	
			Parkinson's disease and parkinsonism	10034005
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Speech articulation and rhythm disturbances	10041462
			SOC secondary	
			Psychiatric disorders	10037175

MSSO Comment: The proposal to add a new LLT Hypokinetic dysarthria is approved but not as requested. In addition to its widely recognized effects on gait, posture, balance, and upper limb coordination, Parkinson's disease (PD) can have a profound effect on speech and voice, within a cluster of speech characteristics termed hypokinetic dysarthria. Hypokinetic dysarthria will be placed as a PT to primary HLT Parkinson's disease and parkinsonism and secondary HLT Speech articulation and rhythm disturbances.

CR Number: 2018288028 **Implementation Date:** 25-Oct-18 Related CR: 2018288028

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ventriculoperitoneal-Shunt Placement*	Rejected		

MSSO Comment: The proposal to add a new LLT Ventriculoperitoneal-Shunt Placement is not approved. The proposed term can be coded with the existing LLT Ventriculo-peritoneal shunt.

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CR Number: 2018288029 **Implementation Date:** 25-Oct-18 Related CR: 2018288029

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*High-flow nasal cannula therapy*	Approved Not as Requested	Proposed LLT	
			High-flow nasal cannula oxygen therapy	10082263 Current
			To PT	
			Oxygen therapy	10078798

MSSO Comment: The proposal to add a new LLT High-flow nasal cannula therapy is approved but not as requested. High-flow nasal cannula oxygen therapy is a non-invasive system for delivery of oxygen in high rate and concentration. High-flow nasal cannula oxygen therapy will be added as sub-concept LLT under PT Oxygen therapy.

CR Number: 2018288030 **Implementation Date:** 25-Oct-18 Related CR: 2018288030

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Sinonasal undifferentiated carcinoma*	Approved as Requested	Proposed LLT	
			Sinonasal undifferentiated carcinoma	10082256 Current
			To PT	
			Nasal sinus cancer	10028767

MSSO Comment: The proposal to add a new LLT Sinonasal undifferentiated carcinoma is approved as requested. Sinonasal undifferentiated carcinoma (SNUC) is a rare cancer of the nasal cavity and/or paranasal sinuses. Etiology has been linked in some cases to prior irradiation exposure, genetic predisposition and occupational exposures. Sinonasal undifferentiated carcinoma will be added as a sub-concept LLT under PT Nasal sinus cancer.

Supplemental Update Report

CR Number: 2018288031 **Implementation Date:** 25-Oct-18 Related CR: 2018288031

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Alpha-thalassemia-intellectual deficit syndrome*	Approved Not as Requested	Proposed PT	
			Alpha-thalassemia-intellectual deficit syndrome	10082244 Current
			HLT primary	
			Haemoglobinopathies congenital	10018903
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Thalassaemic disorders	10043389
			SOC secondary	
			Blood and lymphatic system disorders	10005329

MSSO Comment: The proposal to add a new LLT Alpha-thalassemia-intellectual deficit syndrome is approved but not as requested. There are two types ATR-X and ATR-16, both rare variations of Alpha thalassaemia with intellectual disabilities. Patients present with either alpha-thalassemia trait or mild hemoglobin H disease (HbH disease; see this term) associated with a mild to profound (in most cases) intellectual disability and, in some cases, with mild, nonspecific dysmorphic features (mild hypertelorism, down slanted palpebral fissures, broad or prominent nasal bridge, small ears, short neck), microcephaly and short stature. Genital abnormalities (hypospadias and cryptorchidism) have been reported in males. Club foot is common. Alpha-thalassemia-intellectual deficit syndrome will be added as a PT to primary HLT Haemoglobinopathies congenital, secondary HLT Thalassaemic disorders and secondary HLT Intellectual disabilities.

CR Number: 2018298010 **Implementation Date:** 25-Oct-18 Related CR: 2018288031

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Alpha-thalassemia-intellectual deficit syndrome*	Approved as Requested	Proposed PT	
To HLT	*Intellectual disabilities*		*Alpha-thalassemia-intellectual deficit syndrome*	10082244 Current
			To HLT	
			Intellectual disabilities	10077548

MSSO Comment:

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CR Number: 2018288032 **Implementation Date:** 25-Oct-18 Related CR: 2018288032

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Braces removal*	Approved as Requested	Proposed LLT *Braces removal* To PT *Orthodontic procedure*	 10082254 Current 10031121

MSSO Comment: The proposal to add a new LLT Braces removal is approved as requested. Braces removal is a painless process consisting in the detachment of the bond between the brackets and the teeth by release of the adhesive bond uniting both. During this process, the adhesive is left on the teeth to prevent damage to the enamel and tooth structure. Braces removal will be added as an LLT to PT Orthodontic procedure.

CR Number: 2018288033 **Implementation Date:** 25-Oct-18 Related CR: 2018288033

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Birt-Hogg-Dubé syndrome*	Rejected		

MSSO Comment: The proposal to add a new LLT Birt-Hogg-Dubé syndrome is not approved. MedDRA LLT Birt-Hogg-Dube syndrome was added previously under change request 2007163037 in MedDRA 10.1.

CR Number: 2018288034 **Implementation Date:** 25-Oct-18 Related CR: 2018288034

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Yunis Varon syndrome*	Approved as Requested	Proposed LLT *Yunis Varon syndrome* To PT *Cleidocranial dysostosis*	 10082255 Current 10075994

MSSO Comment: The proposal to add a new LLT Yunis Varon syndrome is approved as requested. Yunis Varon syndrome is a rare genetic multisystem disorder with defects affecting mostly the skeletal system, the nervous system, and ectodermal tissue (hair and teeth). It is characterized by large fontanelles, clavicular hypoplasia, characteristic facial features and/or abnormalities of fingers and toes. Yunis Varon syndrome will be added as a sub-concept LLT under PT Cleidocranial dysostosis.

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CR Number: 2018288035 **Implementation Date:** 21-Nov-18 Related CR: 2018288035

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Burn of unspecified degree of two or more digits of hand*	Approved Not as Requested After Suspension	Proposed LLT *Burns of fingers*	10082372 Current
To PT	*Thermal burn*		To PT *Thermal burn*	10053615

MSSO Comment: The proposal to add a new LLT Burn of unspecified degree of two or more digits of hand to PT Thermal burn is approved but not as requested after suspension. The requested term will be modified to Burns of fingers and added as an LLT to PT Thermal burn. As per discussion with submitter, the requested concept can be represented by split coding with the new LLT Burns of fingers and existing LLT Burns of unspecified degree.

CR Number: 2018291001 **Implementation Date:** 24-Oct-18 Related CR: 2018291001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Sigmoidostomy*	Approved as Requested	Proposed LLT *Sigmoidostomy*	10082236 Current
			To PT *Colostomy*	10010041

MSSO Comment: The proposal to add a new term Sigmoidostomy is approved as requested. Sigmoidostomy, the creation of an artificial opening from the sigmoid colon to the body surface, will be added as LLT to the broader PT Colostomy.

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CR Number: 2018291002 **Implementation Date:** 24-Oct-18 Related CR: 2018291002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Shprintzen-Goldberg syndrome*	Approved Not as Requested	Proposed PT	
			Shprintzen-Goldberg syndrome	10082234
			HLT primary	
			Musculoskeletal and connective tissue disorders of skull congenital	10028382
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Musculoskeletal and connective tissue disorders of skull congenital	10028382
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new LLT Shprintzen-Goldberg syndrome is approved but not as requested. Shprintzen-Goldberg syndrome (SGS) is an extremely rare connective tissue disorder characterized by craniofacial, skeletal, and cardiovascular deformities. Patients with SGS generally present with premature fusion of cranial bones in infancy (craniosynostosis), distinctive facial features, elongated fingers and limbs, umbilical and abdominal hernias, developmental delays, intellectual disability, and cardiac problems. Shprintzen-Goldberg syndrome will be added as PT to bi-axial HLT Musculoskeletal and connective tissue disorders of skull congenital (primary SOC Congenital, familial and genetic disorders and secondary SOC Musculoskeletal and connective tissue disorders), to secondary HLT Vascular malformations and acquired anomalies, and secondary HLT Intellectual disabilities.

CR Number: 2018297001 **Implementation Date:** 24-Oct-18 Related CR: 2018291002

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Shprintzen-Goldberg syndrome*	Approved as Requested	Proposed PT	
To HLT	*Intellectual disabilities*		*Shprintzen-Goldberg syndrome*	10082234
			To HLT	
			Intellectual disabilities	10077548

MSSO Comment:

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CR Number: 2018297002 **Implementation Date:** 24-Oct-18 Related CR: 2018291002

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Shprintzen-Goldberg syndrome*	Approved as Requested	Proposed PT	
			Shprintzen-Goldberg syndrome	10082234
To HLT	*Vascular malformations and acquired anomalies*		To HLT	
			Vascular malformations and acquired anomalies	10047091

MSSO Comment:

CR Number: 2018291003 **Implementation Date:** 24-Oct-18 Related CR: 2018291003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Enterolysis*	Approved as Requested	Proposed LLT	
			Enterolysis	10082235 Current
			To PT	
			Intestinal adhesion lysis	10052993

MSSO Comment: The proposal to add a new term Enterolysis is approved as requested. Enterolysis refers to surgical separation of intestinal adhesions and will be added as synonym LLT to PT Intestinal adhesion lysis.

CR Number: 2018292001 **Implementation Date:** 31-Oct-18 Related CR: 2018292001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Tobacco exposure via breast milk*	Approved Not as Requested After Suspension	Proposed PT	
			Exposure to tobacco	10082288
To PT	*Exposure via breast milk*		HLT primary	
			Exposures to agents or circumstances NEC	10073304
			SOC primary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new LLT Tobacco exposure via breast milk to PT Exposure via breast milk is approved but not as requested after suspension. This comment is applicable to all change requests in Batch 10109947 with respect to submitter's request for consistency with existing terms. It is not feasible to add in the area of exposures in MedDRA all possible additional combination concepts between the person exposed, the agent exposed to the timing and pathway of exposures. To enable coding of this scenario a new PT Exposure to tobacco will be added to HLT Exposures to agents or circumstances NEC. New PT Exposure to tobacco together with existing PT Exposure via breast milk can represent the requested concept.

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CR Number: 2018292002 **Implementation Date:** 25-Oct-18 Related CR: 2018292002

Change Requested		Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Drug exposure during pregnancy, first trimester*	Rejected		
Status	*non-current*			

MSSO Comment: The proposal to change status of LLT Drug exposure during pregnancy, first trimester to non-current is not approved. The MedDRA Term Selection: Points to Consider Section 3.10 – Exposures during Pregnancy and Breast Feeding refers to a situation where the subject exposed (mother, father or fetus) can be ascertained. LLT Drug exposure during pregnancy, first trimester is intended to represent verbatim reported information that is not specific about who was exposed (e.g., mother, fetus or father).

CR Number: 2018292003 **Implementation Date:** 25-Oct-18 Related CR: 2018292003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Drug exposure during pregnancy, second trimester*	Rejected		
Status	*non-current*			

MSSO Comment: The proposal to change status of LLT Drug exposure during pregnancy, second trimester to non-current is not approved. The MedDRA Term Selection: Points to Consider Section 3.10 – Exposures during Pregnancy and Breast Feeding refers to a situation where the subject exposed (mother, father or fetus) can be ascertained. LLT Drug exposure during pregnancy, second trimester is intended to represent verbatim reported information that is not specific about who was exposed (e.g., mother, fetus or father).

CR Number: 2018292004 **Implementation Date:** 25-Oct-18 Related CR: 2018292004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Drug exposure during pregnancy, third trimester*	Rejected		
Status	*non-current*			

MSSO Comment: The proposal to change status of LLT Drug exposure during pregnancy, third trimester to non-current is not approved. The MedDRA Term Selection: Points to Consider Section 3.10 – Exposures during Pregnancy and Breast Feeding refers to a situation where the subject exposed (mother, father or fetus) can be ascertained. LLT Drug exposure during pregnancy, third trimester is intended to represent verbatim reported information that is not specific about who was exposed (e.g., mother, fetus or father).

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CR Number: 2018292005 **Implementation Date:** 25-Oct-18 Related CR: 2018292005

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Radiation exposure during pregnancy*	Rejected		
Status	*non-current*			

MSSO Comment: The proposal to change status of LLT Radiation exposure during pregnancy to non-current is not approved. The MedDRA Term Selection: Points to Consider Section 3.10 – Exposures during Pregnancy and Breast Feeding refers to a situation where the subject exposed (mother, father or fetus) can be ascertained. LLT Radiation exposure during pregnancy is intended to represent verbatim reported information that is not specific about who was exposed (e.g., mother, fetus or father).

CR Number: 2018292006 **Implementation Date:** 25-Oct-18 Related CR: 2018292006

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Unspecified agent exposure during pregnancy*	Rejected		
Status	*non-current*			

MSSO Comment: The proposal to change status of LLT Unspecified agent exposure during pregnancy to non-current is not approved. The MedDRA Term Selection: Points to Consider Section 3.10 – Exposures during Pregnancy and Breast Feeding refers to a situation where the subject exposed (mother, father or fetus) can be ascertained. LLT Unspecified agent exposure during pregnancy is intended to represent verbatim reported information that is not specific about who was exposed (e.g., mother, fetus or father).

CR Number: 2018292007 **Implementation Date:** 25-Oct-18 Related CR: 2018292007

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Vaccine exposure during pregnancy*	Rejected		
Status	*non-current*			

MSSO Comment: The proposal to change status of LLT Vaccine exposure during pregnancy to non-current is not approved. The MedDRA Term Selection: Points to Consider Section 3.10 – Exposures during Pregnancy and Breast Feeding refers to a situation where the subject exposed (mother, father or fetus) can be ascertained. LLT Vaccine exposure during pregnancy is intended to represent verbatim reported information that is not specific about who was exposed (e.g., mother, fetus or father).

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CR Number: **2018292008** **Implementation Date:** 31-Oct-18 Related CR: 2018292008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Maternal tobacco exposure*	Rejected After Suspension		
To PT	*Maternal exposure during pregnancy*			

MSSO Comment: The proposal to add a new LLT Maternal tobacco exposure to PT Maternal exposure during pregnancy is not approved after suspension. The requested term can be represented by split coding with LLT Exposure to tobacco(change request 2018292001) and LLT Maternal exposure during pregnancy.

CR Number: **2018292009** **Implementation Date:** 31-Oct-18 Related CR: 2018292009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Maternal radiation exposure during pregnancy*	Rejected After Suspension		
To PT	*Maternal exposure during pregnancy*			

MSSO Comment: The proposal to add a new LLT Maternal radiation exposure during pregnancy to PT Maternal exposure during pregnancy is not approved after suspension. The proposed term can be represented by split coding with LLT Exposure to radiation and LLT Maternal exposure during pregnancy.

CR Number: **2018292010** **Implementation Date:** 31-Oct-18 Related CR: 2018292010

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Maternal unspecified agent exposure during pregnancy*	Rejected After Suspension		
To PT	*Maternal exposure during pregnancy*			

MSSO Comment: The proposal to add a new LLT Maternal unspecified agent exposure during pregnancy to PT Maternal exposure during pregnancy is not approved after suspension. The requested term can be represented by split coding with LLT Exposure to unspecified agent and LLT Maternal exposure during pregnancy.

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CR Number: 2018292011 **Implementation Date:** 31-Oct-18 Related CR: 2018292011

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Maternal vaccine exposure during pregnancy*	Rejected After Suspension		
To PT	*Maternal exposure during pregnancy*			

MSSO Comment: The proposal to add a new LLT Maternal vaccine exposure during pregnancy to PT Maternal exposure during pregnancy is not approved after suspension. The requested term can be represented by split coding with LLT Vaccine exposure during pregnancy and LLT Maternal exposure during pregnancy.

CR Number: 2018292012 **Implementation Date:** 31-Oct-18 Related CR: 2018292012

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Paternal radiation exposure during pregnancy*	Rejected After Suspension		
To PT	*Paternal exposure during pregnancy*			

MSSO Comment: The proposal to add a new LLT Paternal radiation exposure during pregnancy to PT Paternal exposure during pregnancy is not approved after suspension. The requested term can be represented by split coding with existing terms LLT Exposure to radiation and LLT Paternal exposure during pregnancy.

CR Number: 2018292013 **Implementation Date:** 31-Oct-18 Related CR: 2018292013

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Paternal vaccine exposure during pregnancy*	Rejected After Suspension		
To PT	*Paternal exposure during pregnancy*			

MSSO Comment: The proposal to add a new LLT Paternal vaccine exposure during pregnancy to PT Paternal exposure during pregnancy is not approved after suspension. The requested term can be represented by split coding with existing terms LLT Paternal exposure during pregnancy and LLT Exposure to vaccinated person.

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CR Number: 2018292014 **Implementation Date:** 31-Oct-18 Related CR: 2018292014

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Maternal drug exposure before pregnancy*	Rejected After Suspension		
To PT	*Maternal exposure before pregnancy*			

MSSO Comment: The proposal to add a new LLT Maternal drug exposure before pregnancy to PT Maternal exposure before pregnancy is not approved after suspension. The requested term can be represented by split coding with existing terms LLT Maternal exposure before pregnancy and LLT Maternal drug exposure.

CR Number: 2018292015 **Implementation Date:** 31-Oct-18 Related CR: 2018292015

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Maternal tobacco exposure before pregnancy*	Rejected After Suspension		
To PT	*Maternal exposure before pregnancy*			

MSSO Comment: The proposal to add a new LLT Maternal tobacco exposure before pregnancy to PT Maternal exposure before pregnancy is not approved after suspension. The requested term can be represented by split coding with LLT Exposure to tobacco (change request 2018292001) and LLT Maternal exposure before pregnancy.

CR Number: 2018292016 **Implementation Date:** 31-Oct-18 Related CR: 2018292016

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Maternal radiation exposure before pregnancy*	Rejected After Suspension		
To PT	*Maternal exposure before pregnancy*			

MSSO Comment: The proposal to add a new LLT Maternal radiation exposure before pregnancy to PT Maternal exposure before pregnancy is not approved after suspension. The requested term can be represented by split coding with existing terms LLT Maternal exposure before pregnancy and LLT Exposure to radiation.

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CR Number: 2018292017 **Implementation Date:** 25-Oct-18 Related CR: 2018292017

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Exposure during pregnancy*	Rejected		
Status	*non-current*			

MSSO Comment: The proposal to change status of LLT Exposure during pregnancy to non-current is not approved. The MedDRA Terms Points to Consider: Section 3.10 – Exposures during Pregnancy and Breast Feeding refers to a situation where the subject exposed (mother, father or fetus)can be ascertained. LLT Exposure during pregnancy is intended to represent verbatim reported information that is not specific about who was exposed (e.g., mother, fetus or father).

CR Number: 2018292018 **Implementation Date:** 25-Oct-18 Related CR: 2018292018

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Drug exposure before pregnancy*	Rejected		
Status	*non-current*			

MSSO Comment: The proposal to change status of LLT Drug exposure before pregnancy to non-current is not approved. The MedDRA Terms Points to Consider: Section 3.10 – Exposures during Pregnancy and Breast Feeding refers to a situation where the subject exposed (mother, father or fetus)can be ascertained. LLT Drug exposure before pregnancy is intended to represent verbatim reported information that is not specific about who was exposed (e.g., mother, fetus or father).

CR Number: 2018292019 **Implementation Date:** 31-Oct-18 Related CR: 2018292019

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Maternal unspecified agent exposure before pregnancy*	Rejected After Suspension		
To PT	*Maternal exposure before pregnancy*			

MSSO Comment: The proposal to add a new LLT Maternal unspecified agent exposure before pregnancy to PT Maternal exposure before pregnancy is not approved after suspension. The requested term can be represented by split coding with existing terms LLT Maternal exposure before pregnancy and LLT Exposure to unspecified agent.

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CR Number: 2018292020 **Implementation Date:** 31-Oct-18 Related CR: 2018292020

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Paternal vaccine exposure before pregnancy*	Rejected After Suspension		
To PT	*Paternal exposure before pregnancy*			

MSSO Comment: The proposal to add a new LLT Paternal vaccine exposure before pregnancy to PT Paternal exposure before pregnancy is not approved after suspension. The requested term can be represented by split coding with existing terms LLT Paternal exposure before pregnancy and LLT Exposure to vaccinated person.

CR Number: 2018292021 **Implementation Date:** 31-Oct-18 Related CR: 2018292021

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Paternal tobacco exposure before pregnancy*	Rejected After Suspension		
To PT	*Paternal exposure before pregnancy*			

MSSO Comment: The proposal to add a new LLT Paternal tobacco exposure before pregnancy to PT Paternal exposure before pregnancy is not approved after suspension. The requested term can be represented by split coding with LLT Exposure to tobacco (change request 2018292001) and LLT Paternal exposure during pregnancy.

CR Number: 2018292022 **Implementation Date:** 31-Oct-18 Related CR: 2018292022

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Paternal radiation exposure before pregnancy*	Rejected After Suspension		
To PT	*Paternal exposure before pregnancy*			

MSSO Comment: The proposal to add a new LLT Paternal radiation exposure before pregnancy to PT Paternal exposure before pregnancy is not approved after suspension. The requested term can be represented by split coding with existing terms LLT Exposure to radiation and LLT Paternal exposure before pregnancy.

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CR Number: 2018292023 **Implementation Date:** 31-Oct-18 Related CR: 2018292023

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Paternal unspecified agent exposure before pregnancy*	Rejected After Suspension		
To PT	*Paternal exposure before pregnancy*			

MSSO Comment: The proposal to add a new LLT Paternal unspecified agent exposure before pregnancy to PT Paternal exposure before pregnancy is not approved after suspension. The requested term can be represented by split coding with existing terms LLT Exposure to unspecified agent and LLT Paternal exposure before pregnancy.

CR Number: 2018292024 **Implementation Date:** 31-Oct-18 Related CR: 2018292024

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Maternal vaccine exposure during breast feeding*	Rejected After Suspension		
To PT	*Maternal exposure during breast feeding*			

MSSO Comment: The proposal to add a new LLT Maternal vaccine exposure during breast feeding to PT Maternal exposure during breast feeding is not approved after suspension. The requested term can be represented by split coding with existing terms LLT Maternal exposure during breast feeding and LLT Exposure to vaccinated person.

CR Number: 2018292025 **Implementation Date:** 31-Oct-18 Related CR: 2018292025

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Maternal unspecified agent exposure during breast feeding*	Rejected After Suspension		
To PT	*Maternal exposure during breast feeding*			

MSSO Comment: The proposal to add a new LLT Maternal unspecified agent exposure during breast feeding to PT Maternal exposure during breast feeding is not approved after suspension. The requested term can be represented by split coding with existing terms LLT Maternal exposure during breast feeding and LLT Exposure to unspecified agent.

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CR Number: 2018292026 **Implementation Date:** 26-Oct-18 Related CR: 2018292026

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Muosal lesion*	Approved Not as Requested	Proposed PT	
			Mucosal disorder	10082268
			HLT primary	
			Mucosal findings abnormal	10028114
			SOC primary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Muosal lesion is approved but not as requested. As Section 5.1 of the MedDRA Introductory Guide states, .Lesion terms may be considered for inclusion in MedDRA when the word “lesion” is part of a medical concept, e.g., PT Glomerulonephritis minimal lesion or a well documented medical concept, e.g., LLT Brain lesion. However, the term will not be added when adding a broad “lesion” term only adds an additional imprecise term to existing “disorder” concepts, e.g., “renal lesion,” when one could use for coding the existing LLT Renal disorder under PT Renal disorder. However, the MSSO will add the new broad PT Mucosal disorder to HLT Mucosal findings abnormal to provide a coding option.

CR Number: 2018292027 **Implementation Date:** 26-Oct-18 Related CR: 2018292027

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Chemical burn of genitalia*	Approved as Requested	Proposed PT	
HLT primary	*Chemical injuries*		*Chemical burn of genitalia*	10082269
SOC primary	*Injury, poisoning and procedural complications*		HLT primary	
			Chemical injuries	10008424
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Reproductive tract disorders NEC (excl neoplasms)	10027696
			SOC secondary	
			Reproductive system and breast disorders	10038604

MSSO Comment: The proposal to add a new PT Chemical burn of genitalia to primary HLT Chemical injuries in SOC Injury, poisoning and procedural complications is approved as requested. The incidence of genital burns ranges from 2.8% to 13%. Most chemical burn of genitalia are part of larger set of injuries to an individual. Scald burns are typical for children, whereas flame and chemical burns happen more often in adults. PT Chemical burn of genitalia will be secondarily linked to HLT Reproductive tract disorders NEC (excl neoplasms).

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CR Number: 2018292028 **Implementation Date:** 26-Oct-18 Related CR: 2018292028

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Chemical burn of penis*	Approved as Requested	Proposed LLT	
To PT	*Chemical burn of genitalia*		*Chemical burn of penis*	10082271 Current
			To PT	
			Chemical burn of genitalia	10082269

MSSO Comment: The proposal to add a new LLT Chemical burn of penis to PT Chemical burn of genitalia is approved as requested. LLT Chemical burn of penis is an anatomical sub-concept of the existing broader parent PT Chemical burn of genitalia.

CR Number: 2018292029 **Implementation Date:** 26-Oct-18 Related CR: 2018292029

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Chemical burn of vagina*	Approved as Requested	Proposed LLT	
To PT	*Chemical burn of genitalia*		*Chemical burn of vagina*	10082272 Current
			To PT	
			Chemical burn of genitalia	10082269

MSSO Comment: The proposal to add a new LLT Chemical burn of vagina to PT Chemical burn of genitalia is approved as requested. LLT Chemical burn of vagina is an anatomical specific sub-concept of the newly added PT Chemical burn of genitalia.

CR Number: 2018292030 **Implementation Date:** 26-Oct-18 Related CR: 2018292030

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pharyngeal swelling*	Approved as Requested	Proposed PT	
HLT primary	*Pharyngeal disorders (excl infections and neoplasms)*		*Pharyngeal swelling*	10082270
SOC primary	*Respiratory, thoracic and mediastinal disorders*		HLT primary	
			Pharyngeal disorders (excl infections and neoplasms)	10034823
			SOC primary	
			Respiratory, thoracic and mediastinal disorders	10038738

MSSO Comment: The proposal to add a new PT Pharyngeal swelling to primary HLT Pharyngeal disorders (excl infections and neoplasms) in SOC Respiratory, thoracic and mediastinal disorders is approved as requested. Pharyngeal swelling and pharyngeal oedema are not always synonymously used. Swelling may be due to causes other than edema, such as neoplasms, pharyngeal wall thickening or inflammation.

Supplemental Update Report

CR Number: 2018292031 **Implementation Date:** 26-Oct-18 Related CR: 2018292031

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Throat swelling*	Approved as Requested	Proposed LLT	
From PT	*Pharyngeal oedema*		*Throat swelling*	10043525 Current
To PT	*Pharyngeal swelling*		From PT	
			Pharyngeal oedema	10034829
			To PT	
			Pharyngeal swelling	10082270

MSSO Comment: The proposal to move the LLT Throat swelling from PT Pharyngeal oedema to PT Pharyngeal swelling is approved as requested for better alignment of the medical concept.

CR Number: 2018292032 **Implementation Date:** 26-Oct-18 Related CR: 2018292032

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Throat swelling NOS*	Approved as Requested	Proposed LLT	
From PT	*Pharyngeal oedema*		*Throat swelling NOS*	10043527 Current
To PT	*Pharyngeal swelling*		From PT	
			Pharyngeal oedema	10034829
			To PT	
			Pharyngeal swelling	10082270

MSSO Comment: The proposal to move the LLT Throat swelling NOS from PT Pharyngeal oedema to PT Pharyngeal swelling is approved as requested because swelling and oedema are not always synonymously used.

CR Number: 2018292033 **Implementation Date:** 26-Oct-18 Related CR: 2018292033

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Throat swelling non-specific*	Approved as Requested	Proposed LLT	
From PT	*Pharyngeal oedema*		*Throat swelling non-specific*	10043526 Current
To PT	*Pharyngeal swelling*		From PT	
			Pharyngeal oedema	10034829
			To PT	
			Pharyngeal swelling	10082270

MSSO Comment: The proposal to move the LLT Throat swelling non-specific from PT Pharyngeal oedema to PT Pharyngeal swelling is approved as requested for better alignment of the medical concept.

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CR Number: 2018292034 **Implementation Date:** 26-Oct-18 Related CR: 2018292034

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Rebound acid hypersecretion*	Approved as Requested	Proposed PT	
			Rebound acid hypersecretion	10081647
To HLT	*Withdrawal and rebound effects*		To HLT	
			Withdrawal and rebound effects	10068756

MSSO Comment: The proposal to link the PT Rebound acid hypersecretion to the HLT Withdrawal and rebound effects is approved as requested. Rebound acid hypersecretion develops after withdrawal of acid Inhibitors and a second link to HLT Withdrawal and rebound effects is appropriate.

CR Number: 2018295001 **Implementation Date:** 24-Oct-18 Related CR: 2018295001

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Renal function aggravated*	Rejected		
Replacement term	*Renal function worsened*			

MSSO Comment: The proposal to rename PT/LLT Renal function aggravated to Renal function worsened is not approved. As stated in Appendix B - Concept Descriptions of the MedDRA Introductory Guide, "For the purposes of term placement in MedDRA, the use of modifiers exacerbated, aggravated and worsened is interchangeable." Furthermore, LLT Renal function aggravated is in MedDRA since version 2.1 and flagging non-current may have impact of legacy data.

CR Number: 2018295002 **Implementation Date:** 24-Oct-18 Related CR: 2018295002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Diabetic hypoglycemic coma*	Approved as Requested	Proposed LLT	
			Diabetic hypoglycemic coma	10082237 Current
			To PT	
			Hypoglycaemic coma	10021000

MSSO Comment: The proposal to add a new term Diabetic hypoglycemic coma is approved as requested. Hyper- or hypoglycaemic coma in general refer to patients with diabetes mellitus. Therefore, the requested term, Diabetic hypoglycemic coma will be added together with its British spelled counterpart Diabetic hypoglycaemic coma as LLTs to PT Hypoglycaemic coma.

Supplemental Update Report

CR Number: 2018297003 **Implementation Date:** 24-Oct-18 Related CR: 2018295002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Diabetic hypoglycaemic coma*	Approved as Requested	Proposed LLT	
To PT	*Hypoglycaemic coma*		*Diabetic hypoglycaemic coma*	10082238 Current
			To PT	
			Hypoglycaemic coma	10021000

MSSO Comment:

CR Number: 2018295003 **Implementation Date:** 29-Oct-18 Related CR: 2018295003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Bruising under eye*	Rejected		

MSSO Comment: The proposal to add a new LLT Bruising under eye is not approved. To address the circumstance explained, either LLT Periorbital hematoma, LLT Bruising of face or LLT Black eye could be used depending on the context and other conditions informed in the same case.

CR Number: 2018295004 **Implementation Date:** 29-Oct-18 Related CR: 2018295004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Mycosis groin*	Rejected		

MSSO Comment: The proposal to add a new LLT Mycosis groin is not approved. MedDRA cannot accommodate a unique term for a type of infection of every possible anatomical site. The requested term can be represented by coding with the existing terms such as LLT Fungal skin infection, LLT Tinea cruris, LLT Candidal intertrigo, or the combintion of LLT Groin infection and LLT Mycosis.

Supplemental Update Report

CR Number: 2018298001 **Implementation Date:** 30-Oct-18 Related CR: 2018298001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Ferroprotein abnormal*	Rejected		

MSSO Comment: The proposal to add a new term Ferroprotein abnormal is not approved. Ferroprotein is the general term for any protein that contains or transports iron; especially any protein containing haem as a prosthetic group. Without identification of a specific ferroprotein, the inclusion of the proposed term in MedDRA would be of limited coding value.

CR Number: 2018298002 **Implementation Date:** 30-Oct-18 Related CR: 2018298002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Pulpless tooth*	Approved as Requested	Proposed PT	
			Pulpless tooth	10082273
			HLT primary	
			Dental pulp disorders	10044050
			SOC primary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new term Pulpless tooth is approved as requested. Pulpless tooth is a tooth in which the dental pulp is necrotic or has been removed. Also called devital tooth, nonvital tooth. Pulpless tooth will be added as a PT to HLT Dental pulp disorders.

CR Number: 2018298003 **Implementation Date:** 30-Oct-18 Related CR: 2018298003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Particle disease*	Approved as Requested	Proposed LLT	
			Particle disease	10082274 Current
			To PT	
			Periprosthetic osteolysis	10052306

MSSO Comment: The proposal to add a new term Particle disease is approved as requested. Particulate debris produced by implants most commonly causes osteolysis, and this is called particle-associated periprosthetic osteolysis or particle disease. Particle disease will be added as synonym LLT to PT Periprosthetic osteolysis.

Supplemental Update Report

CR Number: 2018298004 **Implementation Date:** 30-Oct-18 Related CR: 2018298004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Gastric mucosal prolapse*	Approved as Requested	Proposed LLT	
			Gastric mucosal prolapse	10082275 Current
			To PT	
			Gastric prolapse	10074788

MSSO Comment: The proposal to add a new term Gastric mucosal prolapse is approved as requested. Gastric mucosal prolapse is a recognized concept that is represented in the medical literature: Gastric mucosal prolapse (GMP) is a dynamic anatomical condition with movement of gastric mucosa into the distal esophagus. The reported incidence of GMP is between 2-5.5%. Gastric mucosal prolapse will be placed as an LLT to PT Gastric prolapse.

CR Number: 2018298011 **Implementation Date:** 30-Oct-18 Related CR: 2018298011

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Scleral infection*	Approved as Requested	Proposed LLT	
			Scleral infection	10082276 Current
			To PT	
			Infective scleritis	10077918

MSSO Comment: The proposal to add a new LLT Scleral infection is approved as requested. Scleral infection will be added as an synonym LLT to PT Infective scleritis.

CR Number: 2018298012 **Implementation Date:** 30-Oct-18 Related CR: 2018298012

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Squamous cell carcinoma of pinna*	Approved as Requested	Proposed LLT	
			Squamous cell carcinoma of pinna	10082278 Current
			To PT	
			External ear neoplasm malignant	10082277

MSSO Comment: The proposal to add a new LLT Squamous cell carcinoma of pinna is approved as requested. Squamous cell carcinoma that originates in the pinna is thought to have a high risk of metastases (up to 16%) compared with under 5% for cutaneous SCC at any other site. Squamous cell carcinoma of pinna will be added as an LLT to a new PT External ear neoplasm malignant. In a related change, External ear neoplasm malignant will be placed as a PT to primary HLT Aural neoplasms malignant and unspecified and to secondary HLT External ear disorders NEC. Also, PT Adenoid cystic carcinoma of external auditory canal and PT Malignant neoplasm of auricular cartilage will each be demoted under the new PT External ear neoplasm malignant for alignment of other histological types of external ear malignancies.

Supplemental Update Report

CR Number: 2018303002 **Implementation Date:** 30-Oct-18 Related CR: 2018298012

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*External ear neoplasm malignant*	Approved as Requested	Proposed PT	
HLT primary	*Aural neoplasms malignant and unspecified*		*External ear neoplasm malignant*	10082277
SOC primary	*Neoplasms benign, malignant and unspecified (incl cysts and polyps)*		HLT primary	
			Aural neoplasms malignant and unspecified	10003793
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			External ear disorders NEC	10027672
			SOC secondary	
			Ear and labyrinth disorders	10013993

MSSO Comment:

CR Number: 2018303003 **Implementation Date:** 30-Oct-18 Related CR: 2018298012

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Adenoid cystic carcinoma of external auditory canal*	Approved as Requested	PT to merge	
			Adenoid cystic carcinoma of external auditory canal	10078057 Current
To PT	*External ear neoplasm malignant*		To PT	
			External ear neoplasm malignant	10082277

MSSO Comment:

Supplemental Update Report

CR Number: 2018303004 **Implementation Date:** 30-Oct-18 Related CR: 2018298012

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Malignant neoplasm of auricular cartilage*	Approved as Requested	PT to merge	
To PT	*External ear neoplasm malignant*		*Malignant neoplasm of auricular cartilage*	10057272 Current
			To PT	
			External ear neoplasm malignant	10082277

MSSO Comment:

CR Number: 2018298013 **Implementation Date:** 30-Oct-18 Related CR: 2018298013

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Endometriosis Aggravated*	Rejected		
To PT	*Endometriosis*			

MSSO Comment: The proposal to add a new LLT Endometriosis Aggravated to PT Endometriosis is not approved. The MSSO refrains from adding new terms with a qualifier of aggravation / worsening / exacerbation unless such a term represents an internationally accepted unique medical concept. MedDRA cannot accommodate a separate term for an aggravated state of every potential disease or condition. The MedDRA Term Selection: Points to Consider document, in paragraph "3.9 – Modification of Pre-existing Conditions", advises to record the modification in a consistent, documented way in appropriate data fields, or to select a term for the pre-existing condition (with PT Endometriosis, in this case) and a second term for the modification of the condition (e.g., LLT Condition aggravated, LLT Disease progression)."

CR Number: 2018298014 **Implementation Date:** 30-Oct-18 Related CR: 2018298014

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Transfusion dependent thrombocytopenia*	Approved Not as Requested	Proposed LLT	
			Transfusion dependent thrombocytopenia	10082279 Current
			To PT	
			Thrombocytopenia	10043554

MSSO Comment: The proposal to add a new PT Transfusion dependent thrombocytopenia is approved but not as requested. Hematology–oncology patients often become thrombocytopenic and dependent on platelet transfusions for the prevention of spontaneous bleeding. Transfusion dependent thrombocytopenia will be added as sub-element LLT of PT Thrombocytopenia, in accordance with some already existing transfusion dependent forms of anemia.

Supplemental Update Report

CR Number: 2018299001 **Implementation Date:** 30-Oct-18 Related CR: 2018299001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Anti-RNA polymerase III antibody*	Approved as Requested	Proposed PT	
HLT primary	*Autoimmunity analyses*		*Anti-RNA polymerase III antibody*	10082281
SOC primary	*Investigations*		HLT primary	
			Autoimmunity analyses	10003828
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Anti-RNA polymerase III antibody to primary HLT Autoimmunity analyses in SOC Investigations is approved as requested. Anti-RNA polymerase III antibodies are specific markers in patients with Systemic Sclerosis (SSc) and known to be associated with some clinical characteristics associated with poor prognosis in SSc, such as diffuse cutaneous involvement and renal crisis.

CR Number: 2018299002 **Implementation Date:** 30-Oct-18 Related CR: 2018299002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Anti-RNA polymerase III antibody positive*	Approved as Requested	Proposed PT	
HLT primary	*Autoimmunity analyses*		*Anti-RNA polymerase III antibody positive*	10082283
SOC primary	*Investigations*		HLT primary	
			Autoimmunity analyses	10003828
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Anti-RNA polymerase III antibody positive to primary HLT Autoimmunity analyses in SOC Investigations is approved as requested. Anti-RNA polymerase III antibodies are specific markers in patients with Systemic Sclerosis (SSc) and known to be associated with some clinical characteristics associated with poor prognosis in SSc, such as diffuse cutaneous involvement and renal crisis.

CR Number: 2018299003 **Implementation Date:** 30-Oct-18 Related CR: 2018299003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Anti-RNA polymerase III antibody increased*	Approved as Requested	Proposed PT	
HLT primary	*Autoimmunity analyses*		*Anti-RNA polymerase III antibody increased*	10082280
SOC primary	*Investigations*		HLT primary	
			Autoimmunity analyses	10003828
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Anti-RNA polymerase III antibody increased to primary HLT Autoimmunity analyses in SOC Investigations is approved as requested. Anti-RNA polymerase III antibodies are specific markers in patients with Systemic Sclerosis (SSc) and known to be associated with some clinical characteristics associated with poor prognosis in SSc, such as diffuse cutaneous involvement and renal crisis.

Supplemental Update Report

CR Number: 2018299004 **Implementation Date:** 30-Oct-18 Related CR: 2018299004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Anti-RNA polymerase III antibody negative*	Approved as Requested	Proposed PT	
HLT primary	*Autoimmunity analyses*		*Anti-RNA polymerase III antibody negative*	10082282
SOC primary	*Investigations*		HLT primary	
			Autoimmunity analyses	10003828
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Anti-RNA polymerase III antibody negative to primary HLT Autoimmunity analyses in SOC Investigations is approved as requested. Anti-RNA polymerase III antibodies are specific markers in patients with Systemic Sclerosis (SSc) and known to be associated with some clinical characteristics associated with poor prognosis in SSc, such as diffuse cutaneous involvement and renal crisis.

CR Number: 2018299005 **Implementation Date:** 30-Oct-18 Related CR: 2018299005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Anti-RNAP III antibody*	Approved as Requested	Proposed LLT	
			Anti-RNAP III antibody	10082286 Current
			To PT	
			Anti-RNA polymerase III antibody	10082281

MSSO Comment: The proposal to add a new LLT Anti-RNAP III antibody is approved as requested. Anti-RNA polymerase III antibodies are specific markers in patients with Systemic Sclerosis (SSc) and known to be associated with some clinical characteristics associated with poor prognosis in SSc, such as diffuse cutaneous involvement and renal crisis. Anti-RNAP III antibody, the short expression of the concept, will be added as LLT to new PT Anti-RNA polymerase III antibody - see change request 2018299001.

CR Number: 2018299006 **Implementation Date:** 30-Oct-18 Related CR: 2018299006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Anti-RNAP III antibody positive*	Approved as Requested	Proposed LLT	
			Anti-RNAP III antibody positive	10082285 Current
			To PT	
			Anti-RNA polymerase III antibody positive	10082283

MSSO Comment: The proposal to add a new LLT Anti-RNAP III antibody positive is approved as requested. Anti-RNA polymerase III antibodies are specific markers in patients with Systemic Sclerosis (SSc) and known to be associated with some clinical characteristics associated with poor prognosis in SSc, such as diffuse cutaneous involvement and renal crisis. Anti-RNAP III antibody positive, the short expression of the concept, will be added as LLT to new PT Anti-RNA polymerase III antibody positive - see change request 2018299002.

Supplemental Update Report

CR Number: 2018299007 **Implementation Date:** 30-Oct-18 Related CR: 2018299007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Anti-RNAP III antibody increased*	Approved as Requested	Proposed LLT *Anti-RNAP III antibody increased*	10082284 Current
			To PT *Anti-RNA polymerase III antibody increased*	10082280

MSSO Comment: The proposal to add a new LLT Anti-RNAP III antibody increased is approved as requested. Anti-RNA polymerase III antibodies are specific markers in patients with Systemic Sclerosis (SSc) and known to be associated with some clinical characteristics associated with poor prognosis in SSc, such as diffuse cutaneous involvement and renal crisis. Anti-RNAP III antibody increased, the short expression of the concept, will be added as LLT to new PT Anti-RNA polymerase III antibody increased - see change request 2018299003.

CR Number: 2018299008 **Implementation Date:** 30-Oct-18 Related CR: 2018299008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Anti-RNAP III antibody negative*	Approved as Requested	Proposed LLT *Anti-RNAP III antibody negative*	10082287 Current
			To PT *Anti-RNA polymerase III antibody negative*	10082282

MSSO Comment: The proposal to add a new LLT Anti-RNAP III antibody negative is approved as requested. Anti-RNA polymerase III antibodies are specific markers in patients with Systemic Sclerosis (SSc) and known to be associated with some clinical characteristics associated with poor prognosis in SSc, such as diffuse cutaneous involvement and renal crisis. Anti-RNAP III antibody negative, the short expression of the concept, will be added as LLT to new PT Anti-RNA polymerase III antibody negative - see change request 2018299004.

CR Number: 2018299009 **Implementation Date:** 30-Oct-18 Related CR: 2018299009

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cut wound*	Rejected		
From PT	*Wound*			
To PT	*Laceration*			

MSSO Comment: The proposal to move the LLT Cut wound from PT Wound to PT Laceration is not approved. The LLT Cut wound is properly placed within MedDRA given the fact the cut wounds, depending upon their depth, can affect a variety of tissues including tendons, muscles, ligaments, nerves, blood vessels and bone. The proposal to move this term under the PT Laceration would not be appropriate since the MedDRA concept of laceration pertains to the skin, unless otherwise specified.

Supplemental Update Report

CR Number: 2018299010 **Implementation Date:** 31-Oct-18 Related CR: 2018299010

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Septicaemia*	Approved as Requested	PT to merge	
To PT	*Sepsis*		*Septicaemia*	10040072 Current
			To PT	
			Sepsis	10040047

MSSO Comment: The proposal to demote the PT Septicaemia under PT Sepsis is approved as requested. This Change Request pertains to the final actions of recent Change Request 2018242001. Upon reconsideration by the MSSO, the changes performed in this CR will not be implemented in the forthcoming Version 22.0 of MedDRA. In response to the submitter's request to promote LLT Haematological infection from PT Sepsis, the following changes were previously made in CR 2018242001: LLT Septicaemia was promoted to a PT under HLT Sepsis, bacteraemia, viraemia and fungaemia NEC; LLT Haematological infection was moved from PT Sepsis to the promoted PT Septicaemia; and the following LLTs under PT Sepsis were also moved to the recently promoted PT Septicaemia: LLT Hematological infection, LLT Other specified septicaemias, LLT Other specified septicemias, LLT Pyaemia, LLT Pyemia, LLT Septicaemia NOS, LLT Septicemia, LLT Septicopyaemia, LLT Septicopyemia, LLT Unspecified septicaemia, and LLT Unspecified septicemia. Each of these changes will be reversed, restoring their respective hierarchical placements prior to the actions of CR 2018242001. The justifications for not implementing the aforementioned LLT promotion and moves in CR 2018242001 are based upon the following: (1) Dorland's Medical Dictionary definition of sepsis is "The presence in the blood or other tissues of pathogenic microorganisms or their toxins. Septicemia." Thus Dorland considers sepsis and septicemia as synonyms; (2) The MedDRA Introductory Guide, Section 6.11.2, states, "When the concepts of "sepsis" and "septic(a)emia" are paired in the terminology, the "sepsis" terms are PTs and the corresponding "septic(a)emia" terms are LLTs."; and (3) Considering that LLT Septicaemia has been subordinate to PT Sepsis since Version 2.1, the promotion of this term at this time may have a potentially significant impact on legacy pharmacovigilance data.

CR Number: 2018299011 **Implementation Date:** 31-Oct-18 Related CR: 2018299011

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Haematological infection*	Rejected		
From PT	*Septicaemia*			
To PT	*Sepsis*			

MSSO Comment: The proposal to move the LLT Haematological infection from PT Septicaemia to PT Sepsis is not approved. Technical rejection since all LLTs under PT Septicaemia will automatically be moved to PT Sepsis with the merger of PT Septicaemia to PT Sepsis.

CR Number: 2018299012 **Implementation Date:** 31-Oct-18 Related CR: 2018299012

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hematological infection*	Rejected		
From PT	*Septicaemia*			
To PT	*Sepsis*			

MSSO Comment: The proposal to move the LLT Hematological infection from PT Septicaemia to PT Sepsis is not approved. Technical rejection since all LLTs under PT Septicaemia will automatically be moved to PT Sepsis with the merger of PT Septicaemia to PT Sepsis.

Supplemental Update Report

CR Number: **2018299013** **Implementation Date:** 31-Oct-18 Related CR: 2018299013

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Other specified septicaemias*	Rejected		
From PT	*Septicaemia*			
To PT	*Sepsis*			

MSSO Comment: The proposal to move the LLT Other specified septicaemias from PT Septicaemia to PT Sepsis is not approved. Technical rejection since all LLTs under PT Septicaemia will automatically be moved to PT Sepsis with the merger of PT Septicaemia to PT Sepsis.

CR Number: **2018299014** **Implementation Date:** 31-Oct-18 Related CR: 2018299014

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Other specified septicemias*	Rejected		
From PT	*Septicaemia*			
To PT	*Sepsis*			

MSSO Comment: The proposal to move the LLT Other specified septicemias from PT Septicaemia to PT Sepsis is not approved. Technical rejection since all LLTs under PT Septicaemia will automatically be moved to PT Sepsis with the merger of PT Septicaemia to PT Sepsis.

CR Number: **2018299015** **Implementation Date:** 31-Oct-18 Related CR: 2018299015

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pyaemia*	Rejected		
From PT	*Septicaemia*			
To PT	*Sepsis*			

MSSO Comment: The proposal to move the LLT Pyaemia from PT Septicaemia to PT Sepsis is not approved. Technical rejection since all LLTs under PT Septicaemia will automatically be moved to PT Sepsis with the merger of PT Septicaemia to PT Sepsis.

Supplemental Update Report

CR Number: 2018299016 **Implementation Date:** 31-Oct-18 Related CR: 2018299016

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pyemia*	Rejected		
From PT	*Septicaemia*			
To PT	*Sepsis*			

MSSO Comment: The proposal to move the LLT Pyemia from PT Septicaemia to PT Sepsis is not approved. Technical rejection since all LLTs under PT Septicaemia will automatically be moved to PT Sepsis with the merger of PT Septicaemia to PT Sepsis.

CR Number: 2018299017 **Implementation Date:** 31-Oct-18 Related CR: 2018299017

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Septicaemia NOS*	Rejected		
From PT	*Septicaemia*			
To PT	*Sepsis*			

MSSO Comment: The proposal to move the LLT Septicaemia NOS from PT Septicaemia to PT Sepsis is not approved. Technical rejection since all LLTs under PT Septicaemia will automatically be moved to PT Sepsis with the merger of PT Septicaemia to PT Sepsis.

CR Number: 2018299018 **Implementation Date:** 31-Oct-18 Related CR: 2018299018

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Septicemia*	Rejected		
From PT	*Septicaemia*			
To PT	*Sepsis*			

MSSO Comment: The proposal to move the LLT Septicemia from PT Septicaemia to PT Sepsis is not approved. Technical rejection since all LLTs under PT Septicaemia will automatically be moved to PT Sepsis with the merger of PT Septicaemia to PT Sepsis.

Supplemental Update Report

CR Number: 2018299019 **Implementation Date:** 31-Oct-18 Related CR: 2018299019

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Septicopyaemia*	Rejected		
From PT	*Septicaemia*			
To PT	*Sepsis*			

MSSO Comment: The proposal to move the LLT Septicopyaemia from PT Septicaemia to PT Sepsis is not approved. Technical rejection since all LLTs under PT Septicaemia will automatically be moved to PT Sepsis with the merger of PT Septicaemia to PT Sepsis.

CR Number: 2018299020 **Implementation Date:** 31-Oct-18 Related CR: 2018299020

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Septicopyemia*	Rejected		
From PT	*Septicaemia*			
To PT	*Sepsis*			

MSSO Comment: The proposal to move the LLT Septicopyemia from PT Septicaemia to PT Sepsis is not approved. Technical rejection since all LLTs under PT Septicaemia will automatically be moved to PT Sepsis with the merger of PT Septicaemia to PT Sepsis.

CR Number: 2018299021 **Implementation Date:** 31-Oct-18 Related CR: 2018299021

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Unspecified septicaemia*	Rejected		
From PT	*Septicaemia*			
To PT	*Sepsis*			

MSSO Comment: The proposal to move the LLT Unspecified septicaemia from PT Septicaemia to PT Sepsis is not approved. Technical rejection since all LLTs under PT Septicaemia will automatically be moved to PT Sepsis with the merger of PT Septicaemia to PT Sepsis.

Supplemental Update Report

CR Number: **2018299022** **Implementation Date:** 31-Oct-18 Related CR: 2018299022

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Unspecified septicemia*	Rejected		
From PT	*Septicaemia*			
To PT	*Sepsis*			

MSSO Comment: The proposal to move the LLT Unspecified septicemia from PT Septicaemia to PT Sepsis is not approved. Technical rejection since all LLTs under PT Septicaemia will automatically be moved to PT Sepsis with the merger of PT Septicaemia to PT Sepsis.

CR Number: **2018300001** **Implementation Date:** 16-Nov-18 Related CR: 2018300001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hormonal intra-uterine contraception*	Approved Not as Requested After Suspension	Proposed LLT	
HLT primary	*Contraceptive methods female*		*Hormonal intrauterine contraception*	10082360 Current
SOC primary	*Surgical and medical procedures*		To PT	
			Intrauterine contraception	10082352

MSSO Comment: The proposal to add a new PT Hormonal intra-uterine contraception to primary HLT Contraceptive methods female in SOC Surgical and medical procedures is approved but not as requested after suspension. The information regarding contraception with IUD systems hormonal and non-hormonal is too specific to be represented on PT level in the SOC Surgical and medical procedures. The proposed term will be modified to Hormonal intrauterine contraception and added as an LLT to a new PT Intrauterine contraception. In a related change, Intrauterine contraception will be added as PT to HLT Contraceptive methods female. Also, existing PT Intra-uterine contraceptive device will be demoted to an LLT under the new PT Intrauterine contraception.

CR Number: **2018320033** **Implementation Date:** 16-Nov-18 Related CR: 2018300001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Intrauterine contraception*	Approved as Requested	Proposed PT	
HLT primary	*Contraceptive methods female*		*Intrauterine contraception*	10082352
SOC primary	*Surgical and medical procedures*		HLT primary	
			Contraceptive methods female	10010812
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment:

Supplemental Update Report

CR Number: 2018320034 **Implementation Date:** 16-Nov-18 Related CR: 2018300001

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Intra-uterine contraceptive device*	Approved as Requested	PT to merge	
To PT	*Intrauterine contraception*		*Intra-uterine contraceptive device*	10022745 Current
			To PT	
			Intrauterine contraception	10082352

MSSO Comment:

CR Number: 2018300002 **Implementation Date:** 16-Nov-18 Related CR: 2018300002

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hormonal contraception*	Approved After Suspension	Proposed LLT	
From PT	*Chemical contraception*		*Hormonal contraception*	10073728
			From PT	
			Chemical contraception	10067045
			HLT primary	
			Contraceptive methods female	10010812
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to promote the LLT Hormonal contraception from PT Chemical contraception is approved as requested after suspension. Hormonal contraception and chemical contraception are two distinct methods. Most chemical contraceptives contain a variety of substances like spermicides and/or lactic and citric acid which in combination act as spermicides and thus as contraceptives. Hormonal contraception refers to birth control methods that act on the endocrine system. Almost all methods are composed of steroid hormones. LLT Hormonal contraception will be promoted to a PT from under PT Chemical contraception and linked to HLT Contraceptive methods female.

Supplemental Update Report

CR Number: **2018300003** **Implementation Date:** 16-Nov-18 Related CR: 2018300003

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Permanent contraceptive tubal implant*	Approved After Suspension	Proposed LLT	
From PT	*Contraceptive implant*		*Permanent contraceptive tubal implant*	10074446
			From PT	
			Contraceptive implant	10072571
			HLT primary	
			Contraceptive methods female	10010812
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to promote the LLT Permanent contraceptive tubal implant from PT Contraceptive implant is approved as requested after suspension. A contraceptive implant usually represents a flexible plastic rod about the size of a matchstick containing a hormonal preparation that is placed under the skin of the upper arm, whereas a permanent tubal implant is a small metal spring that is placed in each of the two fallopian tubes. As the effective methods of the two procedures are different, LLT Permanent contraceptive tubal implant will be promoted to a PT from under PT Contraceptive implant and linked to HLT Contraceptive methods female.

CR Number: **2018300004** **Implementation Date:** 16-Nov-18 Related CR: 2018300004

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vaginal contraceptive device complication*	Rejected After Suspension		
From PT	*Complication associated with device*			

MSSO Comment: The proposal to promote the LLT Vaginal contraceptive device complication from PT Complication associated with device is not approved after suspension. Vaginal contraceptive device complication is appropriately placed under the umbrella PT Complication associated with device as it is not feasible to represent all possible specific devices including combination devices on the PT level.

CR Number: **2018300005** **Implementation Date:** 16-Nov-18 Related CR: 2018300005

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Contraceptive device complication*	Rejected After Suspension		
From PT	*Complication associated with device*			
To PT	*Vaginal contraceptive device complication*			

MSSO Comment: The proposal to move the LLT Contraceptive device complication from PT Complication associated with device to PT Vaginal contraceptive device complication is not approved after suspension. This is a technical rejection since change request 2018300004 has not been approved.

Supplemental Update Report

CR Number: 2018300006 **Implementation Date:** 16-Nov-18 Related CR: 2018300006

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New PT		Approved Not as Requested After Suspension	Proposed LLT	
Proposed PT	*Intra-uterine contraceptive device complication*		*Intrauterine contraceptive device complication*	10082355 Current
			To PT	
			Complication associated with device	10077107

MSSO Comment: The proposal to add a new PT Intra-uterine contraceptive device complication is approved but not as requested after suspension. It is not feasable to implement PT terms for complications associated with specific devices. For analysis purposes, the specific information can be obtained from LLT level with exisitng LLT IUD complication or LLT IUCD complication. However, the spelled out concept, Intrauterine contraceptive device complication will be added as well as an LLT under PT Complication associated with device.

CR Number: 2018300007 **Implementation Date:** 16-Nov-18 Related CR: 2018300007

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Link (move) an LLT to another PT		Rejected After Suspension		
Proposed LLT	*IUCD complication*			
From PT	*Complication associated with device*			
To PT	*Intra-uterine contraceptive device complication*			

MSSO Comment: The proposal to move the LLT IUCD complication from PT Complication associated with device to PT Intra-uterine contraceptive device complication is not approved after suspension. This is a technical rejection since in change request 2018300006 the proposed term was modified to Intrauterine contraceptive device complication and only has been approved as an LLT to PT Complication associated with device.

CR Number: 2018300008 **Implementation Date:** 16-Nov-18 Related CR: 2018300008

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Link (move) an LLT to another PT		Rejected After Suspension		
Proposed LLT	*IUD complication*			
From PT	*Complication associated with device*			
To PT	*Intra-uterine contraceptive device complication*			

MSSO Comment: The proposal to move the LLT IUD complication from PT Complication associated with device to PT Intra-uterine contraceptive device complication is not approved after suspension. This is a technical rejection since in change request 2018300006 the proposed term was modified to Intrauterine contraceptive device complication and only has been approved as an LLT to PT Complication associated with device.

Supplemental Update Report

CR Number: 2018300009 **Implementation Date:** 16-Nov-18 Related CR: 2018300009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Emergency contaception intra uterine*	Approved Not as Requested After Suspension	Proposed LLT	
To PT	*Intra-uterine contraceptive device*		*Emergency contraception intrauterine*	10082361 Current
			To PT	
			Intrauterine contraception	10082352

MSSO Comment: The proposal to add a new LLT Emergency contaception intra uterine to PT Intra-uterine contraceptive device is approved but not as requested after suspension. While emergency contraceptive pills are commonly used, a copper intrauterine device (IUD) placed after unprotected sex is the most effective form of emergency contraception. The IUDs can be inserted up to 5 days after unprotected intercourse with no reduction in effectiveness over time. The proposed term will be modified to the more frequently used form in MedDRA to Emergency contraception intrauterine as an LLT to newly added PT Intrauterine contraception in change request 2018300001.

CR Number: 2018300010 **Implementation Date:** 16-Nov-18 Related CR: 2018300010

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hormonal intra-uterine device complication*	Rejected After Suspension		
To PT	*Intra-uterine contraceptive device complication*			

MSSO Comment: The proposal to add a new LLT Hormonal intra-uterine device complication to PT Intra-uterine contraceptive device complication is not approved after suspension. It is not feasible to provide such high granularity for complication associated with specific devices regarding hormonal versus non-hormonal. The requested term can be represented by split coding with the newly added broader LLT Intrauterine contraceptive device complication in change request 2018300006 and LLT Hormonal intrauterine contraception change request 2018300001.

CR Number: 2018300011 **Implementation Date:** 16-Nov-18 Related CR: 2018300011

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Emergency contraception*	Approved After Suspension	Proposed LLT	
To PT	*Post coital contraception*		*Emergency contraception*	10082358 Current
			To PT	
			Post coital contraception	10036251

MSSO Comment: The proposal to add a new LLT Emergency contraception to PT Post coital contraception is approved as requested after suspension. The term Emergency contraception can be considered a synonym of PT Post coital contraception. In a related change, since there are two frequently used methods for emergency contraception, the emergency contraceptive pill and the emergency intrauterine contraception, LLT Emergency contraceptive pill will also be added proactively to PT Post coital contraception.

Supplemental Update Report

CR Number: 2018320032 **Implementation Date:** 16-Nov-18 Related CR: 2018300011

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Emergency contraceptive pill*	Approved as Requested	Proposed LLT	
To PT	*Post coital contraception*		*Emergency contraceptive pill*	10082354 Current
			To PT	
			Post coital contraception	10036251

MSSO Comment:

CR Number: 2018300012 **Implementation Date:** 16-Nov-18 Related CR: 2018300012

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vaginal ring*	Approved After Suspension	Proposed PT	
			Vaginal ring	10082353
			HLT primary	
			Contraceptive methods female	10010812
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT Vaginal ring is approved as requested after suspension. A vaginal ring is a type of hormonal contraception that works in a similar way to the oral contraceptive pill to prevent pregnancy. Vaginal ring will be added as PT to HLT Contraceptive methods female.

CR Number: 2018300013 **Implementation Date:** 16-Nov-18 Related CR: 2018300013

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cervical cap*	Approved After Suspension	Proposed LLT	
To PT	*Contraceptive cap*		*Cervical cap*	10082357 Current
			To PT	
			Contraceptive cap	10010810

MSSO Comment: The proposal to add a new LLT Cervical cap to PT Contraceptive cap is approved as requested after suspension. The cervical cap is a form of barrier contraception. A cervical cap fits over the cervix and blocks sperm from entering the uterus through the external orifice of the uterus.

Supplemental Update Report

CR Number: 2018300014 **Implementation Date:** 16-Nov-18 Related CR: 2018300014

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New LLT				
Proposed LLT	*Spermicides*	Approved Not as Requested After Suspension	Proposed LLT	
			Spermicidal contraception	10082356 Current
			To PT	
			Chemical contraception	10067045

MSSO Comment: The proposal to add a new LLT Spermicides is approved but not as requested after suspension. Spermicide is a contraceptive substance that destroys sperm, inserted vaginally prior to intercourse to prevent pregnancy. As a contraceptive, spermicide may be used alone. The requested term will be modified for clarification and added as LLT Spermicidal contraception to PT Chemical contraception.

CR Number: 2018300015 **Implementation Date:** 16-Nov-18 Related CR: 2018300015

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New Term				
Proposed Term	*Contraceptive film*	Approved Not as Requested After Suspension	Proposed LLT	
			Vaginal contraceptive film	10082362 Current
			To PT	
			Chemical contraception	10067045

MSSO Comment: The proposal to add a new term Contraceptive film is approved but not as requested after suspension. Vaginal contraceptive film is a translucent square of material containing the active ingredient Nonoxynol-9, a widely used highly efficient spermicide. The requested term will be modified for clarification and added as LLT Vaginal contraceptive film to PT Chemical contraception.

CR Number: 2018300016 **Implementation Date:** 16-Nov-18 Related CR: 2018300016

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New Term				
Proposed Term	*Contraceptive foam*	Approved After Suspension	Proposed LLT	
			Contraceptive foam	10082359 Current
			To PT	
			Chemical contraception	10067045

MSSO Comment: The proposal to add a new term Contraceptive foam is approved as requested after suspension. Contraceptive foam is a type of spermicide that contains a high level of spermicidal chemical and will be added as LLT to PT Chemical contraception.

Supplemental Update Report

CR Number: 2018302001 **Implementation Date:** 06-Nov-18 Related CR: 2018302001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Pfeiffer syndrome*	Approved as Requested	Proposed PT	
			Pfeiffer syndrome	10082289
			HLT primary	
			Musculoskeletal and connective tissue disorders of skull congenital	10028382
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Musculoskeletal and connective tissue disorders of skull congenital	10028382
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new term Pfeiffer syndrome is approved as requested. Pfeiffer syndrome is a genetic disorder characterized by the premature fusion of certain skull bones (craniosynostosis). This early fusion prevents the skull from growing normally and affects the shape of the head and face. Pfeiffer syndrome also affects bones in the hands and feet. It will be added as PT to the bi-axial HLT Musculoskeletal and connective tissue disorders of skull congenital (primary SOC Congenital, familial and genetic disorders and secondary SOC Musculoskeletal and connective tissue disorders), with a additional secondary link to HLT Nervous system disorders NEC, in relation with the several neurologic alterations found in the more severe types 2 and 3 of this syndrome.

CR Number: 2018310003 **Implementation Date:** 06-Nov-18 Related CR: 2018302001

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pfeiffer syndrome*	Approved as Requested	Proposed PT	
To HLT	*Nervous system disorders NEC*		*Pfeiffer syndrome*	10082289
			To HLT	
			Nervous system disorders NEC	10057185

MSSO Comment:

Supplemental Update Report

CR Number: 2018302002 **Implementation Date:** 15-Nov-18 Related CR: 2018302002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Asthenia-vegetative syndrome*	Approved Not as Requested After Suspension	Proposed LLT *Asthenic-vegetative syndrome*	10082350 Current
			To PT *Autonomic nervous system imbalance*	10003840

MSSO Comment: The proposal to add a new term Asthenia-vegetative syndrome is approved but not as requested after suspension. The Asthenia-vegetative syndrome (Asthenic-vegetative syndrome, or Astheno-vegetative syndrome) has been described as a functional disorder of the autonomic nervous system that regulates the normal functioning of all internal organs and systems of the body, whose symptoms are characterized by the affective organs. The syndrome is often described as a having been preceded by stress, sleep deprivation, and psychological factors. The requested term will be modified to Asthenic-vegetative syndrome and added as an LLT to PT Autonomic nervous system imbalance.

CR Number: 2018302004 **Implementation Date:** 14-Nov-18 Related CR: 2018302004

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cheilitis*	Approved Not as Requested	Proposed PT *Cheilitis*	10008417
To SMQ	*Hypersensitivity (SMQ)*		To SMQ *Hypersensitivity (SMQ)*	20000214
Term scope	*Narrow*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Cheilitis to Hypersensitivity (SMQ) as a narrow term is approved but not as requested. PT Cheilitis warrants inclusion as a broad scope term in Hypersensitivity SMQ, rather than as a narrow term as proposed, because although systemic or contact hypersensitivity reactions are not uncommon causes of cheilitis, cheilitis is also associated with a variety of other etiologies. PT Cheilitis fulfills the inclusion criterion "...terms indicative of potential drug/vaccine and other medical product related hypersensitivity/allergic conditions."

Supplemental Update Report

CR Number: 2018302005 **Implementation Date:** 04-Dec-18 Related CR: 2018302005

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ocular stem cell transplant*	Approved as Requested	Proposed PT *Ocular stem cell transplant*	10082039
To SMQ	*Corneal disorders (SMQ)*		To SMQ *Corneal disorders (SMQ)*	20000156
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Ocular stem cell transplant to Corneal disorders (SMQ) as a broad term is approved as requested. PT Ocular stem cell transplant was added in V 22.0. Stem cells are unspecialized cells that have been a major focus of the field of regenerative medicine, and many investigations are being conducted to develop stem cell transplant therapy procedures for a broad variety of ocular disorders, currently concentrated on the retina, cornea, and lens. Corneal indications for stem cell transplantation pertain to regeneration of epithelial, stromal, and endothelial tissue in the treatment of conditions such as corneal scars, corneal edema, and corneal dystrophies. PT Ocular stem cell transplant will be added as a broad scope term to Corneal disorders (SMQ), because corneal disorders are an important therapeutic objective of ocular stem cell transplantation clinical investigations, and the term may be of potential value in identifying relevant cases of corneal disorders. https://www.cell.com/cell-stem-cell/pdf/S1934-5909(18)30231-5.pdf

CR Number: 2018302006 **Implementation Date:** 04-Dec-18 Related CR: 2018302006

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Phototherapeutic keratectomy*	Approved as Requested	Proposed PT *Phototherapeutic keratectomy*	10082005
To SMQ	*Corneal disorders (SMQ)*		To SMQ *Corneal disorders (SMQ)*	20000156
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Phototherapeutic keratectomy to Corneal disorders (SMQ) as a narrow term is approved as requested. PT Phototherapeutic keratectomy was added in V 22.0. Laser phototherapeutic keratectomy has been found to be an effective treatment for corneal surface irregularity, epithelial instability, and superficial opacities, such as scars, degenerations, dystrophies, bullous keratopathy, and band-shaped keratopathy. PT Phototherapeutic keratectomy will be added as a narrow scope term to Corneal disorders (SMQ), because phototherapeutic keratectomy is only performed as a treatment for corneal diseases. Of note, PT Photorefractive keratectomy, PT Keratotomy, and PT Keratectomy are existing narrow terms in this Corneal disorders (SMQ), also representing procedures that are specific for corneal disorders.

Supplemental Update Report

CR Number: **2018302007** **Implementation Date:** 04-Dec-18 Related CR: 2018302007

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Retinoscopy abnormal*	Approved as Requested	Proposed PT *Retinoscopy abnormal*	10082017
To SMQ	*Corneal disorders (SMQ)*		To SMQ *Corneal disorders (SMQ)*	20000156
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Retinoscopy abnormal to Corneal disorders (SMQ) as a broad term is approved as requested. PT Retinoscopy abnormal was added in V 22.0. Retinoscopy is primarily used to assess the spherical and astigmatic refractive status of the eye, utilizing a retinoscope to shine light into the patient's eye and observing the reflex off the patient's retina. However, abnormalities found with retinoscopy can help to identify why a patient with a clear cornea cannot see well. Retinoscopy may help to detect morphological disorders of the cornea such as irregular astigmatism, keratoconus, and other regularities of the corneal surface. Because abnormal retinoscopic findings may indicate corneal disorders, PT Retinoscopy abnormal will be added as a broad scope term to Corneal disorders (SMQ).

CR Number: **2018302008** **Implementation Date:** 04-Dec-18 Related CR: 2018302008

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Glycopenia*	Approved as Requested	Proposed PT *Glycopenia*	10082172
To SMQ	*Hypoglycaemia (SMQ)*		To SMQ *Hypoglycaemia (SMQ)*	20000226
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Glycopenia to Hypoglycaemia (SMQ) as a narrow term is approved as requested. PT Glycopenia, added in V 22.0, represents a deficiency of sugar in the tissues, which frequently results from hypoglycemia. Glycopenia affects the function of neurons, and may alter brain function and behavior. PT Glycopenia will be added as a narrow scope term to Hypoglycaemia (SMQ), because the term is highly associated with hypoglycaemia, and it fulfills the inclusion criterion for this SMQ: "Terms for characteristic signs and symptoms of hypoglycemia."

Supplemental Update Report

CR Number: 2018302009 **Implementation Date:** 04-Dec-18 Related CR: 2018302009

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Paraneoplastic hypoglycaemia*	Approved as Requested	Proposed PT *Paraneoplastic hypoglycaemia*	10082152
To SMQ	*Hypoglycaemia (SMQ)*		To SMQ *Hypoglycaemia (SMQ)*	20000226
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Paraneoplastic hypoglycaemia to Hypoglycaemia (SMQ) as a narrow term is approved as requested. PT Paraneoplastic hypoglycaemia, added in V 22.0, is a rare clinical entity that may occur in patients with diverse types of tumor lineages which may be characterized by different mechanisms. These pathogenic mechanisms include eutopic insulin secretion by a pancreatic islet β-cell tumor, and also the ectopic tumor insulin secretion by non-islet-cell tumor, such as bronchial carcinoids and gastrointestinal stromal tumors. Insulinoma is, by far, the most common tumor associated with clinical and biochemical hypoglycemia. Other mechanisms that may, more uncommonly, account for tumor-associated hypoglycemia without excess insulin secretion are the tumor secretion of peptides capable of causing glucose consumption by different mechanisms. These are the cases of tumors producing IGF2 precursors, IGF1, somatostatin, and glucagon-like peptide. Tumor autoimmune hypoglycemia occurs due to the production of insulin by tumor cells or insulin receptor autoantibodies. https://www.ncbi.nlm.nih.gov/pubmed/24459236 PT Paraneoplastic hypoglycaemia will be added as a narrow scope term to Hypoglycaemia (SMQ) as it is a type of hypoglycaemia that fulfills the following inclusion criterion for this SMQ: “Terms for various forms of hypoglycemia, which generally include the word ‘hypoglycaemia’.”

Supplemental Update Report

CR Number: 2018302010 **Implementation Date:** 04-Dec-18 Related CR: 2018302010

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ocular stem cell transplant*	Approved as Requested	Proposed PT *Ocular stem cell transplant*	10082039
To SMQ	*Lens disorders (SMQ)*		To SMQ *Lens disorders (SMQ)*	20000155
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Ocular stem cell transplant to Lens disorders (SMQ) as a broad term is approved as requested. PT Ocular stem cell transplant was added in V 22.0. Stem cells are unspecialized cells that have been a major focus of the field of regenerative medicine, and many investigations are being conducted to develop stem cell transplant therapy procedures for a broad variety of ocular disorders, currently concentrated on the retina, cornea, and lens. Indications for stem cell transplantation pertaining to the crystalline lens include regeneration of lens tissue for the replacement of cataracts. PT Ocular stem cell transplant will be added as a broad scope term to Lens disorders (SMQ) as it is a therapeutic procedural term of potential relevance to the lens. https://www.cell.com/cell-stem-cell/pdf/S1934-5909(18)30231-5.pdf

CR Number: 2018302011 **Implementation Date:** 04-Dec-18 Related CR: 2018302011

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hordeolum excision*	Approved as Requested	Proposed PT *Hordeolum excision*	10081987
To SMQ	*Periorbital and eyelid disorders (SMQ)*		To SMQ *Periorbital and eyelid disorders (SMQ)*	20000179
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Hordeolum excision to Periorbital and eyelid disorders (SMQ) as a narrow term is approved as requested. PT Hordeolum excision was added in V 22.0. A hordeolum is a localized, purulent, inflammatory staphylococcal infection of one or more sebaceous glands (meibomian or zeisian) of the eyelids; also called a stye. PT Hordeolum will be added to Periorbital and eyelid disorders (SMQ), fulfilling the inclusion criterion "Terms for eyelid procedures." All terms in this SMQ are narrow.

Supplemental Update Report

CR Number: 2018302012 **Implementation Date:** 04-Dec-18 Related CR: 2018302012

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ocular stem cell transplant*	Approved as Requested	Proposed PT	
To SMQ	*Retinal disorders (SMQ)*		*Ocular stem cell transplant*	10082039
Term scope	*Broad*		To SMQ	
			Retinal disorders (SMQ)	20000158
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Ocular stem cell transplant to Retinal disorders (SMQ) as a broad term is approved as requested. PT Ocular stem cell transplant was added in V 22.0. Stem cells are unspecialized cells that have been a major focus of the field of regenerative medicine, and many investigations are being conducted to develop stem cell transplant therapy procedures for a broad variety of ocular disorders, currently concentrated on the retina, cornea, and lens. Ocular stem cell transplantation techniques are in development for the regeneration of retinal ganglion cells, photoreceptor cells, and other tissues for disorders such as retinitis pigmentosa, other chorioretinal degenerations, and macular degeneration. PT Ocular stem cell transplant will be added as a broad scope term to Retinal disorders (SMQ) because of the ongoing investigations of this therapy, and its potential value in identifying cases of underlying retinal diseases. https://www.cell.com/cell-stem-cell/pdf/S1934-5909(18)30231-5.pdf

CR Number: 2018302013 **Implementation Date:** 04-Dec-18 Related CR: 2018302013

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vogt-Koyanagi-Harada disease*	Approved as Requested	Proposed PT	
To SMQ	*Retinal disorders (SMQ)*		*Vogt-Koyanagi-Harada disease*	10082001
Term scope	*Broad*		To SMQ	
			Retinal disorders (SMQ)	20000158
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Vogt-Koyanagi-Harada disease to Retinal disorders (SMQ) as a broad term is approved as requested. PT Vogt-Koyanagi-Harada disease, added in V 22.0, initially described as an uveomeningoencephalitic syndrome, is a systemic granulomatous autoimmune disease that targets melanocyte-rich tissues, such as the eye, inner ear, meninges, skin and hair. Ocular manifestations may include diffuse choroiditis, serous retinal detachment or focal areas of subretinal fluid. PT Vogt-Koyanagi-Harada disease will be added as a broad scope term to Retinal disorders (SMQ) because this autoimmune disease is frequently associated with retinal pathology. Of note, PT Autoimmune eye disorder is an existing broad term in Retinal disorders (SMQ).

Supplemental Update Report

CR Number: 2018302014 **Implementation Date:** 04-Dec-18 Related CR: 2018302014

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Oligoarthritis*	Approved as Requested	Proposed PT *Oligoarthritis*	10082100
To SMQ	*Arthritis (SMQ)*		To SMQ *Arthritis (SMQ)*	20000216
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Oligoarthritis to Arthritis (SMQ) as a narrow term is approved as requested. Oligoarthritis is a new PT for v22.0 which fits inclusion criteria as narrow in scope.

CR Number: 2018302015 **Implementation Date:** 04-Dec-18 Related CR: 2018302015

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hypersensitivity pneumonitis*	Approved as Requested	Proposed PT *Hypersensitivity pneumonitis*	10081988
To SMQ	*Asthma/bronchospasm (SMQ)*		To SMQ *Asthma/bronchospasm (SMQ)*	20000025
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Hypersensitivity pneumonitis to Asthma/bronchospasm (SMQ) as a broad term is approved as requested. Hypersensitivity pneumonitis is a new PT for v22.0. Former PT Alveolitis allergic is now an LLT to this new PT and was broad in scope.

Supplemental Update Report

CR Number: 2018302016 **Implementation Date:** 04-Dec-18 Related CR: 2018302016

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neonatal bradyarrhythmia*	Approved as Requested	Proposed PT *Neonatal bradyarrhythmia*	10082054
To SMQ	*Congenital and neonatal arrhythmias (SMQ)*		To SMQ *Congenital and neonatal arrhythmias (SMQ)*	20000052
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Neonatal bradyarrhythmia to Congenital and neonatal arrhythmias (SMQ) as a narrow term is approved as requested. Neonatal bradyarrhythmia is a new PT for v22.0 which fits the inclusion criteria as narrow in scope.

CR Number: 2018302017 **Implementation Date:** 04-Dec-18 Related CR: 2018302017

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neonatal tachyarrhythmia*	Approved as Requested	Proposed PT *Neonatal tachyarrhythmia*	10082055
To SMQ	*Congenital and neonatal arrhythmias (SMQ)*		To SMQ *Congenital and neonatal arrhythmias (SMQ)*	20000052
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Neonatal tachyarrhythmia to Congenital and neonatal arrhythmias (SMQ) as a narrow term is approved as requested. Neonatal tachyarrhythmia is a new PT for v22.0 which fits inclusion criteria as narrow in scope.

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CR Number: 2018302018 **Implementation Date:** 04-Dec-18 Related CR: 2018302018

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Frederick's syndrome*	Approved as Requested	Proposed PT	
To SMQ	*Supraventricular tachyarrhythmias (SMQ)*		*Frederick's syndrome*	10082089
Term scope	*Narrow*		To SMQ	
			Supraventricular tachyarrhythmias (SMQ)	20000057
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Frederick's syndrome to Supraventricular tachyarrhythmias (SMQ) as a narrow term is approved as requested. Frederick's syndrome is a new PT for v22.0 which fits inclusion criteria as narrow in scope. Frederick's syndrome is a symptom complex consisting of clinical features of pathology and electrocardiographic manifestations that occur with complete atrioventricular blockade and atrial fibrillation.

CR Number: 2018302019 **Implementation Date:** 04-Dec-18 Related CR: 2018302019

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Implantable cardiac monitor replacement*	Approved as Requested	Proposed PT	
To SMQ	*Cardiac failure (SMQ)*		*Implantable cardiac monitor replacement*	10082009
Term scope	*Broad*		To SMQ	
			Cardiac failure (SMQ)	20000004
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Implantable cardiac monitor replacement to Cardiac failure (SMQ) as a broad term is approved as requested. Implantable cardiac monitor replacement is a new PT for v22.0 which fits the inclusion criteria for a broad in scope term - similar to included PT Cardiac resynchronisation therapy. The device is used to detect atrial fibrillation in patients with hypertrophic cardiomyopathy and congestive heart failure.

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CR Number: 2018302020 **Implementation Date:** 04-Dec-18 Related CR: 2018302020

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Implantable cardiac monitor replacement*	Approved as Requested	Proposed PT	
To SMQ	*Cardiomyopathy (SMQ)*		*Implantable cardiac monitor replacement*	10082009
Term scope	*Broad*		To SMQ	
			Cardiomyopathy (SMQ)	20000150
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Implantable cardiac monitor replacement to Cardiomyopathy (SMQ) as a broad term is approved as requested. Implantable cardiac monitor replacement is a new PT for v22.0 which fits inclusion criteria for a broad in scope term - similar to included PT Cardiac resynchronisation therapy. The device is used to detect atrial fibrillation in patients with hypertrophic cardiomyopathy and congestive heart failure.

CR Number: 2018302021 **Implementation Date:** 04-Dec-18 Related CR: 2018302021

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hypersensitivity pneumonitis*	Approved as Requested	Proposed PT	
To SMQ	*Hypersensitivity (SMQ)*		*Hypersensitivity pneumonitis*	10081988
Term scope	*Narrow*		To SMQ	
			Hypersensitivity (SMQ)	20000214
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Hypersensitivity pneumonitis to Hypersensitivity (SMQ) as a narrow term is approved as requested. Hypersensitivity pneumonitis is a new PT for v22.0. Former PT Alveolitis allergic is now an LLT to this new PT and fits the inclusion criteria as narrow in scope.

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CR Number: 2018302022 **Implementation Date:** 04-Dec-18 Related CR: 2018302022

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Human anti-hamster antibody positive*	Approved as Requested	Proposed PT *Human anti-hamster antibody positive*	10082109
To SMQ	*Hypersensitivity (SMQ)*		To SMQ *Hypersensitivity (SMQ)*	20000214
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Human anti-hamster antibody positive to Hypersensitivity (SMQ) as a broad term is approved as requested. Human anti-hamster antibody positive is a new term which fits inclusion criteria as broad in scope like other test terms. There is a potential risk of residual hamster protein in certain biologics provoking an immunological response in the patient resulting in Human anti-hamster antibody formation.

CR Number: 2018302023 **Implementation Date:** 04-Dec-18 Related CR: 2018302023

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hypersensitivity pneumonitis*	Rejected		
To SMQ	*Hypersensitivity (SMQ)*			
Term scope	*Narrow*			

MSSO Comment: The proposal to add PT Hypersensitivity pneumonitis to Hypersensitivity (SMQ) as a narrow term is not approved. This is a duplicate of CR# 2018302021.

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CR Number: 2018302024 **Implementation Date:** 04-Dec-18 Related CR: 2018302024

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Drug level abnormal*	Approved as Requested	Proposed PT	
To SMQ	*Lack of efficacy/effect (SMQ)*		*Drug level abnormal*	10082169
Term scope	*Narrow*		To SMQ	
			Lack of efficacy/effect (SMQ)	20000032
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Drug level abnormal to Lack of efficacy/effect (SMQ) as a narrow term is approved as requested. Drug level abnormal is a new PT for v22.0. Drug level abnormal indicates lower than expected i.e., lack of efficacy. PT Drug level decreased is included as well. All terms are narrow in scope.

CR Number: 2018302025 **Implementation Date:** 04-Dec-18 Related CR: 2018302025

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Human anti-hamster antibody increased*	Approved as Requested	Proposed PT	
To SMQ	*Hypersensitivity (SMQ)*		*Human anti-hamster antibody increased*	10082107
Term scope	*Broad*		To SMQ	
			Hypersensitivity (SMQ)	20000214
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Human anti-hamster antibody increased to Hypersensitivity (SMQ) as a broad term is approved as requested. Human anti-hamster antibody increased is a new term which fits inclusion criteria as broad in scope like other test terms. There is a potential risk of residual hamster protein in certain biologics provoking an immunological response in the patient resulting in Human anti-hamster antibody formation.

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CR Number: 2018302026 **Implementation Date:** 04-Dec-18 Related CR: 2018302026

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Portal vein embolism*	Approved as Requested	Proposed PT *Portal vein embolism*	10082030
To SMQ	*Embolic and thrombotic events, venous (SMQ)*		To SMQ *Embolic and thrombotic events, venous (SMQ)*	20000084
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Portal vein embolism to Embolic and thrombotic events, venous (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ for venous embolism terms. All terms in this SMQ are narrow scope.

CR Number: 2018302027 **Implementation Date:** 04-Dec-18 Related CR: 2018302027

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Spinal stroke*	Approved as Requested	Proposed PT *Spinal stroke*	10082031
To SMQ	*Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (SMQ)*		To SMQ *Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (SMQ)*	20000083
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Spinal stroke to Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ for infarction- and stroke-related events. A similar term, PT Brain stem stroke is already included. All terms in this SMQ are narrow scope.

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CR Number: 2018302028 **Implementation Date:** 04-Dec-18 Related CR: 2018302028

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hypersensitivity pneumonitis*	Approved as Requested	Proposed PT *Hypersensitivity pneumonitis*	10081988
To SMQ	*Eosinophilic pneumonia (SMQ)*		To SMQ *Eosinophilic pneumonia (SMQ)*	20000157
Term scope	*Broad*		Term scope *Broad*	
			Term_category *C*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Hypersensitivity pneumonitis to Eosinophilic pneumonia (SMQ) as a broad term is approved as requested. This term fits the inclusion criteria for this SMQ. Hypersensitivity pneumonitis, also called extrinsic allergic alveolitis, is a respiratory syndrome involving the lung parenchyma and specifically the alveoli, terminal bronchioli, and alveolar interstitium, due to a delayed allergic reaction. The previously included PT Alveolitis allergic (Broad scope, category C) was demoted under this new PT.

CR Number: 2018302029 **Implementation Date:** 04-Dec-18 Related CR: 2018302029

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hypersensitivity pneumonitis*	Approved as Requested	Proposed PT *Hypersensitivity pneumonitis*	10081988
To SMQ	*Interstitial lung disease (SMQ)*		To SMQ *Interstitial lung disease (SMQ)*	20000042
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Hypersensitivity pneumonitis to Interstitial lung disease (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ. Hypersensitivity pneumonitis, also called extrinsic allergic alveolitis, is a respiratory syndrome involving the lung parenchyma and specifically the alveoli, terminal bronchioli, and alveolar interstitium, due to a delayed allergic reaction. The previously included PT Alveolitis allergic (narrow scope) was demoted under this new PT.

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CR Number: 2018302030 **Implementation Date:** 04-Dec-18 Related CR: 2018302030

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Tumour thrombectomy*	Approved as Requested	Proposed PT *Tumour thrombectomy*	10081994
To SMQ	*Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (SMQ)*		To SMQ *Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (SMQ)*	20000083
Term scope	*Narrow*		Term scope *Narrow* Term_category *A* Term_weight *0*	

MSSO Comment: The proposal to add PT Tumour thrombectomy to Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous (SMQ) as a narrow term is approved as requested. Tumour thrombosis is a collective term for intravascular metastases with thrombotic elements. This term fits the inclusion criteria for this SMQ for terms that are procedure-related. A similar term, PT Thrombectomy, is already included. All terms in this SMQ are narrow scope.

CR Number: 2018302031 **Implementation Date:** 04-Dec-18 Related CR: 2018302031

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Uterine hypokinesia*	Approved as Requested	Proposed PT *Uterine hypokinesia*	10082029
To SMQ	*Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)*		To SMQ *Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)*	20000186
Term scope	*Narrow*		Term scope *Narrow* Term_category *A* Term_weight *0*	

MSSO Comment: The proposal to add PT Uterine hypokinesia to Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ) as a narrow term is approved as requested. Uterine hypokinesia is characterized by a decrease in the duration and/or intensity and/or frequency of uterine contractions and, because this condition increases the risk of delivery complications, it meets criteria for inclusion in the narrow search terms of this SMQ.

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CR Number: 2018302032 **Implementation Date:** 04-Dec-18 Related CR: 2018302032

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Target skin lesion*	Approved as Requested	Proposed PT *Target skin lesion*	10081998
To SMQ	*Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)*		To SMQ *Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)*	20000225
Term scope	*Broad*		Term scope *Broad*	
			Term_category *B*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Target skin lesion to Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ) as a broad term is approved as requested. A target skin lesion, named for its resemblance to the bull's-eye, is the typical lesion of erythema multiforme in which a vesicle is surrounded by an often hemorrhagic maculopapule. These lesions can be seen in drug-related eruptions such as DRESS syndrome. Cutaneous manifestations are included in the Category B broad search terms of this SMQ.

CR Number: 2018302033 **Implementation Date:** 04-Dec-18 Related CR: 2018302033

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Target skin lesion*	Approved as Requested	Proposed PT *Target skin lesion*	10081998
To SMQ	*Severe cutaneous adverse reactions (SMQ)*		To SMQ *Severe cutaneous adverse reactions (SMQ)*	20000020
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Target skin lesion to Severe cutaneous adverse reactions (SMQ) as a narrow term is approved as requested. A target skin lesion, named for its resemblance to the bull's-eye, is the typical lesion of erythema multiforme in which a vesicle is surrounded by an often hemorrhagic maculopapule. These lesions can be seen in exfoliative conditions like Stevens-Johnson syndrome and it will added to the narrow search terms of this SMQ.

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CR Number: 2018302034 **Implementation Date:** 04-Dec-18 Related CR: 2018302034

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Tumour ablation*	Approved as Requested	Proposed PT	
To SMQ	*Malignancy related therapeutic and diagnostic procedures (SMQ)*		*Tumour ablation*	10082081
Term scope	*Narrow*		To SMQ	
			Malignancy related therapeutic and diagnostic procedures (SMQ)	20000093
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Tumour ablation to Malignancy related therapeutic and diagnostic procedures (SMQ) as a narrow term is approved as requested. Terms for procedures used to treat malignancies meet inclusion criteria for this SMQ composed of narrow search terms.

CR Number: 2018302035 **Implementation Date:** 04-Dec-18 Related CR: 2018302035

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Tumour thrombectomy*	Approved as Requested	Proposed PT	
To SMQ	*Malignancy related therapeutic and diagnostic procedures (SMQ)*		*Tumour thrombectomy*	10081994
Term scope	*Narrow*		To SMQ	
			Malignancy related therapeutic and diagnostic procedures (SMQ)	20000093
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Tumour thrombectomy to Malignancy related therapeutic and diagnostic procedures (SMQ) as a narrow term is approved as requested. Terms for procedures used to treat malignancies meet inclusion criteria for this SMQ composed of narrow search terms.

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CR Number: 2018302036 **Implementation Date:** 04-Dec-18 Related CR: 2018302036

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Paraneoplastic hypoglycaemia*	Approved as Requested	Proposed PT *Paraneoplastic hypoglycaemia*	10082152
To SMQ	*Malignancy related conditions (SMQ)*		To SMQ *Malignancy related conditions (SMQ)*	20000092
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Paraneoplastic hypoglycaemia to Malignancy related conditions (SMQ) as a narrow term is approved as requested. Terms for malignancy related conditions meet inclusion criteria for this SMQ composed of narrow search terms.

CR Number: 2018302037 **Implementation Date:** 04-Dec-18 Related CR: 2018302037

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ovarian melanoma*	Approved as Requested	Proposed PT *Ovarian melanoma*	10082079
To SMQ	*Ovarian malignant tumours (SMQ)*		To SMQ *Ovarian malignant tumours (SMQ)*	20000200
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Ovarian melanoma to Ovarian malignant tumours (SMQ) as a narrow term is approved as requested. This term describes a specific ovarian malignancy and meets inclusion criteria for the narrow search terms of this SMQ.

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CR Number: 2018302038 **Implementation Date:** 04-Dec-18 Related CR: 2018302038

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ovarian melanoma*	Approved as Requested	Proposed PT	
To SMQ	*Non-haematological malignant tumours (SMQ)*		*Ovarian melanoma*	10082079
Term scope	*Narrow*		To SMQ	
			Non-haematological malignant tumours (SMQ)	20000228
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Ovarian melanoma to Non-haematological malignant tumours (SMQ) as a narrow term is approved as requested. This term describes a specific non-hematological malignancy and meets inclusion criteria for this SMQ composed of narrow search terms.

CR Number: 2018302039 **Implementation Date:** 04-Dec-18 Related CR: 2018302039

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Immature granulocyte percentage increased*	Approved as Requested	Proposed PT	
To SMQ	*Myelodysplastic syndrome (SMQ)*		*Immature granulocyte percentage increased*	10082033
Term scope	*Broad*		To SMQ	
			Myelodysplastic syndrome (SMQ)	20000217
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Immature granulocyte percentage increased to Myelodysplastic syndrome (SMQ) as a broad term is approved as requested. This term describes a laboratory finding which can be seen as a precursor to development of myelodysplasia and meets criteria for inclusion as a broad search term in this SMQ.

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CR Number: 2018302040 **Implementation Date:** 04-Dec-18 Related CR: 2018302040

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cerebral cyst haemorrhage*	Approved as Requested	Proposed PT *Cerebral cyst haemorrhage*	10082099
To SMQ	*Haemorrhage terms (excl laboratory terms) (SMQ)*		To SMQ *Haemorrhage terms (excl laboratory terms) (SMQ)*	20000039
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Cerebral cyst haemorrhage to Haemorrhage terms (excl laboratory terms) (SMQ) as a narrow term is approved as requested. This term, which describes a specific location of hemorrhage, meets criteria for inclusion in this SMQ which is composed of narrow search terms.

CR Number: 2018302041 **Implementation Date:** 04-Dec-18 Related CR: 2018302041

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Mononuclear cell count increased*	Approved as Requested	Proposed PT *Mononuclear cell count increased*	10082032
To SMQ	*Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)*		To SMQ *Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)*	20000225
Term scope	*Broad*		Term scope *Broad*	
			Term_category *E*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Mononuclear cell count increased to Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ) as a broad term, category E, is approved as requested. This term describes a laboratory finding which is associated with an increase in numbers of a specific type of white blood cell. It meets criteria for inclusion as a broad search, category E term in this SMQ. The related PT, Monocyte count increased, is already included in this SMQ.

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CR Number: 2018302042 **Implementation Date:** 04-Dec-18 Related CR: 2018302042

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Mononuclear cell count decreased*	Approved as Requested	Proposed PT	
To SMQ	*Haematopoietic leukopenia (SMQ)*		*Mononuclear cell count decreased*	10082036
Term scope	*Broad*		To SMQ	
			Haematopoietic leukopenia (SMQ)	20000030
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Mononuclear cell count decreased to Haematopoietic leukopenia (SMQ) as a broad term is approved as requested. This term describes a laboratory finding which is associated with a reduction in the numbers of a specific type of white blood cell. It meets criteria for inclusion as a broad search term in this SMQ.

CR Number: 2018302043 **Implementation Date:** 04-Dec-18 Related CR: 2018302043

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cold burn*	Approved as Requested	Proposed PT	
To SMQ	*Accidents and injuries (SMQ)*		*Cold burn*	10081985
Term scope	*Narrow*		To SMQ	
			Accidents and injuries (SMQ)	20000135
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Cold burn to Accidents and injuries (SMQ) as a narrow term is approved as requested. This term describes a specific type of injury and meets for the narrow search terms of this SMQ.

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CR Number: 2018302044 **Implementation Date:** 04-Dec-18 Related CR: 2018302044

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cervix cryotherapy*	Approved Not as Requested	Proposed PT	
To SMQ	*Uterine and fallopian tube tumours of unspecified malignancy (SMQ)*		*Cervix cryotherapy*	10082060
Term scope	*Broad*		To SMQ	
			Uterine and fallopian tube tumours of unspecified malignancy (SMQ)	20000207
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Cervix cryotherapy to Uterine and fallopian tube tumours of unspecified malignancy (SMQ) as a broad term is approved but not as requested. Terms for procedures used to treat pre-cancerous lesions (such as cervical dysplasia) meet inclusion criteria for the narrow search terms of this SMQ.

CR Number: 2018302045 **Implementation Date:** 04-Dec-18 Related CR: 2018302045

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cervix cryotherapy*	Approved as Requested	Proposed PT	
To SMQ	*Reproductive premalignant disorders (SMQ)*		*Cervix cryotherapy*	10082060
Term scope	*Narrow*		To SMQ	
			Reproductive premalignant disorders (SMQ)	20000088
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Cervix cryotherapy to Reproductive premalignant disorders (SMQ) as a narrow term is approved as requested. Terms for procedures used to treat pre-cancerous lesions (such as cervical dysplasia) meet inclusion criteria for this SMQ composed of narrow search terms.

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CR Number: 2018302046 **Implementation Date:** 04-Dec-18 Related CR: 2018302046

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Puncture site bruise*	Approved as Requested	Proposed PT *Puncture site bruise*	10082035
To SMQ	*Haemorrhage terms (excl laboratory terms) (SMQ)*		To SMQ *Haemorrhage terms (excl laboratory terms) (SMQ)*	20000039
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Puncture site bruise to Haemorrhage terms (excl laboratory terms) (SMQ) as a narrow term is approved as requested. This term meets the criteria for inclusion in this SMQ, which consists of narrow search terms only. The related term, PT Vessel puncture site bruise, is already included in this SMQ.

CR Number: 2018302047 **Implementation Date:** 04-Dec-18 Related CR: 2018302047

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neonatal tachyarrhythmia*	Approved as Requested	Proposed PT *Neonatal tachyarrhythmia*	10082055
To SMQ	*Neonatal disorders (SMQ)*		To SMQ *Neonatal disorders (SMQ)*	20000191
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Neonatal tachyarrhythmia to Neonatal disorders (SMQ) as a narrow term is approved as requested. This SMQ contains all terms related to conditions of the neonate. Since the term describes a specific clinical condition (i.e., cardiac arrhythmia), it will be included in the narrow search terms.

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CR Number: 2018302048 **Implementation Date:** 04-Dec-18 Related CR: 2018302048

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neonatal bradyarrhythmia*	Approved as Requested	Proposed PT *Neonatal bradyarrhythmia*	10082054
To SMQ	*Neonatal disorders (SMQ)*		To SMQ *Neonatal disorders (SMQ)*	20000191
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Neonatal bradyarrhythmia to Neonatal disorders (SMQ) as a narrow term is approved as requested. This SMQ contains all terms related to conditions of the neonate. Since the term describes a specific clinical condition (i.e., cardiac arrhythmia), it will be included in the narrow search terms.

CR Number: 2018302049 **Implementation Date:** 04-Dec-18 Related CR: 2018302049

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neonatal pneumothorax*	Approved as Requested	Proposed PT *Neonatal pneumothorax*	10082056
To SMQ	*Neonatal disorders (SMQ)*		To SMQ *Neonatal disorders (SMQ)*	20000191
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Neonatal pneumothorax to Neonatal disorders (SMQ) as a narrow term is approved as requested. This SMQ contains all terms related to conditions of the neonate. Since the term describes a specific clinical condition (i.e., pneumothorax), it will be included in the narrow search terms.

Supplemental Update Report

CR Number: 2018302050 **Implementation Date:** 04-Dec-18 Related CR: 2018302050

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Carbohydrate antigen 72-4 increased*	Approved as Requested	Proposed PT	
To SMQ	*Tumour markers (SMQ)*		*Carbohydrate antigen 72-4 increased*	10082080
Term scope	*Narrow*		To SMQ	
			Tumour markers (SMQ)	20000094
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Carbohydrate antigen 72-4 increased to Tumour markers (SMQ) as a narrow term is approved as requested. This term describes a tumor marker which is highly specific for gastrointestinal and gynecological cancers. All terms in this SMQ are narrow in scope.

CR Number: 2018302051 **Implementation Date:** 04-Dec-18 Related CR: 2018302051

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neonatal seizure*	Approved as Requested	Proposed PT	
To SMQ	*Neonatal disorders (SMQ)*		*Neonatal seizure*	10082067
Term scope	*Narrow*		To SMQ	
			Neonatal disorders (SMQ)	20000191
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Neonatal seizure to Neonatal disorders (SMQ) as a narrow term is approved as requested. This SMQ contains all terms related to conditions of the neonate. Since the term describes a specific clinical condition (i.e., seizures), it will be included in the narrow search terms.

Supplemental Update Report

CR Number: 2018302052 **Implementation Date:** 04-Dec-18 Related CR: 2018302052

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hypersensitivity pneumonitis*	Approved as Requested	Proposed PT	
To SMQ	*Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)*		*Hypersensitivity pneumonitis*	10081988
Term scope	*Broad*		To SMQ	
			Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)	20000225
			Term scope	
			Broad	
			Term_category	
			B	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Hypersensitivity pneumonitis to Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ) as a Category B, broad term, is approved as requested. This term, which describes a specific type of hypersensitivity-related organ damage, meets the criteria for inclusion in the Category B broad search terms of this SMQ. The previously included PT Alveolitis allergic (broad scope, category B) was demoted under this new PT.

CR Number: 2018302053 **Implementation Date:** 04-Dec-18 Related CR: 2018302053

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Grey matter heterotopia*	Approved as Requested	Proposed PT	
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		*Grey matter heterotopia*	10082084
Term scope	*Narrow*		To SMQ	
			Congenital, familial and genetic disorders (SMQ)	20000077
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Grey matter heterotopia to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

Supplemental Update Report

CR Number: 2018302054 **Implementation Date:** 04-Dec-18 Related CR: 2018302054

Change Requested	Change term status in a SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gastrointestinal stromal tumour*	Approved as Requested	Proposed PT	
To SMQ	*Non-haematological tumours of unspecified malignancy (SMQ)*		*Gastrointestinal stromal tumour*	10051066
Status	*I*		To SMQ	
			Non-haematological tumours of unspecified malignancy (SMQ)	20000230
			Status	
			I	

MSSO Comment: The proposal to change status of the term Gastrointestinal stromal tumour in Non-haematological tumours of unspecified malignancy (SMQ) to Inactive is approved as requested. This term was previously flagged as active in this SMQ because a stromal tumour was considered to range from benign, to intermediate, to malignant in their behavior. However, the understanding of GIST biology has changed significantly with identification of their molecular basis, which has led to a reclassification of the group, in which all GIST tumors are now considered to have malignant potential, and no GIST tumor can be definitively classified as "benign". Therefore, the status of PT Gastrointestinal stromal tumour will be changed from active to inactive in this SMQ. In a related change, the status of PT Gastrointestinal stromal tumour will be changed from inactive to active in SMQ Non-haematological malignant tumours. See CR# 2018302055.

CR Number: 2018302055 **Implementation Date:** 04-Dec-18 Related CR: 2018302055

Change Requested	Change term status in a SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gastrointestinal stromal tumour*	Approved as Requested	Proposed PT	
To SMQ	*Non-haematological malignant tumours (SMQ)*		*Gastrointestinal stromal tumour*	10051066
Status	*A*		To SMQ	
			Non-haematological malignant tumours (SMQ)	20000228
			Status	
			A	

MSSO Comment: The proposal to change status of the term Gastrointestinal stromal tumour in Non-haematological malignant tumours (SMQ) to Active is approved as requested. This term was previously flagged as inactive in this SMQ because a stromal tumour was considered to range from benign, to intermediate, to malignant in their behavior. However, the understanding of GIST biology has changed significantly with identification of their molecular basis, which has led to a reclassification of the group, in which all GIST tumors are now considered to have malignant potential, and no GIST tumor can be definitively classified as "benign". Therefore, the status of PT Gastrointestinal stromal tumour will be changed from inactive to active in this SMQ. Note that previously included PT Gastrointestinal stromal cancer has been demoted under PT Gastrointestinal stromal tumour. In a related change, the status of PT Gastrointestinal stromal tumour will be changed from active to inactive in SMQ Non-haematological tumours of unspecified malignancy. See CR# 2018302054.

Supplemental Update Report

CR Number: 2018302056 **Implementation Date:** 04-Dec-18 Related CR: 2018302056

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Spinal stroke*	Approved as Requested	Proposed PT *Spinal stroke*	10082031
To SMQ	*Haemorrhagic central nervous system vascular conditions (SMQ)*		To SMQ *Haemorrhagic central nervous system vascular conditions (SMQ)*	20000064
Term scope	*Narrow*		Term scope *Narrow* Term_category *A* Term_weight *0*	

MSSO Comment: The proposal to add PT Spinal stroke to Haemorrhagic central nervous system vascular conditions (SMQ) as a narrow term is approved as requested. A stroke involving spinal tissue meets criteria for inclusion in the narrow search terms of this SMQ.

CR Number: 2018302057 **Implementation Date:** 04-Dec-18 Related CR: 2018302057

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Spinal stroke*	Approved as Requested	Proposed PT *Spinal stroke*	10082031
To SMQ	*Ischaemic central nervous system vascular conditions (SMQ)*		To SMQ *Ischaemic central nervous system vascular conditions (SMQ)*	20000063
Term scope	*Narrow*		Term scope *Narrow* Term_category *A* Term_weight *0*	

MSSO Comment: The proposal to add PT Spinal stroke to Ischaemic central nervous system vascular conditions (SMQ) as a narrow term is approved as requested. A stroke involving spinal tissue meets criteria for inclusion in the narrow search terms of this SMQ.

Supplemental Update Report

CR Number: 2018302058 **Implementation Date:** 04-Dec-18 Related CR: 2018302058

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hemiataxia*	Approved as Requested	Proposed PT	
To SMQ	*Conditions associated with central nervous system haemorrhages and cerebrovascular accidents (SMQ)*		*Hemiataxia*	10081999
Term scope	*Narrow*		To SMQ	
			Conditions associated with central nervous system haemorrhages and cerebrovascular accidents (SMQ)	20000166
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Hemiataxia to Conditions associated with central nervous system haemorrhages and cerebrovascular accidents (SMQ) as a narrow term is approved as requested. This term describes a coordination deficit of one half of the body which is typically associated with a cerebrovascular accident. It meets criteria for inclusion in the narrow search terms of this SMQ.

CR Number: 2018302059 **Implementation Date:** 04-Dec-18 Related CR: 2018302059

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cerebral cyst haemorrhage*	Approved as Requested	Proposed PT	
To SMQ	*Haemorrhagic central nervous system vascular conditions (SMQ)*		*Cerebral cyst haemorrhage*	10082099
Term scope	*Narrow*		To SMQ	
			Haemorrhagic central nervous system vascular conditions (SMQ)	20000064
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Cerebral cyst haemorrhage to Haemorrhagic central nervous system vascular conditions (SMQ) as a narrow term is approved as requested. This term describes a hemorrhage into an otherwise benign lesion of the brain and it meets criteria for inclusion in the narrow search terms of this SMQ.

Supplemental Update Report

CR Number: 2018302060 **Implementation Date:** 04-Dec-18 Related CR: 2018302060

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neonatal seizure*	Approved as Requested	Proposed PT	
To SMQ	*Convulsions (SMQ)*		*Neonatal seizure*	10082067
Term scope	*Narrow*		To SMQ	
			Convulsions (SMQ)	20000079
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Neonatal seizure to Convulsions (SMQ) as a narrow term is approved as requested. This term, which describes a specific type of seizure, meets the criteria for inclusion in the narrow search terms of this SMQ.

CR Number: 2018302061 **Implementation Date:** 04-Dec-18 Related CR: 2018302061

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neonatal seizure*	Approved as Requested	Proposed PT	
To SMQ	*Generalised convulsive seizures following immunisation (SMQ)*		*Neonatal seizure*	10082067
Term scope	*Narrow*		To SMQ	
			Generalised convulsive seizures following immunisation (SMQ)	20000212
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Neonatal seizure to Generalised convulsive seizures following immunisation (SMQ) as a narrow term is approved as requested. This term, which describes a specific type of seizure, meets the criteria for inclusion in the narrow search terms of this SMQ.

Supplemental Update Report

CR Number: 2018302062 **Implementation Date:** 04-Dec-18 Related CR: 2018302062

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neonatal seizure*	Approved as Requested	Proposed PT *Neonatal seizure*	10082067
To SMQ	*Noninfectious encephalitis (SMQ)*		To SMQ *Noninfectious encephalitis (SMQ)*	20000132
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Neonatal seizure to Noninfectious encephalitis (SMQ) as a broad term is approved as requested. This term, which describes a specific type of seizure, meets the criteria for inclusion in the broad search terms of this SMQ. The related term, PT Convulsion neonatal, was previously included in this SMQ.

CR Number: 2018302063 **Implementation Date:** 04-Dec-18 Related CR: 2018302063

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neonatal seizure*	Approved as Requested	Proposed PT *Neonatal seizure*	10082067
To SMQ	*Noninfectious encephalopathy/delirium (SMQ)*		To SMQ *Noninfectious encephalopathy/delirium (SMQ)*	20000133
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Neonatal seizure to Noninfectious encephalopathy/delirium (SMQ) as a broad term is approved as requested. This term, which describes a specific type of seizure, meets the criteria for inclusion in the broad search terms of this SMQ. The related term, PT Convulsion neonatal, was previously included in this SMQ.

Supplemental Update Report

CR Number: 2018302064 **Implementation Date:** 04-Dec-18 Related CR: 2018302064

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neonatal seizure*	Approved as Requested	Proposed PT *Neonatal seizure*	10082067
To SMQ	*Noninfectious meningitis (SMQ)*		To SMQ *Noninfectious meningitis (SMQ)*	20000134
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Neonatal seizure to Noninfectious meningitis (SMQ) as a broad term is approved as requested. This term, which describes a specific type of seizure, meets the criteria for inclusion in the broad search terms of this SMQ. The related term, PT Convulsion neonatal, was previously included in this SMQ.

CR Number: 2018302065 **Implementation Date:** 04-Dec-18 Related CR: 2018302065

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Grey matter heterotopia*	Approved as Requested	Proposed PT *Grey matter heterotopia*	10082084
To SMQ	*Convulsions (SMQ)*		To SMQ *Convulsions (SMQ)*	20000079
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Grey matter heterotopia to Convulsions (SMQ) as a narrow term is approved as requested. Grey matter heterotopia, which is caused by clumps of grey matter located in the wrong part of the brain, is frequently associated with the presence of seizures. As a recognized etiology for seizures, it meets criteria for inclusion in the narrow search terms of this SMQ.

Supplemental Update Report

CR Number: 2018302066 **Implementation Date:** 04-Dec-18 Related CR: 2018302066

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Acquired perforating dermatosis*	Approved as Requested	Proposed PT *Acquired perforating dermatosis*	10082163
To SMQ	*Chronic kidney disease (SMQ)*		To SMQ *Chronic kidney disease (SMQ)*	20000213
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Acquired perforating dermatosis to Chronic kidney disease (SMQ) as a broad term is approved as requested. Acquired perforating dermatosis is a skin disorder occurring in patients with chronic renal failure, diabetes mellitus or both. The lesions are characterized by eruption of generally pruritic keratotic papules and nodules, primarily on the extensor surface of the extremities and the trunk. Being a non-uremic cutaneous manifestation of chronic renal disease, the term should be added to the broad scope of this SMQ.

CR Number: 2018302067 **Implementation Date:** 04-Dec-18 Related CR: 2018302067

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Peritoneal dialysate leakage*	Approved as Requested	Proposed PT *Peritoneal dialysate leakage*	10082066
To SMQ	*Chronic kidney disease (SMQ)*		To SMQ *Chronic kidney disease (SMQ)*	20000213
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Peritoneal dialysate leakage to Chronic kidney disease (SMQ) as a broad term is approved as requested. Peritoneal dialysate leakage refers to the appearance of any moisture around the peritoneal dialysis catheter, including also any dialysate loss from the peritoneal cavity other than via the lumen of the catheter. Like other PTs within the HLT Dialysis related complications, this term should be included in the broad scope of this SMQ.

Supplemental Update Report

CR Number: 2018302068 **Implementation Date:** 04-Dec-18 Related CR: 2018302068

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Haemorrhagic cholecystitis*	Approved as Requested	Proposed PT *Haemorrhagic cholecystitis*	10082088
To SMQ	*Gallbladder related disorders (SMQ)*		To SMQ *Gallbladder related disorders (SMQ)*	20000124
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Haemorrhagic cholecystitis to Gallbladder related disorders (SMQ) as a narrow term is approved as requested. Haemorrhagic cholecystitis is an uncommon, acute, serious complication of acute cholecystitis that may or may not be associated with lithiasis. Like in the case of PT Cholecystitis, this new PT should be part of Gallbladder related disorders (SMQ), which is composed of narrow scope terms only.

CR Number: 2018302069 **Implementation Date:** 04-Dec-18 Related CR: 2018302069

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Dysbiosis*	Approved as Requested	Proposed PT *Dysbiosis*	10082129
To SMQ	*Gastrointestinal nonspecific dysfunction (SMQ)*		To SMQ *Gastrointestinal nonspecific dysfunction (SMQ)*	20000139
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Dysbiosis to Gastrointestinal nonspecific dysfunction (SMQ) as a broad term is approved as requested. Dysbiosis (also called dysbacteriosis) is a term for a microbial imbalance or maladaptation on or inside the body, leading to an impairement of the ecological community of commensal, symbiotic and pathogenic microorganisms. It is a non-specific functional negative effect of some drugs, such as antibiotics. Since Dysbiosis may not only be applied to the gastrointestinal tract (but also to other cavities or surfaces of the body), the term should be added to the broad scope of this SMQ.

Supplemental Update Report

CR Number: 2018302070 **Implementation Date:** 04-Dec-18 Related CR: 2018302070

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gastric electrical stimulation*	Approved as Requested	Proposed PT *Gastric electrical stimulation*	10082102
To SMQ	*Gastrointestinal obstruction (SMQ)*		To SMQ *Gastrointestinal obstruction (SMQ)*	20000105
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Gastric electrical stimulation to Gastrointestinal obstruction (SMQ) as a narrow term is approved as requested. Gastric electrical stimulation uses a device implanted in the abdomen to send mild electrical pulses to the nerves and smooth muscle of the lower stomach. This helps decrease nausea and vomiting in conditions causing functional obstruction, such as gastroparesis. This new PT should be part of this SMQ, which is composed of narrow scope terms only.

CR Number: 2018302071 **Implementation Date:** 04-Dec-18 Related CR: 2018302071

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gastrointestinal decompression*	Approved as Requested	Proposed PT *Gastrointestinal decompression*	10082064
To SMQ	*Gastrointestinal obstruction (SMQ)*		To SMQ *Gastrointestinal obstruction (SMQ)*	20000105
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Gastrointestinal decompression to Gastrointestinal obstruction (SMQ) as a narrow term is approved as requested. Gastrointestinal decompression is the removal of contents of the intestinal tract by use of suction, usually through a tube inserted into the upper gastrointestinal tract. This maneuver is meant to release obstruction and this term should be added to the broad scope of this SMQ as are other surgical and procedural interventions used to treat gastrointestinal obstructions.

Supplemental Update Report

CR Number: 2018302072 **Implementation Date:** 04-Dec-18 Related CR: 2018302072

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Partial splenic embolisation*	Approved as Requested	Proposed PT	
			Partial splenic embolisation	10081995
To SMQ	*Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ)*		To SMQ	
			Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ)	20000013
Term scope	*Broad*		Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Partial splenic embolisation to Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ) as a broad term is approved as requested. Partial splenic artery embolization is an adjuvant procedure to control bleeding in portal hypertension complications in cirrhotic patients. Partial splenic artery embolization has been demonstrated to effectively increase hematologic indices in cirrhotic patients with splenomegaly. Similarly to other procedures meant to lower portal hypertension in the cirrhotic patient (such as Peritoneovenous shunt, Portal shunt procedure, or Splenorenal shunt procedure), this new term should be added to the broad scope of this SMQ.

CR Number: 2018302073 **Implementation Date:** 04-Dec-18 Related CR: 2018302073

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Haemorrhagic cholecystitis*	Approved as Requested	Proposed PT	
			Haemorrhagic cholecystitis	10082088
To SMQ	*Infectious biliary disorders (SMQ)*		To SMQ	
			Infectious biliary disorders (SMQ)	20000120
Term scope	*Narrow*		Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Haemorrhagic cholecystitis to Infectious biliary disorders (SMQ) as a narrow term is approved as requested. Haemorrhagic cholecystitis is an uncommon, acute, serious complication of acute cholecystitis that may or may not be associated with lithiasis. Like in the case of PT Cholecystitis, this new PT should be part of Infectious biliary disorders (SMQ), which is composed of narrow scope terms only.

Supplemental Update Report

CR Number: 2018303001 **Implementation Date:** 06-Nov-18 Related CR: 2018303001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Urticarial dermatitis*	Approved Not as Requested	Proposed PT	
To PT	*Dermatitis allergic*		*Urticarial dermatitis*	10082290
			HLT primary	
			Dermatitis and eczema	10012435
			SOC primary	
			Skin and subcutaneous tissue disorders	10040785
			HLT secondary	
			Allergic conditions NEC	10027654
			SOC secondary	
			Immune system disorders	10021428

MSSO Comment: The proposal to add a new LLT Urticarial dermatitis to PT Dermatitis allergic is approved but not as requested. The term "urticarial dermatitis" describes an intensely pruritic, recalcitrant skin eruption characterized by erythematous papules and plaques that resemble urticaria, but last longer than 24 hours and are sometimes accompanied by eczematous lesions. Although the clinical presentation is not restricted to a specific entity, eczema and drug reactions seem to be the most frequent clinical associations; and in a subset of patients, urticarial dermatitis remains as a recognizable reaction pattern. Urticarial dermatitis will be added as a PT to primary HLT Dermatitis and eczema and secondary HLT Allergic conditions NEC.

CR Number: 2018304001 **Implementation Date:** 06-Nov-18 Related CR: 2018304001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Alpha-thalassaemia-intellectual deficit syndrome*	Approved as Requested	Proposed LLT	
To PT	*Alpha-thalassemia-intellectual deficit syndrome*		*Alpha-thalassaemia-intellectual deficit syndrome*	10082291
			To PT	
			Alpha-thalassemia-intellectual deficit syndrome	10082244 Current

MSSO Comment: The proposal to add a new LLT Alpha-thalassaemia-intellectual deficit syndrome to PT Alpha-thalassemia-intellectual deficit syndrome is approved as requested. In accordance with MedDRA rules, the British spelled term will be added as LLT Alpha-thalassaemia-intellectual deficit syndrome to PT Alpha-thalassemia-intellectual deficit syndrome and swapped to have the British English spelling as the PT. Please see change request 2018304002.

Supplemental Update Report

CR Number: 2018304002 **Implementation Date:** 06-Nov-18 Related CR: 2018304002

Change Requested	Swap a PT with an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Alpha-thalassemia-intellectual deficit syndrome*	Approved as Requested	Proposed PT	
With LLT	*Alpha-thalassaemia-intellectual deficit syndrome*		*Alpha-thalassemia-intellectual deficit syndrome*	10082244 Current
			With LLT	
			Alpha-thalassaemia-intellectual deficit syndrome	10082291

MSSO Comment: The proposal to swap the PT Alpha-thalassemia-intellectual deficit syndrome with the LLT Alpha-thalassaemia-intellectual deficit syndrome is approved as requested. In accordance with MedDRA rules, the British spelled term will be swapped with its American counterpart in order to represent it as PT.

CR Number: 2018304003 **Implementation Date:** 12-Nov-18 Related CR: 2018304003

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Exposure during pregnancy*	Rejected After Suspension		
Status	*non-current*			

MSSO Comment: The proposal to change status of LLT Exposure during pregnancy to non-current is not approved after suspension. The MSSO will forward your request about adding a note to the MedDRA Term Selection document to the ICH M1 Points to Consider Working Group for its consideration. Section 3.10, Exposures in Pregnancy and Breastfeeding could be modified to include information about when it is appropriate to use general terms such as LLT Exposure during pregnancy. If implemented, the note would appear in the next release of the MedDRA Term Selection: Points to Consider document, corresponding to MedDRA Version 22.0.

CR Number: 2018304004 **Implementation Date:** 06-Nov-18 Related CR: 2018304004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Drug titration*	Approved as Requested	Proposed PT	
HLT primary	*Therapeutic procedures NEC*		*Drug titration*	10082292
SOC primary	*Surgical and medical procedures*		HLT primary	
			Therapeutic procedures NEC	10027700
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT Drug titration to primary HLT Therapeutic procedures NEC in SOC Surgical and medical procedures is approved as requested. Drug titration is the process of progressively adjusting the dose of a medication for the maximum benefit, while minimizing adverse effects.

Supplemental Update Report

CR Number: 2018304005 **Implementation Date:** 06-Nov-18 Related CR: 2018304005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Drug up-titration*	Approved as Requested	Proposed LLT	
To PT	*Drug titration*		*Drug up-titration*	10082294 Current
			To PT	
			Drug titration	10082292

MSSO Comment: The proposal to add a new LLT Drug up-titration to PT Drug titration is approved as requested. Drug up-titration is the gradual incremental increase in the dosage of a medication to achieve an optimal therapeutic response while avoiding as many side effects as possible. The patient's response is closely assessed prior to deciding whether or not to increase the dose further.

CR Number: 2018304006 **Implementation Date:** 06-Nov-18 Related CR: 2018304006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Drug down-titration*	Approved as Requested	Proposed LLT	
To PT	*Drug titration*		*Drug down-titration*	10082293 Current
			To PT	
			Drug titration	10082292

MSSO Comment: The proposal to add a new LLT Drug down-titration to PT Drug titration is approved as requested. Drug down-titration is the gradual incremental decrease in dosage of a medication to achieve a desired therapeutic response while avoiding as many side effects as possible. The patient's response is closely assessed prior to deciding whether or not to decrease the dose further.

CR Number: 2018306001 **Implementation Date:** 09-Nov-18 Related CR: 2018306001

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Mucous membrane disorder*	Approved as Requested	PT to merge	
To PT	*Mucosal disorder*		*Mucous membrane disorder*	10028133 Current
			To PT	
			Mucosal disorder	10082268

MSSO Comment: The proposal to demote the PT Mucous membrane disorder under PT Mucosal disorder is approved as requested. In order to avoid safety signal dispersion, existing PT Mucous membrane disorder will be demoted as a synonym LLT to PT Mucosal disorder, which was recently added in change request 2018292026 for version 22.0.

Supplemental Update Report

CR Number: 2018306002 **Implementation Date:** 12-Nov-18 Related CR: 2018306002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pulmonary artery oxygen saturation decreased*	Approved Not as Requested	Proposed LLT	
To PT	*Mixed venous blood saturation decreased*		*Pulmonary artery oxygen saturation decreased*	10082316 Current
			To PT	
			Venous oxygen saturation decreased	10068427

MSSO Comment: The proposal to add a new LLT Pulmonary artery oxygen saturation decreased to PT Mixed venous blood saturation decreased is approved but not as requested. Mixed venous oxygen saturation (SvO2) is the percentage of oxygen bound to hemoglobin in blood returning to the right side of the heart. This reflects the amount of oxygen "left over" after the tissues remove what they need. It is used to help us to recognize when a patient's body is extracting more oxygen than normally. An increase in extraction is the bodies way to meet tissue oxygen needs when the amount of oxygen reaching the tissues is less than needed. A true mixed venous sample (called SvO2) is drawn from the tip of the pulmonary artery catheter, and includes all of the venous blood returning from the head and arms (via superior vena cava), the gut and lower extremities (via the inferior vena cava) and the coronary veins (via the coronary sinus). Pulmonary artery oxygen saturation decreased will be added as an LLT to PT Venous oxygen saturation decreased.

CR Number: 2018306003 **Implementation Date:** 12-Nov-18 Related CR: 2018306003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Total intervertebral disc arthroplasty*	Approved as Requested	Proposed LLT	
To PT	*Intervertebral disc operation*		*Total intervertebral disc arthroplasty*	10082311 Current
			To PT	
			Intervertebral disc operation	10057322

MSSO Comment: The proposal to add a new LLT Total intervertebral disc arthroplasty to PT Intervertebral disc operation is approved as requested. Total intervertebral disc arthroplasty is a type of arthroplasty, in which degenerated intervertebral discs in the spinal column are replaced with prosthetic devices. It is currently widely used in Europe and in North America to treat chronic discogenic back pain.

Supplemental Update Report

CR Number: 2018306004 **Implementation Date:** 12-Nov-18 Related CR: 2018306004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Battle's sign*	Approved as Requested	Proposed PT *Battle's sign*	10082307
			HLT primary *Mastoid disorders*	10026895
			SOC primary *Ear and labyrinth disorders*	10013993
			HLT secondary *Bruising, ecchymosis and purpura*	10006513
			SOC secondary *Vascular disorders*	10047065

MSSO Comment: The proposal to add a new term Battle's sign is approved as requested. Battle's sign, also known as mastoid ecchymosis, is an indication of fracture of middle cranial fossa of the skull. These fractures may be associated with underlying brain trauma. Battle's sign consists of bruising over the mastoid process as a result of extravasation of blood along the path of the posterior auricular artery. Battle's sign will be added as PT to primary HLT Mastoid disorders, secondary HLT Bruising, ecchymosis and purpura and secondary HLT Cerebral injuries NEC. In a related change,the synonym LLT Mastoid ecchymosis will be added to PT Battle's sign.

CR Number: 2018312006 **Implementation Date:** 12-Nov-18 Related CR: 2018306004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Mastoid ecchymosis*	Approved as Requested	Proposed LLT *Mastoid ecchymosis*	10082310 Current
To PT	*Battle's sign*		To PT *Battle's sign*	10082307

MSSO Comment:

Supplemental Update Report

CR Number: 2018316001 **Implementation Date:** 12-Nov-18 Related CR: 2018306004

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Battle's sign*	Approved as Requested	Proposed PT	
To HLT	*Cerebral injuries NEC*		*Battle's sign*	10082307
			To HLT	
			Cerebral injuries NEC	10052638

MSSO Comment:

CR Number: 2018306005 **Implementation Date:** 12-Nov-18 Related CR: 2018306005

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Unusual failure in efficacy*	Approved as Requested	Proposed LLT	
From PT	*Drug ineffective*		*Unusual failure in efficacy*	10081447 Current
To PT	*Therapeutic product ineffective*		From PT	
			Drug ineffective	10013709
			To PT	
			Therapeutic product ineffective	10060769

MSSO Comment: The proposal to move the LLT Unusual failure in efficacy from PT Drug ineffective to PT Therapeutic product ineffective is approved as requested. Unusual failure in efficacy can refer to therapeutic products other than drugs.

CR Number: 2018306006 **Implementation Date:** 12-Nov-18 Related CR: 2018306006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Fungating breast tumour*	Rejected		

MSSO Comment: The proposal to add a new PT Fungating breast tumour is not approved. Fungating tumor is a type of skin lesion that is marked by ulcerations and necrosis. This kind of lesion may occur in many types of cancer, including breast cancer, melanoma, and squamous cell carcinoma, and especially in advanced disease. The requested term can be represented by split coding with LLT Fungating tumor and LLT Breast neoplasm as it is not feasible to add for all possible tumors where fungating is reported a single new PT.

Supplemental Update Report

CR Number: 2018306007 **Implementation Date:** 12-Nov-18 Related CR: 2018306007

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Tongue abnormal feeling of*	Rejected		
From PT	*Paraesthesia oral*			
To PT	*Tongue discomfort*			

MSSO Comment: The proposal to move the LLT Tongue abnormal feeling of from PT Paraesthesia oral to PT Tongue discomfort is not approved. Tongue abnormal feeling of is in MedDRA since Version 2.1 under an paraesthesia PT - first under PT Paraesthesia tongue which was merged under PT Paraesthesia oral in Version 5.0. Moving this LLT to a "discomfort" PT may have impact on legacy data.

CR Number: 2018306008 **Implementation Date:** 12-Nov-18 Related CR: 2018306008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Baker's cyst haemorrhage*	Rejected		

MSSO Comment: The proposal to add a new term Baker's cyst haemorrhage is not approved. A Baker's cyst can rupture (burst). If it does, the fluid from the cyst leaks down into your calf, which will become red and swollen. The requested term can be represented by split coding with LLT Hemorrhagic cyst and LLT Baker's cyst ruptured.

CR Number: 2018306009 **Implementation Date:** 12-Nov-18 Related CR: 2018306009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Encrusted ureteral stent*	Approved Not as Requested	Proposed LLT	
			Ureteral stent encrustation	10082313 Current
			To PT	
			Device deposit issue	10070692

MSSO Comment: The proposal to add a new term Encrusted ureteral stent is approved but not as requested. Encrustation is one of the most difficult complications of ureteral stents and its management is a complex clinical scenario for the treating surgeon. The requested term will be reworded and added as LLT Ureteral stent encrustation to PT Device deposit issue.

Supplemental Update Report

CR Number: 2018306010 **Implementation Date:** 12-Nov-18 Related CR: 2018306010

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Tracheal polyp*	Approved Not as Requested	Proposed PT	
To PT	*Benign tracheal neoplasm*		*Tracheal polyp*	10082305
			HLT primary	
			Upper respiratory tract neoplasms	10046311
			SOC primary	
			Respiratory, thoracic and mediastinal disorders	10038738
			HLT secondary	
			Respiratory tract and pleural neoplasms benign NEC	10038722
			SOC secondary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104

MSSO Comment: The proposal to add a new LLT Tracheal polyp to PT Benign tracheal neoplasm is approved but not as requested. Tracheal polyp, a rare benign tumor of the tracheobronchial tree, will be added as PT to primary HLT Upper respiratory tract neoplasms and secondary HLT Respiratory tract and pleural neoplasms benign NEC. Polyps in MedDRA are represented on PT level with primary link to the organ of manifestation and only secondary link to SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps).

CR Number: 2018306011 **Implementation Date:** 12-Nov-18 Related CR: 2018306011

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Cancer-related fatigue*	Rejected		

MSSO Comment: The proposal to add a new term Cancer-related fatigue is not approved. Cancer fatigue (and LLT Chemotherapy related fatigue as a sub-concept LLT) has been recently added to MedDRA Version 22.0; please see change request 2018288009.

Supplemental Update Report

CR Number: 2018306012 **Implementation Date:** 12-Nov-18 Related CR: 2018306012

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Schneiderian papilloma*	Approved as Requested	Proposed LLT	
			Schneiderian papilloma	10082317 Current
To PT	*Sinonasal papilloma*		To PT	
			Sinonasal papilloma	10071665

MSSO Comment: The proposal to add a new LLT Schneiderian papilloma to PT Sinonasal papilloma is approved as requested. Schneiderian epithelium/membrane is the unique lining of the nasal cavity and paranasal sinuses, and is an ectodermally derived ciliated columnar epithelium with goblet cells. It differs from the similarly appearing respiratory epithelium, which is endodermally derived. Schneiderian papillomas are uncommon sinonasal tumours that arise from the sinonasal Schneiderian epithelium.

CR Number: 2018306013 **Implementation Date:** 12-Nov-18 Related CR: 2018306013

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Endocervical mucosal thickening*	Approved as Requested	Proposed PT	
			Endocervical mucosal thickening	10082304
			HLT primary	
			Cervix disorders NEC	10008352
			SOC primary	
			Reproductive system and breast disorders	10038604

MSSO Comment: The proposal to add a new term Endocervical mucosal thickening is approved as requested. The endocervical mucosa within the supravaginal cervical canal is characterized by villi lined with a single layer of mucus-secreting columnar epithelial cells separated by crypts extending 3–10 mm into the stroma of the cervix. Endometrial thickening of the cervical canal may be related to atypical endometrial hyperplasia, a precancerous condition. Endocervical mucosal thickening will be placed as PT to HLT Cervix disorders NEC.

Supplemental Update Report

CR Number: 2018306014 **Implementation Date:** 12-Nov-18 Related CR: 2018306014

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Cardiometabolic syndrome*	Approved as Requested	Proposed PT *Cardiometabolic syndrome*	10082306
			HLT primary *Hyperglycaemic conditions NEC*	10020638
			SOC primary *Metabolism and nutrition disorders*	10027433
			HLT secondary *Hyperglycaemic conditions NEC*	10020638
			SOC secondary *Endocrine disorders*	10014698

MSSO Comment: The proposal to add a new term Cardiometabolic syndrome is approved as requested. Cardiometabolic syndrome is a constellation of metabolic dysfunction characterized by insulin resistance and impaired glucose tolerance, atherogenic dyslipidemia, hypertension and intra-abdominal adiposity (IAA). Other names used for cardiometabolic syndrome are insulin resistance syndrome, syndrome X, Reavan's syndrome, Beer belly syndrome. Cardiometabolic syndrome will be added as a PT to primary HLT Hyperglycaemic conditions NEC (primary SOC Metabolism and nutrition disorders and secondary SOC Endocrine disorders) and secondary HLT Vascular hypertensive disorders NEC. In a related change, PT Insulin resistance syndrome and PT Metabolic syndrome will be merged as synonym LLTs under the new PT Cardiometabolic syndrome.

CR Number: 2018312007 **Implementation Date:** 12-Nov-18 Related CR: 2018306014

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cardiometabolic syndrome*	Approved as Requested	Proposed PT *Cardiometabolic syndrome*	10082306
To HLT	*Vascular hypertensive disorders NEC*		To HLT *Vascular hypertensive disorders NEC*	10020774

MSSO Comment:

Supplemental Update Report

CR Number: 2018312008 **Implementation Date:** 12-Nov-18 Related CR: 2018306014

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Insulin resistance syndrome*	Approved as Requested	PT to merge	
To PT	*Cardiometabolic syndrome*		*Insulin resistance syndrome*	10022490 Current
			To PT	
			Cardiometabolic syndrome	10082306

MSSO Comment:

CR Number: 2018312009 **Implementation Date:** 12-Nov-18 Related CR: 2018306014

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Metabolic syndrome*	Approved as Requested	PT to merge	
To PT	*Cardiometabolic syndrome*		*Metabolic syndrome*	10052066 Current
			To PT	
			Cardiometabolic syndrome	10082306

MSSO Comment:

CR Number: 2018306015 **Implementation Date:** 12-Nov-18 Related CR: 2018306015

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Diabetic glomerulopathy*	Approved as Requested	Proposed LLT	
To PT	*Intercapillary glomerulosclerosis*		*Diabetic glomerulopathy*	10082314 Current
			To PT	
			Intercapillary glomerulosclerosis	10022530

MSSO Comment: The proposal to add a new LLT Diabetic glomerulopathy to PT Intercapillary glomerulosclerosis is approved as requested. Diabetic glomerulopathy, Diabetic Kimmelstiel-Wilson syndrome, or Nodular glomerulosclerosis are synonymously used representing one form of diabetic nephropathy.

Supplemental Update Report

CR Number: 2018306016 **Implementation Date:** 12-Nov-18 Related CR: 2018306016

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Mesenchymal uterine tumor*	Approved as Requested	Proposed LLT	
			Mesenchymal uterine tumor	10082312 Current
			To PT	
			Uterine neoplasm	10046803

MSSO Comment: The proposal to add a new term Mesenchymal uterine tumor is approved as requested. Uterine mesenchymal tumors are a heterogeneous group of neoplasms that can frequently be diagnostically challenging. Differentiation between the benign and malignant counterparts of mesenchymal tumors is significant due to differences in clinical outcome, and the role of the surgical pathologist in making this distinction. Mesenchymal uterine tumor and its British English spelled counterpart Mesenchymal uterine tumour will be added as LLTs to PT Uterine neoplasm.

CR Number: 2018312010 **Implementation Date:** 12-Nov-18 Related CR: 2018306016

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Mesenchymal uterine tumour*	Approved as Requested	Proposed LLT	
To PT	*Uterine neoplasm*		*Mesenchymal uterine tumour*	10082309 Current
			To PT	
			Uterine neoplasm	10046803

MSSO Comment:

CR Number: 2018306017 **Implementation Date:** 12-Nov-18 Related CR: 2018306017

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Nerve root compression*	Approved as Requested	PT to merge	
To PT	*Radiculopathy*		*Nerve root compression*	10061866 Current
			To PT	
			Radiculopathy	10037779

MSSO Comment: The proposal to demote the PT Nerve root compression under PT Radiculopathy is approved as requested. Radiculopathy, also commonly referred to as pinched nerve, refers to a set of conditions in which one or more nerves are affected and do not work properly (a neuropathy). This can result in pain (radicular pain), weakness, numbness, or difficulty controlling specific muscles. Nerve root compression can be considered as sub-concept of the broader PT Radiculopathy.

Supplemental Update Report

CR Number: 2018306018 **Implementation Date:** 12-Nov-18 Related CR: 2018306018

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Intentional wrong technique in product usage process*	Rejected		

MSSO Comment: The proposal to add a new term Intentional wrong technique in product usage process is not approved. MedDRA cannot accommodate a unique term for every combination of product use issues. The scenario described can be represented by split coding using LLT Wrong technique in product usage process and LLT Intentional product use issue.

CR Number: 2018306019 **Implementation Date:** 12-Nov-18 Related CR: 2018306019

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Internal carotid artery deformity*	Approved as Requested	Proposed PT	
HLT primary	*Central nervous system vascular disorders NEC*		*Internal carotid artery deformity*	10082308
SOC primary	*Nervous system disorders*		HLT primary	
			Central nervous system vascular disorders NEC	10007962
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Cerebrovascular and spinal necrosis and vascular insufficiency	10008192
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new PT Internal carotid artery deformity to primary HLT Central nervous system vascular disorders NEC in SOC Nervous system disorders and secondary HLT Cerebrovascular and spinal necrosis and vascular insufficiency in SOC Vascular disorders is approved as requested. Internal carotid artery deformity represents a broad umbrella PT for different types of pathologically deformities of the internal carotid artery such as tortuosity, kinking etc. Please see change request 2018306020 for merging PT Internal carotid artery kinking under PT Internal carotid artery deformity. Also, in change request 2018306021 sub-concept LLT Internal carotid artery tortuosity and in change request 2018306022 LLT Internal carotid artery coiling will both be added to PT Internal carotid artery deformity.

Supplemental Update Report

CR Number: 2018306020 **Implementation Date:** 12-Nov-18 Related CR: 2018306020

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Internal carotid artery kinking*	Approved as Requested	PT to merge	
To PT	*Internal carotid artery deformity*		*Internal carotid artery kinking*	10071355 Current
			To PT	
			Internal carotid artery deformity	10082308

MSSO Comment: The proposal to demote the PT Internal carotid artery kinking under PT Internal carotid artery deformity is approved as requested. Internal carotid artery kinking can be considered as a sub-concept of the broader new PT Internal carotid artery deformity.

CR Number: 2018306021 **Implementation Date:** 12-Nov-18 Related CR: 2018306021

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Internal carotid artery tortuosity*	Approved as Requested	Proposed LLT	
To PT	*Internal carotid artery deformity*		*Internal carotid artery tortuosity*	10082315 Current
			To PT	
			Internal carotid artery deformity	10082308

MSSO Comment: The proposal to add a new LLT Internal carotid artery tortuosity to PT Internal carotid artery deformity is approved as requested. Abnormalities in course and geometry (tortuosity, kinking, and coiling) of the internal carotid arteries are considered as risk factors of cerebral vascular insufficiency.

CR Number: 2018306022 **Implementation Date:** 12-Nov-18 Related CR: 2018306022

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Internal carotid artery coiling*	Approved as Requested	Proposed LLT	
To PT	*Internal carotid artery deformity*		*Internal carotid artery coiling*	10082318 Current
			To PT	
			Internal carotid artery deformity	10082308

MSSO Comment: The proposal to add a new LLT Internal carotid artery coiling to PT Internal carotid artery deformity is approved as requested. Abnormalities in course and geometry (tortuosity, kinking, and coiling) of the internal carotid arteries are considered as risk factors of cerebral vascular insufficiency.

Supplemental Update Report

CR Number: 2018306023 **Implementation Date:** 12-Nov-18 Related CR: 2018306023

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Small fontanelle*	Approved as Requested	Proposed PT	
HLT primary	*Musculoskeletal and connective tissue deformities of skull, face and buccal cavity*		*Small fontanelle*	10082319
SOC primary	*Musculoskeletal and connective tissue disorders*		HLT primary	
			Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	10028378
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new PT Small fontanelle to primary HLT Musculoskeletal and connective tissue deformities of skull, face and buccal cavity in SOC Musculoskeletal and connective tissue disorders is approved as requested. Assessment of the size of the anterior fontanel is part of the routine examination of the infant. This assessment is used together with the head circumference measurement as an index of cranial development from birth and to the second year of life. An unusually small fontanel for age may be secondary to brain growth retardation, craniosynostosis, or hyperthyroidism. In a related change, American English spelled counterpart LLT Small fontanel will be added to the new PT Small fontanelle.

CR Number: 2018313001 **Implementation Date:** 12-Nov-18 Related CR: 2018306023

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Small fontanel*	Approved as Requested	Proposed LLT	
To PT	*Small fontanelle*		*Small fontanel*	10082320 Current
			To PT	
			Small fontanelle	10082319

MSSO Comment:

CR Number: 2018308001 **Implementation Date:** 09-Nov-18 Related CR: 2018308001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Cervical dorsal ramus syndrome*	Approved as Requested	Proposed LLT	
			Cervical dorsal ramus syndrome	10082298 Current
			To PT	
			Dorsal ramus syndrome	10082295

MSSO Comment: The proposal to add a new term Cervical dorsal ramus syndrome is approved as requested. Dorsal ramus syndrome refers to a variety of symptoms caused by dorsal ramus irritation. Any abnormality of a zygapophysial joint such as subluxation, degenerative changes, osteophytes, hypertrophy of ligament or joint capsule, and fracture can irritate the common dorsal ramus and medial branch, and irritation of dorsal ramus can cause symptoms including chronic pain of the cervical or lumbar spine. Cervical dorsal ramus syndrome will be added as a sub-concept LLT to PT Dorsal ramus syndrome added in change request 2018308002. In a related change, PT Lumbar dorsal ramus syndrome will be merged as a sub-concept LLT to the new PT Dorsal ramus syndrome added in change request 2018308002.

Supplemental Update Report

CR Number: 2018312002 **Implementation Date:** 09-Nov-18 Related CR: 2018308001

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Lumbar dorsal ramus syndrome*	Approved as Requested	PT to merge	
			Lumbar dorsal ramus syndrome	10081614 Current
To PT	*Dorsal ramus syndrome*		To PT	
			Dorsal ramus syndrome	10082295

MSSO Comment:

CR Number: 2018308002 **Implementation Date:** 09-Nov-18 Related CR: 2018308002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Dorsal ramus syndrome*	Approved as Requested	Proposed PT	
			Dorsal ramus syndrome	10082295
			HLT primary	
			Spinal cord and nerve root disorders NEC	10041544
			SOC primary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new term Dorsal ramus syndrome is approved as requested. Dorsal ramus syndrome refers to a variety of symptoms caused by dorsal ramus irritation. Any abnormality of zygapophysial joint such as subluxation, degenerative changes, osteophytes, hypertrophy of ligament or joint capsule, and fracture can irritate the common dorsal ramus and medial branch, and irritation of dorsal ramuscan cause symptoms including chronic pain of the cervical or lumbar spine. Dorsal ramus syndrome will be added as a new PT to HLT Spinal cord and nerve root disorders NEC.

CR Number: 2018308003 **Implementation Date:** 09-Nov-18 Related CR: 2018308003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Thoracolumbar junction syndrome*	Approved as Requested	Proposed LLT	
			Thoracolumbar junction syndrome	10082302 Current
			To PT	
			Dorsal ramus syndrome	10082295

MSSO Comment: The proposal to add a new term Thoracolumbar junction syndrome is approved as requested. Thoracolumbar junction syndrome is characterized by referred pain which may originate at the thoracolumbar junction, which extends from 12th thoracic vertebra to 2nd lumbar vertebra, due to functional abnormalities. Clinical manifestations include back pain, pseudo-visceral pain and pseudo-pain on the posterior iliac crest, as well as irritable bowel symptoms. Radiological studies show only mild and insignificant degenerative changes in most cases. Thoracolumbar junction syndrome will be added as a sub-concept LLT to PT Dorsal ramus syndrome.

Supplemental Update Report

CR Number: 2018308004 **Implementation Date:** 09-Nov-18 Related CR: 2018308004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Acute blood loss anemia*	Approved as Requested	Proposed LLT *Acute blood loss anemia* To PT *Blood loss anaemia*	10082299 Current 10082297

MSSO Comment: The proposal to add a new term Acute blood loss anemia is approved as requested. Acute blood loss anemia and the British English spelled counterpart LLT Acute blood loss anaemia will be added to a new PT Blood loss anaemia. In a related change, Blood loss anaemia will be added to primary HLT Anaemias NEC and secondary HLT Haemorrhages NEC. Furthermore, the existing PT Haemorrhagic anaemia will be merged as a synonym under the new PT Blood loss anaemia, which appears to be the more commonly used expression for this concept.

CR Number: 2018312003 **Implementation Date:** 09-Nov-18 Related CR: 2018308004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT To PT	*Acute blood loss anaemia* *Blood loss anaemia*	Approved as Requested	Proposed LLT *Acute blood loss anaemia* To PT *Blood loss anaemia*	10082303 Current 10082297

MSSO Comment:

Supplemental Update Report

CR Number: 2018312004 **Implementation Date:** 09-Nov-18 Related CR: 2018308004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Blood loss anaemia*	Approved as Requested	Proposed PT	
HLT primary	*Anaemias NEC*		*Blood loss anaemia*	10082297
SOC primary	*Blood and lymphatic system disorders*		HLT primary	
			Anaemias NEC	10002067
			SOC primary	
			Blood and lymphatic system disorders	10005329
			HLT secondary	
			Haemorrhages NEC	10018987
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment:

CR Number: 2018312005 **Implementation Date:** 09-Nov-18 Related CR: 2018308004

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Haemorrhagic anaemia*	Approved as Requested	PT to merge	
To PT	*Blood loss anaemia*		*Haemorrhagic anaemia*	10052293 Current
			To PT	
			Blood loss anaemia	10082297

MSSO Comment:

CR Number: 2018308005 **Implementation Date:** 09-Nov-18 Related CR: 2018308005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Blood loss anemia*	Approved as Requested	Proposed LLT	
			Blood loss anemia	10082300 Current
			To PT	
			Blood loss anaemia	10082297

MSSO Comment: The proposal to add a new term Blood loss anemia is approved as requested. Blood loss anemia, the American spelled synonym will be added as an LLT to new PT Blood loss anaemia added in change request 2018308004.

Supplemental Update Report

CR Number: 2018308006 **Implementation Date:** 09-Nov-18 Related CR: 2018308006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Serous incision site discharge*	Approved as Requested	Proposed LLT	
			Serous incision site discharge	10082301 Current
			To PT	
			Incision site discharge	10082296

MSSO Comment: The proposal to add a new term Serous incision site discharge is approved as requested. Serous incision site discharge, a discharge comprised of or resembling serum emanating from an incision wound, will be added as a sub-concept LLT to PT Incision site discharge, added in change request 2018308008.

CR Number: 2018308007 **Implementation Date:** 15-Nov-18 Related CR: 2018308007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Incision site serosanguineous discharge*	Approved After Suspension	Proposed LLT	
			Incision site serosanguineous discharge	10082351 Current
			To PT	
			Incision site discharge	10082296

MSSO Comment: The proposal to add a new term Incision site serosanguineous discharge is approved as requested after suspension. Incision site serosanguineous discharge, a discharge pertaining to or containing both serum and blood emanating from an incision wound, will be added as a sub-concept LLT to PT Incision site discharge, which was added in CR 2018308008 of this batch.

CR Number: 2018308008 **Implementation Date:** 09-Nov-18 Related CR: 2018308008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Incision site discharge*	Approved as Requested	Proposed PT	
			Incision site discharge	10082296
			HLT primary	
			Non-site specific procedural complications	10029559
			SOC primary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new term Incision site discharge is approved as requested. Incision site discharge, a bodily liquid that flows out of an incision wound, will be added as a new PT to primary HLT Non-site specific procedural complications.

Supplemental Update Report

CR Number: 2018309006 **Implementation Date:** 13-Nov-18 Related CR: 2018309006

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Eyelid abrasion*	Approved as Requested	Proposed LLT	
From PT	*Eyelid erosion*		*Eyelid abrasion*	10081521
			From PT	
			Eyelid erosion	10060762
			HLT primary	
			Eye injuries NEC	10027674
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Lid, lash and lacrimal structural disorders	10024446
			SOC secondary	
			Eye disorders	10015919

MSSO Comment: The proposal to promote the LLT Eyelid abrasion from PT Eyelid erosion is approved as requested. Abrasion, a superficial linear break in the skin surface or an area damaged by due to superficial injury such as scraping, is not medically synonymous with erosion, which is defined as an eating away or loss of skin integrity of the superficial skin or the mucous membranes usually due to pathological reasons such as inflammation. Therefore, LLT Eyelid abrasion will be promoted to a PT level from PT Eyelid erosion and linked to primary HLT Eye injuries NEC, secondary HLT Lid, lash and lacrimal structural disorders, and secondary HLT Skin and subcutaneous tissue ulcerations.

CR Number: 2018317001 **Implementation Date:** 13-Nov-18 Related CR: 2018309006

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Eyelid abrasion*	Approved as Requested	Proposed PT	
To HLT	*Skin and subcutaneous tissue ulcerations*		*Eyelid abrasion*	10081521
			To HLT	
			Skin and subcutaneous tissue ulcerations	10040796

MSSO Comment:

Supplemental Update Report

CR Number: 2018309007 **Implementation Date:** 13-Nov-18 Related CR: 2018309007

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Sacroiliitis*	Approved Not as Requested	Proposed PT	
From HLT	*Arthropathies NEC*		*Sacroiliitis*	10039361
To HLT	*Immune and associated conditions NEC*		To HLT	
			Immune and associated conditions NEC	10027682

MSSO Comment: The proposal to move the PT Sacroiliitis from HLT Arthropathies NEC to HLT Immune and associated conditions NEC is approved but not as requested. Sacroiliitis has been associated with a broad variety of etiologies including but not limited to: degenerative, rheumatic, other immunologic disorders, infectious, drug-related, oncologic, hyperparathyroidism, pregnancy, and trauma. Because sacroiliitis is associated with a variety of immunological disorders, rather than moving PT Sacroiliitis from Arthropathies NEC to HLT Immune and associated conditions NEC as proposed, the PT will be linked to secondary HLT Immune and associated conditions NEC following MedDRA conventions site of manifestation determines the primary SOC allocation of a concept.

CR Number: 2018309008 **Implementation Date:** 10-Dec-18 Related CR: 2018309008

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Complications of transplanted liver*	Approved Not as Requested	Proposed PT	
To SMQ	*Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ)*		*Complications of transplanted liver*	10010186
Term scope	*Narrow*		To SMQ	
			Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ)	20000013
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Complications of transplanted liver to Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ) as a narrow term is approved but not as requested. Complications of transplanted liver will be added as a broad scope term to Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ) since complications represent secondary events following the original procedure of transplantation.

Supplemental Update Report

CR Number: 2018309009 **Implementation Date:** 10-Dec-18 Related CR: 2018309009

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Liver and pancreas transplant rejection*	Approved Not as Requested	Proposed PT	
To SMQ	*Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ)*		*Liver and pancreas transplant rejection*	10051603
Term scope	*Narrow*		To SMQ	
			Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ)	20000013
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Liver and pancreas transplant rejection to Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ) as a narrow term is approved but not as requested. Liver and pancreas transplant rejection will be added as a broad scope term to Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ) since rejection represents a secondary event following the original procedure of transplantation.

CR Number: 2018309010 **Implementation Date:** 10-Dec-18 Related CR: 2018309010

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Liver transplant rejection*	Approved Not as Requested	Proposed PT	
To SMQ	*Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ)*		*Liver transplant rejection*	10024715
Term scope	*Narrow*		To SMQ	
			Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ)	20000013
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Liver transplant rejection to Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ) as a narrow term is approved but not as requested. Liver transplant rejection will be added as a broad scope term to Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ) since rejection represents a secondary event following the original procedure of transplantation.

Supplemental Update Report

CR Number: 2018310001 **Implementation Date:** 13-Nov-18 Related CR: 2018310001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Cholangiojejunostomy*	Approved as Requested	Proposed PT	
			Cholangiojejunostomy	10082321
			HLT primary	
			Biliary tract and gallbladder therapeutic procedures	10004675
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Cholangiojejunostomy is approved as requested. Cholangio-jejunostomy, the surgical anastomosis of a bile duct to the Jejunum, is a surgical bypass procedure in patients with benign bile obsturction or in patients who present with hilar cholangiocarcinoma and require only palliation. Cholangiojejunostomy will be added as PT to HLT Biliary tract and gallbladder therapeutic procedures.

CR Number: 2018310002 **Implementation Date:** 13-Nov-18 Related CR: 2018310002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Bariatric gastric balloon removal*	Approved as Requested	Proposed PT	
HLT primary	*Gastric therapeutic procedures*		*Bariatric gastric balloon removal*	10082322
SOC primary	*Surgical and medical procedures*		HLT primary	
			Gastric therapeutic procedures	10017813
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT Bariatric gastric balloon removal to primary HLT Gastric therapeutic procedures in SOC Surgical and medical procedures is approved as requested. The bariatric gastric balloon is a procedure in which a balloon is inserted via a minimally invasive endoscopic procedure and inflated with a saline solution once in place in the stomach. The balloon is designed to remain in place for several months, while the patient receives counseling on diet, exercise, and healthy lifestyle changes. Prior to the intended duration, the balloon may be removed because of an associated adverse event. PT Bariatric gastric balloon removal complements the existing PT Bariatric gastric balloon insertion.

Supplemental Update Report

CR Number: 2018310004 **Implementation Date:** 14-Nov-18 Related CR: 2018310004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Aberrant motor behaviour*	Approved as Requested	Proposed PT	
			Aberrant motor behaviour	10082331
			HLT primary	
			Abnormal behaviour NEC	10000117
			SOC primary	
			Psychiatric disorders	10037175
			HLT secondary	
			Neurological signs and symptoms NEC	10029306
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new term Aberrant motor behaviour is approved as requested. Aberrant motor behavior encompasses a range of activities such as wandering away from home; repetitive, purposeless behaviors; social inappropriate activities including those associated with disinhibition (tendency to disregard social and cultural norms and not restrain inner feelings, such as sexual drives). Aberrant motor behaviour will be placed as a PT to primary HLT Abnormal behaviour NEC and secondary HLT Neurological signs and symptoms NEC. In a related change, the American English spelled counterpart LLT Aberrant motor behavior will be added to new PT Aberrant motor behaviour. Furthermore, LLT Psychomotor restlessness will be moved from PT Restlessness to PT Psychomotor hyperactivity for better alignment.

CR Number: 2018318002 **Implementation Date:** 14-Nov-18 Related CR: 2018310004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Aberrant motor behavior*	Approved as Requested	Proposed LLT	
To PT	*Aberrant motor behaviour*		*Aberrant motor behavior*	10082333 Current
			To PT	
			Aberrant motor behaviour	10082331

MSSO Comment:

Supplemental Update Report

CR Number: 2018318009 **Implementation Date:** 14-Nov-18 Related CR: 2018310004

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Psychomotor restlessness*	Approved as Requested	Proposed LLT	
From PT	*Restlessness*		*Psychomotor restlessness*	10037212 Current
To PT	*Psychomotor hyperactivity*		From PT	
			Restlessness	10038743
			To PT	
			Psychomotor hyperactivity	10037211

MSSO Comment:

CR Number: 2018310005 **Implementation Date:** 14-Nov-18 Related CR: 2018310005

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Snout reflex positive*	Approved as Requested	Proposed LLT	
			Snout reflex positive	10082339 Current
			To PT	
			Primitive reflex test positive	10073714

MSSO Comment: The proposal to add a new term Snout reflex positive is approved as requested. Snout reflex positive is a primitive reflex with pouting or pursing of the lips induced by light tapping of closed lips near the midline; seen in defective pyramidal innervation of facial musculature. Snout reflex positive will be added as an LLT to PT Primitive reflex test positive.

CR Number: 2018310006 **Implementation Date:** 14-Nov-18 Related CR: 2018310006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Breast prosthesis rupture*	Approved as Requested	Proposed LLT	
			Breast prosthesis rupture	10082340 Current
			To PT	
			Device breakage	10012575

MSSO Comment: The proposal to add a new term Breast prosthesis rupture is approved as requested. Breast implant ruptures are a recognised complication of a breast implant. It can be intracapsular, when confined by the surrounding fibrous capsule, or extracapsular, when silicone freely extravasates. Breast prosthesis rupture will be placed as an LLT to the broad PT Device breakage. In a related change, the frequently used synonym Breast implant rupture will be added as an LLT to PT Device breakage.

Supplemental Update Report

CR Number: 2018318003 **Implementation Date:** 14-Nov-18 Related CR: 2018310006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Breast implant rupture*	Approved as Requested	Proposed LLT	
To PT	*Device breakage*		*Breast implant rupture*	10082334 Current
			To PT	
			Device breakage	10012575

MSSO Comment:

CR Number: 2018310007 **Implementation Date:** 14-Nov-18 Related CR: 2018310007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Metrorrhoea*	Approved as Requested	Proposed PT	
			Metrorrhoea	10082324
			HLT primary	
			Uterine disorders NEC	10013376
			SOC primary	
			Reproductive system and breast disorders	10038604

MSSO Comment: The proposal to add a new PT Metrorrhoea is approved as requested. Metrorrhoea, defined as continuous morbid discharge from the uterus e.g. of mucus or pus, will be added to HLT Uterine disorders NEC. In a related change, American English spelled counterpart LLT Metrorrhea will be added to the new PT Metrorrhoea.

CR Number: 2018318004 **Implementation Date:** 14-Nov-18 Related CR: 2018310007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Metrorrhea*	Approved as Requested	Proposed LLT	
To PT	*Metrorrhoea*		*Metrorrhea*	10082335 Current
			To PT	
			Metrorrhoea	10082324

MSSO Comment:

Supplemental Update Report

CR Number: 2018310008 **Implementation Date:** 14-Nov-18 Related CR: 2018310008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Paratonia*	Approved as Requested	Proposed PT	
			Paratonia	10082325
			HLT primary	
			Muscle tone abnormal	10028342
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Muscle tone abnormalities	10028343
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new term Paratonia is approved as requested. Paratonia is the inability to relax muscles during muscle tone assessment. There are two types of paratonia: oppositional and facilitatory. Oppositional paratonia occurs when subjects involuntarily resist to passive movements, while facilitatory paratonia occurs when subjects involuntary assist passive movements. Paratonia is a less specific sign but is generally thought to represent bilateral frontal lobe dysfunction. However, it can be seen in diffuse cerebral disorders as well. It is frequently seen in advanced dementia. Paratonia will be added as PT to primary HLT Muscle tone abnormal and secondary HLT Muscle tone abnormalities.

CR Number: 2018310009 **Implementation Date:** 14-Nov-18 Related CR: 2018310009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Gegenhalten*	Approved as Requested	Proposed LLT	
			Gegenhalten	10082338 Current
			To PT	
			Paratonia	10082325

MSSO Comment: The proposal to add a new LLT Gegenhalten is approved as requested. Gegenhalten is a German word used for the phenomenon of "against-stop" paratonia, which is an inability to relax the limb fully for testing of passive range of motion. The German expression Gegenhalten, which is an English oppositional paratonia will be added as an LLT to newly added PT Paratonia (see change request 2018310008). In a related change, Oppositional paratonia and Facilitatory paratonia, the second type of paratonia will be added as LLTs to PT Paratonia.

Supplemental Update Report

CR Number: 2018318005 **Implementation Date:** 14-Nov-18 Related CR: 2018310009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Oppositional paratonia*	Approved as Requested	Proposed LLT	
To PT	*Paratonia*		*Oppositional paratonia*	10082336 Current
			To PT	
			Paratonia	10082325

MSSO Comment:

CR Number: 2018318010 **Implementation Date:** 14-Nov-18 Related CR: 2018310009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Facilitatory paratonia*	Approved as Requested	Proposed LLT	
To PT	*Paratonia*		*Facilitatory paratonia*	10082332 Current
			To PT	
			Paratonia	10082325

MSSO Comment:

CR Number: 2018310010 **Implementation Date:** 14-Nov-18 Related CR: 2018310010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Nervous bladder*	Rejected		

MSSO Comment: The proposal to add a new term Nervous bladder is not approved. Overactive bladder is the name for a group of bladder symptoms. There are three main symptoms: A feeling that you have to go to the bathroom, urgently. Sometimes incontinence, usually the need to go to the bathroom often, day and night. Nervous bladder is a colloquial expression which rarely is used for overactive bladder syndrome. Please consider LLT Overactive bladder for your coding needs.

Supplemental Update Report

CR Number: 2018310011 **Implementation Date:** 14-Nov-18 Related CR: 2018310011

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Mueller-Weiss syndrome*	Approved as Requested	Proposed PT	
			Mueller-Weiss syndrome	10082326
			HLT primary	
			Bone disorders NEC	10027658
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395
			HLT secondary	
			Musculoskeletal necrosis and vascular insufficiency	10065876
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new term Mueller-Weiss syndrome is approved as requested. Mueller-Weiss syndrome, or spontaneous osteonecrosis of the tarsal navicular bone in adults, is an important but under-recognised idiopathic foot condition that causes chronic mid- and hind-foot pain. Mueller-Weiss Syndrome will be added as PT to primary HLT Bone disorders NEC and secondary HLT Musculoskeletal necrosis and vascular insufficiency.

CR Number: 2018310012 **Implementation Date:** 14-Nov-18 Related CR: 2018310012

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Trombidiasis*	Approved as Requested	Proposed PT	
HLT primary	*Ectoparasitic infestations*		*Trombidiasis*	10082327
SOC primary	*Infections and infestations*		HLT primary	
			Ectoparasitic infestations	10014143
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Skin and subcutaneous arthropod and parasitic infestations	10040787
			SOC secondary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment: The proposal to add a new PT Trombidiasis to primary HLT Ectoparasitic infestations in SOC Infections and infestations is approved as requested. Trombidiasis is defined as infestation with mites of the family Trombiculidae. The most problematic symptom of infestation with mites of that family is the intense skin itching. PT Trombidiasis will also be secondarily linked to HLT Skin and subcutaneous arthropod and parasitic infestations. In a related change, the secondary link for PT Acarodermatitis will be changed from HLT Dermatitis and eczema to HLT Skin and subcutaneous arthropod and parasitic infestations for better alignment.

Supplemental Update Report

CR Number: 2018318006 **Implementation Date:** 14-Nov-18 Related CR: 2018310012

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Acarodermatitis*	Approved as Requested	Proposed PT	
From HLT	*Dermatitis and eczema*		*Acarodermatitis*	10063409
To HLT	*Skin and subcutaneous arthropod and parasitic infestations*		From HLT	
			Dermatitis and eczema	10012435
			To HLT	
			Skin and subcutaneous arthropod and parasitic infestations	10040787

MSSO Comment:

CR Number: 2018310013 **Implementation Date:** 14-Nov-18 Related CR: 2018310013

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Benign connective tissue neoplasm*	Approved as Requested	Proposed PT	
HLT primary	*Soft tissue neoplasms benign NEC*		*Benign connective tissue neoplasm*	10082330
SOC primary	*Neoplasms benign, malignant and unspecified (incl cysts and polyps)*		HLT primary	
			Soft tissue neoplasms benign NEC	10041295
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Musculoskeletal and connective tissue neoplasms NEC	10028390
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new PT Benign connective tissue neoplasm to primary HLT Soft tissue neoplasms benign NEC in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is approved as requested. PT Benign connective tissue neoplasm, a broad term for unspecified benign neoplasms of the connective tissue will also be linked to secondary HLT Musculoskeletal and connective tissue neoplasms NEC.

Supplemental Update Report

CR Number: 2018310014 **Implementation Date:** 14-Nov-18 Related CR: 2018310014

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Propulsive gait*	Approved Not as Requested	Proposed PT	
To PT	*Gait disturbance*		*Propulsive gait*	10082328
			HLT primary	
			Gait disturbances	10017578
			SOC primary	
			General disorders and administration site conditions	10018065
			HLT secondary	
			Parkinson's disease and parkinsonism	10034005
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new LLT Propulsive gait to PT Gait disturbance is approved but not as requested. Propulsive gait, a gait disorder in which the body's centre of gravity appears to be in front of the patient, who struggles to keep the feet near the centre of gravity, is characteristic for Parkinson's disease but can be sign of other underlying causes as well, such as poisoning with e.g. carbon monoxide, manganese, extrapyramidal effect of certain drugs etc. Therefore, Propulsive gait will be added as PT to primary HLT Gait disturbances (with spelling correction) and secondary HLT Parkinson's disease and parkinsonism. In a related change, the following LLT Festinating gait and LLT Gait festinating will be moved from PT Parkinsonian gait to the new PT Propulsive gait because they are synonymously and not limited to Parkinsonian's disease.

CR Number: 2018318007 **Implementation Date:** 14-Nov-18 Related CR: 2018310014

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Festinating gait*	Approved as Requested	Proposed LLT	
From PT	*Parkinsonian gait*		*Festinating gait*	10016474 Current
To PT	*Propulsive gait*		From PT	
			Parkinsonian gait	10056242
			To PT	
			Propulsive gait	10082328

MSSO Comment:

Supplemental Update Report

CR Number: 2018318008 **Implementation Date:** 14-Nov-18 Related CR: 2018310014

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Gait festinating*	Approved as Requested	Proposed LLT	
From PT	*Parkinsonian gait*		*Gait festinating*	10017579 Current
To PT	*Propulsive gait*		From PT	
			Parkinsonian gait	10056242
			To PT	
			Propulsive gait	10082328

MSSO Comment:

CR Number: 2018310015 **Implementation Date:** 14-Nov-18 Related CR: 2018310015

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Catastrophic reaction*	Approved as Requested	Proposed PT	
			Catastrophic reaction	10082329
			HLT primary	
			Stress disorders	10042211
			SOC primary	
			Psychiatric disorders	10037175

MSSO Comment: The proposal to add a new term Catastrophic reaction is approved as requested. Catastrophic reaction is described in literature as the inability to cope with trauma or shock that results in highly-disorganized behavior. This is characterized by deep feelings of anxiety, inadequacy, and helplessness. It manifests as extremely-emotional behavior such as sudden crying or outbursts of agression and hostility. Catastrophic reaction will be placed as PT to HLT Stress disorders, aligned with related concept of PT Post-traumatic stress disorder.

CR Number: 2018310016 **Implementation Date:** 14-Nov-18 Related CR: 2018310016

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Laryngeal Chondrosarcoma*	Approved Not as Requested	Proposed LLT	
			Laryngeal chondrosarcoma	10082341 Current
			To PT	
			Laryngeal cancer	10023825

MSSO Comment: The proposal to add a new PT Laryngeal Chondrosarcoma is approved but not as requested. Laryngeal chondrosarcoma is a rare tumor requiring clinical, histologic, and radiographic correlation for definitive diagnosis. Although it typically presents with low-grade histology, even high-grade histology has a fairly indolent progression in this location, with a relatively low-likelihood for metastatic potential or recurrence. Laryngeal chondrosarcoma, will be added with corrected capitalization as an LLT to PT Laryngeal cancer aligned with LLT Malignant neoplasm of laryngeal cartilages.

Supplemental Update Report

CR Number: 2018310017 **Implementation Date:** 14-Nov-18 Related CR: 2018310017

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Exposure to rabies*	Approved as Requested	Proposed LLT	
To PT	*Exposure to communicable disease*		*Exposure to rabies*	10082337 Current
			To PT	
			Exposure to communicable disease	10049711

MSSO Comment: The proposal to add a new LLT Exposure to rabies to PT Exposure to communicable disease is approved as requested. Human cases of rabies are almost entirely preventable if suspected exposures are identified and managed promptly and properly. If it has been determined that a patient has had a potential rabies virus exposure, post-exposure prophylaxis (PEP) should always begin with proper wound treatment. For previously unvaccinated persons, PEP consists of a regimen of one dose of rabies immune globulin and four doses of rabies vaccine given over a 14-day period.

CR Number: 2018311001 **Implementation Date:** 13-Nov-18 Related CR: 2018311001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Early worsening of diabetic retinopathy*	Approved as Requested	Proposed LLT	
To PT	*Diabetic retinopathy*		*Early worsening of diabetic retinopathy*	10082323 Current
			To PT	
			Diabetic retinopathy	10012689

MSSO Comment: The proposal to add a new LLT Early worsening of diabetic retinopathy to PT Diabetic retinopathy is approved as requested. Early worsening of diabetic retinopathy, a relatively recently identified complication, is a paradoxical temporary accelerated worsening of diabetic retinopathy associated with a rapid therapeutic improvement of inadequately controlled hyperglycemia. Early worsening of diabetic retinopathy has been reported following treatment with Glucagon-like peptide-1 receptor agonists (GLP-1 RA), and also with intensive insulin therapy. The mechanism is unknown but has been postulated to be related to one or more of the following: a decrease in nutrient substrate, decreased ability of the retinal circulation to autoregulate, and increase in growth factors, resulting in vascular proliferation. Early worsening of diabetic retinopathy has been observed to subside at 18 months and beyond following the initiation of aggressive treatment for inadequately controlled hyperglycemia.

Supplemental Update Report

CR Number: 2018313002 **Implementation Date:** 15-Nov-18 Related CR: 2018313002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Congenital supraventricular tachycardia*	Approved as Requested	Proposed PT	
			Congenital supraventricular tachycardia	10082343
			HLT primary	
			Cardiac disorders congenital NEC	10007542
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Supraventricular arrhythmias	10042600
			SOC secondary	
			Cardiac disorders	10007541

MSSO Comment: The proposal to add a new PT Congenital supraventricular tachycardia is approved as requested. Supraventricular tachycardia is the most common arrhythmia diagnosed in children. It is said to occur in up to 1 in 2500 children. While the problem is often congenital, the onset and severity of symptoms varies. Most of the time, the problem occurs in children with otherwise normal hearts but it can occur along with other congenital heart problems such as congenital Wolff-Parkinson-White Syndrome. Congenital supraventricular tachycardia will be placed as PT with primary HLT Cardiac disorders congenital NEC and secondary HLT Supraventricular arrhythmias.

CR Number: 2018313003 **Implementation Date:** 15-Nov-18 Related CR: 2018313003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vaccine-induced seropositivity*	Approved Not as Requested	Proposed LLT	
			Vaccine-induced seropositivity	10082345 Current
			To PT	
			Vaccine-induced seroconversion	10082344

MSSO Comment: The proposal to add a new PT Vaccine-induced seropositivity is approved but not as requested. Vaccine-induced seropositivity or VISP is the phenomenon wherein a person who has received a vaccine against a disease would thereafter give a positive or reactive test result for having that disease when tested for it, despite not actually having the disease. Vaccine-induced seropositivity will be added as an LLT to PT Vaccine-induced seroconversion; please see change request 2018313004 for this addition.

Supplemental Update Report

CR Number: 2018313004 **Implementation Date:** 15-Nov-18 Related CR: 2018313004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vaccine-induced seroconversion*	Approved as Requested	Proposed PT	
			Vaccine-induced seroconversion	10082344
			HLT primary	
			Microbiology and serology tests NEC	10027530
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Vaccine-induced seroconversion is approved as requested. Vaccine-induced seroconversion, the process of producing antibodies in response to a specific antigen via vaccination will be added as a PT to HLT Microbiology and serology tests NEC.

CR Number: 2018313005 **Implementation Date:** 15-Nov-18 Related CR: 2018313005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*HIV vaccine-induced seropositivity*	Approved as Requested	Proposed PT	
			HIV vaccine-induced seropositivity	10082342
			HLT primary	
			Virus identification and serology	10047490
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT HIV vaccine-induced seropositivity is approved as requested. Although the goal of much vaccine development is to induce the production of protective antibodies, they might also cause a state of vaccine-induced seropositivity/reactivity (VISP), which can confound the interpretation of HIV tests in the absence of HIV infection. HIV vaccine-induced seropositivity will be added as PT to HLT Virus identification and serology.

CR Number: 2018316002 **Implementation Date:** 15-Nov-18 Related CR: 2018316002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Subobstruction intestinal*	Approved Not as Requested	Proposed LLT	
			Intestinal subobstruction	10082346 Current
			To PT	
			Intestinal obstruction	10022687

MSSO Comment: The proposal to add a new term Subobstruction intestinal is approved but not as requested. Intestinal subobstruction is essentially synonymous with existing terms LLT Partial bowel obstruction and LLT Subacute intestinal obstruction, each subordinate to PT Intestinal obstruction. To provide a coding option for healthcare professionals who use the expression intestinal subobstruction, proposed term Subobstruction intestinal will be phrased in natural word order to Intestinal subobstruction and will be added as an LLT to PT Intestinal obstruction.

Supplemental Update Report

CR Number: 2018316003 **Implementation Date:** 15-Nov-18 Related CR: 2018316003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Subocclusion intestinal*	Rejected		

MSSO Comment: The proposal to add a new term Subocclusion intestinal is not approved. The requested term concept can be represented by LLT Intestinal subobstruction which was added in change request 2018316002 of this batch.

CR Number: 2018316004 **Implementation Date:** 15-Nov-18 Related CR: 2018316004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Glomangiopericytoma*	Approved as Requested	Proposed PT	
			Glomangiopericytoma	10082347
			HLT primary	
			Paranasal sinus and nasal cavity neoplasms malignant and unspecified	10033853
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Upper respiratory tract neoplasms	10046311
			SOC secondary	
			Respiratory, thoracic and mediastinal disorders	10038738

MSSO Comment: The proposal to add a new term Glomangiopericytoma is approved as requested. Glomangiopericytoma, sinonasal type hemangiopericytoma, is a rare sinonasal neoplasm with a perivascular myoid phenotype, and accounts for less than 0.5% of all sinonasal tumors. It is considered a distinct entity and differs from conventional soft-tissue hemangiopericytoma in location, clinical and histopathologic features. Glomangiopericytoma is a borderline low malignancy tumor with a good prognosis after complete surgical resection. Glomangiopericytoma will be added as PT with primary HLT Paranasal sinus and nasal cavity neoplasms malignant and unspecified and secondary HLT Upper respiratory tract neoplasms. In a related change, the frequently used synonyms Sinonasal-type hemangiopericytoma and Sinonasal-type haemangiopericytoma will be added as LLTs to new PT Glomangiopericytoma.

Supplemental Update Report

CR Number: 2018319005 **Implementation Date:** 15-Nov-18 Related CR: 2018316004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Sinonasal-type hemangiopericytoma*	Approved as Requested	Proposed LLT	
To PT	*Glomangiopericytoma*		*Sinonasal-type hemangiopericytoma*	10082348 Current
			To PT	
			Glomangiopericytoma	10082347

MSSO Comment:

CR Number: 2018319006 **Implementation Date:** 15-Nov-18 Related CR: 2018316004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Sinonasal-type haemangiopericytoma*	Approved as Requested	Proposed LLT	
To PT	*Glomangiopericytoma*		*Sinonasal-type haemangiopericytoma*	10082349 Current
			To PT	
			Glomangiopericytoma	10082347

MSSO Comment:

Supplemental Update Report

CR Number: 2018317002 **Implementation Date:** 20-Nov-18 Related CR: 2018317002

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Intraosseous meningioma*	Approved as Requested	Proposed PT	
HLT primary	*Bone neoplasms unspecified malignancy*		*Intraosseous meningioma*	10082365
SOC primary	*Neoplasms benign, malignant and unspecified (incl cysts and polyps)*		HLT primary	
			Bone neoplasms unspecified malignancy	10005999
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Nervous system disorders NEC	10057185
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new PT Intraosseous meningioma to primary HLT Bone neoplasms unspecified malignancy in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is approved as requested. Intraosseous meningioma, also referred to as primary intraosseous meningioma, is a rare subtype of meningioma that accounts for less than 1% of all osseous tumours. They fall under the subgroup of primary extradural meningiomas. As a general approach, the diagnostic of 'intraosseous' meningioma is accepted when there is little if any intracranial extra-osseous disease, and use the term 'en plaque' where there is a definite, albeit sessile, intracranial mass. PT Intraosseous meningioma will also be secondarily linked to HLT Nervous system disorders NEC.

CR Number: 2018318001 **Implementation Date:** 20-Nov-18 Related CR: 2018318001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Erotophonophilia*	Approved as Requested	Proposed PT	
			Erotophonophilia	10082366
			HLT primary	
			Paraphilias and paraphilic disorders	10077549
			SOC primary	
			Psychiatric disorders	10037175

MSSO Comment: The proposal to add a new PT Erotophonophilia is approved as requested. Erotophonophilia is a sexual paraphilia in which individuals derive sexual pleasure and arousal from murdering (or imagining they are murdering) someone. Many academics in the forensic field refer to such killings as ‘lust murder’. Erotophonophilia will be added as PT to HLT Paraphilias and paraphilic disorders.

Supplemental Update Report

CR Number: 2018318011 **Implementation Date:** 26-Nov-18 Related CR: 2018318011

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Visual impairment*	Rejected		
To HLT	*Visual impairment and blindness (excl colour blindness)*			

MSSO Comment: The proposal to link the PT Visual impairment to the HLT Visual impairment and blindness (excl colour blindness) is not approved. In change request 2018263045, this proposed move of PT Visual impairment from HLT Visual disorders NEC to HLT Visual impairment and blindness (excl colour blindness) has already been made, for a more appropriate alignment of concepts. This change will be available in the forthcoming version 22.0 of MedDRA.

CR Number: 2018318012 **Implementation Date:** 20-Nov-18 Related CR: 2018318012

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Left atrial volume decreased*	Approved as Requested	Proposed PT	
HLT primary	*Cardiac function diagnostic procedures*		*Left atrial volume decreased*	10082368
SOC primary	*Investigations*		HLT primary	
			Cardiac function diagnostic procedures	10007566
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Left atrial volume decreased to primary HLT Cardiac function diagnostic procedures in SOC Investigations is approved as requested. Atrial volume is an assessment of the heart that is most frequently obtained by echocardiography. A decreased left atrial volume is identified when the measured value is less than the established normal reference range. Left atrial volume is part of cardiac remodelling in a variety of cardiovascular diseases and a strong predictor of cardiovascular morbidity and mortality. The assessment of RA enlargement is of importance, since it may occur in conditions like several pulmonary disorders, congenital heart disease, acquired valvular disease, and heart failure.

CR Number: 2018318013 **Implementation Date:** 20-Nov-18 Related CR: 2018318013

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Left atrial volume abnormal*	Approved as Requested	Proposed PT	
HLT primary	*Cardiac function diagnostic procedures*		*Left atrial volume abnormal*	10082367
SOC primary	*Investigations*		HLT primary	
			Cardiac function diagnostic procedures	10007566
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Left atrial volume abnormal to primary HLT Cardiac function diagnostic procedures in SOC Investigations is approved as requested. Atrial volume is an assessment of the heart that is most frequently obtained by echocardiography. An abnormal left atrial volume is identified when the measured value is outside of the established normal reference range. Left atrial volume overload is an two dimensional echocardiographic diagnostic feature of severe mitral regurgitation.

Supplemental Update Report

CR Number: 2018318014 **Implementation Date:** 20-Nov-18 Related CR: 2018318014

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Left atrial volume increased*	Approved as Requested	Proposed PT	
HLT primary	*Cardiac function diagnostic procedures*		*Left atrial volume increased*	10082369
SOC primary	*Investigations*		HLT primary	
			Cardiac function diagnostic procedures	10007566
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Left atrial volume increased to primary HLT Cardiac function diagnostic procedures in SOC Investigations is approved as requested. Atrial volume is an assessment of the heart that is most frequently obtained by echocardiography. An increased left atrial volume is identified when the measured value exceeds the established normal reference range. Left atrial volume overload is a two dimensional echocardiographic diagnostic feature of severe mitral regurgitation.

CR Number: 2018318015 **Implementation Date:** 20-Nov-18 Related CR: 2018318015

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Maxillary Sinus Retention Cyst*	Approved Not as Requested	Proposed LLT	
HLT primary	*Paranasal sinus disorders (excl infections and neoplasms)*		*Maxillary sinus retention cyst*	10082370 Current
SOC primary	*Respiratory, thoracic and mediastinal disorders*		To PT	
			Paranasal cyst	10062321

MSSO Comment: The proposal to add a new PT Maxillary Sinus Retention Cyst to primary HLT Paranasal sinus disorders (excl infections and neoplasms) in SOC Respiratory, thoracic and mediastinal disorders is approved but not as requested. A maxillary sinus retention cyst is a benign dome-shaped cystic lesion that occurs in the interior of the maxillary sinus due to ductal obstruction of the submucosal mucinous glands. Maxillary Sinus Retention Cyst will be expressed as Maxillary sinus retention cyst to comply with MedDRA capitalization conventions, and rather than added as a new PT, will be added as a sub-concept LLT to PT Paranasal cyst.

CR Number: 2018319001 **Implementation Date:** 21-Nov-18 Related CR: 2018319001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Drug ineffective for an unapproved dosing frequency*	Rejected		
HLT primary	*Therapeutic and nontherapeutic responses*			
SOC primary	*General disorders and administration site conditions*			

MSSO Comment: The proposal to add a new PT Drug ineffective for an unapproved dosing frequency to primary HLT Therapeutic and nontherapeutic responses in SOC General disorders and administration site conditions is not approved. MedDRA cannot accommodate every possible combination of concepts for drug effectiveness or ineffectiveness and the manner in which the product is used. The requested term "Drug ineffective for an unapproved dosing frequency" can be represented by split coding with more than one MedDRA term, for example: LLT Drug ineffective plus either LLT Off label dosing frequency, LLT Drug use for unapproved dosing regimen, or LLT Ineffective drug dosing regimen.

Supplemental Update Report

CR Number: 2018319003 **Implementation Date:** 21-Nov-18 Related CR: 2018319003

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hypertensive urgency*	Approved as Requested	Proposed LLT	
From PT	*Hypertensive crisis*		*Hypertensive urgency*	10058181
HLT primary	*Accelerated and malignant hypertension*		From PT	
			Hypertensive crisis	10020802
			HLT primary	
			Accelerated and malignant hypertension	10000356
			SOC primary	
			Vascular disorders	10047065

MSSO Comment: The proposal to promote the LLT Hypertensive urgency from PT Hypertensive crisis to primary HLT Accelerated and malignant hypertension in SOC Vascular disorders is approved as requested. Hypertensive urgency is a clinical situation in which blood pressure is very high (e.g., =180/=110 mmHg) with minimal or no symptoms, and no signs or symptoms indicating acute organ damage. This contrasts with a hypertensive emergency where severe blood pressure is accompanied by evidence of progressive organ or system damage. Hypertensive urgency needs to be represented on the same level as PT Hypertensive emergency. PT Hypertensive crisis is umbrella for both types; A hypertensive crisis is divided into two categories: urgent and emergency.

CR Number: 2018319004 **Implementation Date:** 20-Nov-18 Related CR: 2018319004

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Mixed anxiety & depressive*	Approved as Requested	Proposed LLT	
From PT	*Depression*		*Mixed anxiety & depressive*	10027741 Current
To PT	*Mixed anxiety and depressive disorder*		From PT	
			Depression	10012378
			To PT	
			Mixed anxiety and depressive disorder	10080836

MSSO Comment: The proposal to move the LLT Mixed anxiety & depressive from PT Depression to PT Mixed anxiety and depressive disorder is approved as requested. LLT Mixed anxiety & depressive is a quasi-synonym of PT Mixed anxiety and depressive disorder. In a related change, PT Mixed anxiety and depressive disorder will be moved from HLT Adjustment disorders to HLT Depressive disorders for better grouping purposes.

Supplemental Update Report

CR Number: 2018324022 **Implementation Date:** 20-Nov-18 Related CR: 2018319004

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Mixed anxiety and depressive disorder*	Approved as Requested	Proposed PT	
From HLT	*Adjustment disorders*		*Mixed anxiety and depressive disorder*	10080836
To HLT	*Depressive disorders*		From HLT	
			Adjustment disorders	10001301
			To HLT	
			Depressive disorders	10012401

MSSO Comment:

CR Number: 2018320001 **Implementation Date:** 20-Nov-18 Related CR: 2018320001

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Sezary syndrome*	Approved Not as Requested	Proposed PT	
From PT	*Mycosis fungoides*		*Mycosis fungoides*	10028483 Current
			With LLT	
			Cutaneous T-cell lymphoma	10011677

MSSO Comment: The proposal to promote the LLT Sezary syndrome from PT Mycosis fungoides is approved but not as requested. Following, newer classifications Mycosis fungoides and Sezary syndrome are primary Cutaneous T-cell lymphoma and therefore Sezary syndrome should not be subordinated to Mycosis fungoides. Since re-organization area of primary cutaneous T-cell lymphomas needs complex changes, the following actions represent interim placements only until version 23.0 where complex changes may be implemented. PT Mycosis fungoides will be swapped with LLT Cutaneous T-cell lymphoma to have the broader concept as PT with sub-types of Mycosis fungoides and Sezary syndrome on LLT level. In related changes, similiar actions will be done for all stages/refractory and recurrent concepts. As a result the following changes will be made: swap PT Mycosis fungoides recurrent with LLT Cutaneous T-cell lymphoma recurrent, swap PT Mycosis fungoides refractory with LLT Cutaneous T-cell lymphoma refractory, swap PT Mycosis fungoides stage I with LLT Cutaneous T-cell lymphoma stage I, swap PT Mycosis fungoides stage II with LLT Cutaneous T-cell lymphoma stage II, swap PT Mycosis fungoides stage III with LLT Cutaneous T-cell lymphoma stage III, and swap PT Mycosis fungoides stage IV with LLT Cutaneous T-cell lymphoma stage IV.

CR Number: 2018324015 **Implementation Date:** 20-Nov-18 Related CR: 2018320001

Change Requested	Swap a PT with an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Mycosis fungoides recurrent*	Approved as Requested	Proposed PT	
With LLT	*Cutaneous T-cell lymphoma recurrent*		*Mycosis fungoides recurrent*	10028501 Current
			With LLT	
			Cutaneous T-cell lymphoma recurrent	10011678

MSSO Comment:

Supplemental Update Report

CR Number: 2018324016 **Implementation Date:** 20-Nov-18 Related CR: 2018320001

Change Requested	Swap a PT with an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Mycosis fungoides refractory*	Approved as Requested	Proposed PT	
With LLT	*Cutaneous T-cell lymphoma refractory*		*Mycosis fungoides refractory*	10028502 Current
			With LLT	
			Cutaneous T-cell lymphoma refractory	10011679

MSSO Comment:

CR Number: 2018324017 **Implementation Date:** 20-Nov-18 Related CR: 2018320001

Change Requested	Swap a PT with an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Mycosis fungoides stage I*	Approved as Requested	Proposed PT	
With LLT	*Cutaneous T-cell lymphoma stage I*		*Mycosis fungoides stage I*	10028503 Current
			With LLT	
			Cutaneous T-cell lymphoma stage I	10011680

MSSO Comment:

CR Number: 2018324018 **Implementation Date:** 20-Nov-18 Related CR: 2018320001

Change Requested	Swap a PT with an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Mycosis fungoides stage II*	Approved as Requested	Proposed PT	
With LLT	*Cutaneous T-cell lymphoma stage II*		*Mycosis fungoides stage II*	10028504 Current
			With LLT	
			Cutaneous T-cell lymphoma stage II	10011681

MSSO Comment:

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CR Number: 2018324019 **Implementation Date:** 20-Nov-18 Related CR: 2018320001

Change Requested	Swap a PT with an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Mycosis fungoides stage III*	Approved as Requested	Proposed PT	
With LLT	*Cutaneous T-cell lymphoma stage III*		*Mycosis fungoides stage III*	10028505 Current
			With LLT	
			Cutaneous T-cell lymphoma stage III	10011682

MSSO Comment:

CR Number: 2018324020 **Implementation Date:** 20-Nov-18 Related CR: 2018320001

Change Requested	Swap a PT with an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Mycosis fungoides stage IV*	Approved as Requested	Proposed PT	
With LLT	*Cutaneous T-cell lymphoma stage IV*		*Mycosis fungoides stage IV*	10028506 Current
			With LLT	
			Cutaneous T-cell lymphoma stage IV	10011683

MSSO Comment:

CR Number: 2018320002 **Implementation Date:** 20-Nov-18 Related CR: 2018320002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Prophylaxis against metastatic bone disease*	Approved Not as Requested	Proposed PT	
			Metastatic bone disease prophylaxis	10082363
			HLT primary	
			Bone therapeutic procedures NEC	10006000
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Prophylaxis against metastatic bone disease is approved but not as requested. Effective systemic cancer treatments, including bone targeted agents like biphosphonates and the receptor activator of nuclear factor-kB ligand antibodies, have changed the course of metastatic cancer to the bone by reducing skeletal morbidity. The use of these bone modifying agents, together with improvements in pain management and advancements in surgical and radiation therapy, contribute to a better evolution of metastatic bone disease. The proposed term will be renamed to its shorter synonym Metastatic bone disease prophylaxis which will be added as PT to HLT Bone therapeutic procedures NEC.

Supplemental Update Report

CR Number: 2018320003 **Implementation Date:** 20-Nov-18 Related CR: 2018320003

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New Term				
Proposed Term	*Prophylaxis against pathological fracture*	Approved Not as Requested	Proposed PT	
			Pathological fracture prophylaxis	10082364
			HLT primary	
			Bone therapeutic procedures NEC	10006000
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Prophylaxis against pathological fracture is approved but not as requested. Pathologic fractures occur as a result of weakening of the mechanical properties of bone. Both neoplastic and non-neoplastic diseases may lead to bone softening and cause pathologic fractures. Preventive measures include appropriate calcium and vitamin D intake, weight-bearing exercise, fall prevention, and other ways to reduce risk (eg, avoiding tobacco and limiting alcohol). Drug therapy tends to involve the same drugs as are given for treatment of osteoporosis, and is indicated for patients who have osteoporosis or who have osteopenia if they are at increased risk of fracture, such as those taking glucocorticoids. The proposed term will be renamed to its shorter synonym Pathological fracture prophylaxis and will be added as a PT to HLT Bone therapeutic procedures NEC.

CR Number: 2018320004 **Implementation Date:** 20-Nov-18 Related CR: 2018320004

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Add a New Term				
Proposed Term	*Prophylaxis against skeletal related events*	Rejected		

MSSO Comment: The proposal to add a new term Prophylaxis against skeletal related events is not approved. The proposed term is too broad and may involve a too large variety of preventive measures which render the term highly unspecific.

Supplemental Update Report

CR Number: 2018320005 **Implementation Date:** 20-Nov-18 Related CR: 2018320005

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Pituitary apoplexy*	Approved as Requested	Proposed LLT	
From PT	*Pituitary haemorrhage*		*Pituitary apoplexy*	10056447
			From PT	
			Pituitary haemorrhage	10049760
			HLT primary	
			Hypothalamic and pituitary disorders NEC	10021109
			SOC primary	
			Endocrine disorders	10014698
			HLT secondary	
			Central nervous system haemorrhages and cerebrovascular accidents	10007948
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to promote the LLT Pituitary apoplexy from PT Pituitary haemorrhage is approved as requested. Pituitary apoplexy is a clinical endocrine emergency leading to an acute pituitary hypofunction, which may result in severe hypoglycemia, hypotension and shock, central nervous system hemorrhage, and death. Acute symptoms may include severe headache with signs of meningeal irritation, bilateral visual changes, ophthalmoplegia, and, in severe cases, cardiovascular collapse and loss of consciousness. Pituitary apoplexy may occur spontaneously in a preexisting adenoma; postpartum (Sheehan's syndrome); or in association with diabetes, hypertension, sickle cell anemia, or acute shock. Pituitary computed tomography or MRI may reveal signs of intratumoral or sellar hemorrhage, with pituitary stalk deviation and compression of pituitary tissue. The LLT Pituitary apoplexy represents a clinical emergency, independently from its hemorrhagic or infarction substrate, and will be promoted to PT level, with a primary link to HLT Hypothalamic and pituitary disorders NEC, and secondary links to HLT Central nervous system haemorrhages and cerebrovascular accidents and HLT Nervous system haemorrhagic disorders, in accordance with the physio-pathological vascular origine of the event.

CR Number: 2018324021 **Implementation Date:** 20-Nov-18 Related CR: 2018320005

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pituitary apoplexy*	Approved as Requested	Proposed PT	
To HLT	*Nervous system haemorrhagic disorders*		*Pituitary apoplexy*	10056447
			To HLT	
			Nervous system haemorrhagic disorders	10008206

MSSO Comment:

Supplemental Update Report

CR Number: 2018320006 **Implementation Date:** 27-Nov-18 Related CR: 2018320006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ogden Syndrome*	Approved Not as Requested	Proposed PT	
HLT primary	*Congenital disorders NEC*		*Ogden syndrome*	10082376
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Musculoskeletal and connective tissue disorders of face, neck and jaw congenital	10028380
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Musculoskeletal and connective tissue disorders of face, neck and jaw congenital	10028380
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new PT Ogden Syndrome to primary HLT Congenital disorders NEC in SOC Congenital, familial and genetic disorders is approved but not as requested. This is an X-linked condition affecting males and characterized by postnatal growth failure with developmental delays and dysmorphic features. Craniofacial abnormalities and cardiac arrhythmias are the most representative signs of this congenital syndrome. Ogden Syndrome, modified according to MedDRA capitalization conventions, will be added as a PT Ogden syndrome with primary link to the bi-axial HLT Musculoskeletal and connective tissue disorders of face, neck and jaw congenital (primary SOC Congenital, familial and genetic disorders and secondary SOC Musculoskeletal and connective tissue disorders), and a secondary link to HLT Rate and rhythm disorders NEC.

CR Number: 2018330022 **Implementation Date:** 27-Nov-18 Related CR: 2018320006

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ogden syndrome*	Approved as Requested	Proposed PT	
To HLT	*Rate and rhythm disorders NEC*		*Ogden syndrome*	10082376
			To HLT	
			Rate and rhythm disorders NEC	10037908

MSSO Comment:

Supplemental Update Report

CR Number: 2018320007 **Implementation Date:** 27-Nov-18 Related CR: 2018320007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hyperpipecolic acidemia*	Approved Not as Requested	Proposed LLT	
To PT	*Acidosis*		*Hyperpipecolic acidemia*	10082387 Current
			To PT	
			Hyperpipecolic acidaemia	10082383

MSSO Comment: The proposal to add a new LLT Hyperpipecolic acidemia to PT Acidosis is approved but not as requested. Pipecolic acidemia, also called hyperpipecolic acidemia or hyperpipecolatemia, is a very rare autosomal recessive metabolic disorder that is caused by a peroxisomal defect. The disorder is characterized by an increase in pipecolic acid levels in the blood, leading to neuropathy and hepatomegaly. Hyperpipecolic acidemia will be added as an LLT to new PT Hyperpipecolic acidaemia. In a related change, PT Hyperpipecolic acidaemia will be added and linked to bi-axial HLT Inborn errors of amino acid metabolism (primary SOC Congenital, familial and genetic disorders, and secondary SOC Metabolism and nutrition disorders).

CR Number: 2018330023 **Implementation Date:** 27-Nov-18 Related CR: 2018320007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hyperpipecolic acidaemia*	Approved as Requested	Proposed PT	
HLT primary	*Inborn errors of amino acid metabolism*		*Hyperpipecolic acidaemia*	10082383
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Inborn errors of amino acid metabolism	10021602
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Inborn errors of amino acid metabolism	10021602
			SOC secondary	
			Metabolism and nutrition disorders	10027433

MSSO Comment:

Supplemental Update Report

CR Number: 2018320008 **Implementation Date:** 27-Nov-18 Related CR: 2018320008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Allergy to edible fungus*	Approved as Requested	Proposed LLT	
To PT	*Food allergy*		*Allergy to edible fungus*	10082393 Current
			To PT	
			Food allergy	10016946

MSSO Comment: The proposal to add a new LLT Allergy to edible fungus to PT Food allergy is approved as requested. Exposure to fungal allergens can occur by inhalation of mold spores, skin contact with saprophytic species or ingestion of edible mushrooms.

CR Number: 2018320009 **Implementation Date:** 27-Nov-18 Related CR: 2018320009

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Schwartz Jampel syndrome*	Approved as Requested	Proposed PT	
HLT primary	*Musculoskeletal disorders congenital NEC*		*Schwartz Jampel syndrome*	10082378
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Musculoskeletal disorders congenital NEC	10029513
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Musculoskeletal disorders congenital NEC	10029513
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new PT Schwartz Jampel syndrome to primary HLT Musculoskeletal disorders congenital NEC in SOC Congenital, familial and genetic disorders is approved as requested. Schwartz Jampel syndrome (SJS) is a genetic disorder that affects bone and muscle development. Signs and symptoms may include muscle stiffness and weakness; joint deformities that affect mobility (contractures); short stature; small "fixed" facial features; and eye abnormalities. Schwartz Jampel syndrome will be added as PT to the bi-axial HLT Musculoskeletal disorders congenital NEC (primary SOC Congenital, familial and genetic disorders and secondary SOC Musculoskeletal and connective tissue disorders).

Supplemental Update Report

CR Number: 2018320010 **Implementation Date:** 27-Nov-18 Related CR: 2018320010

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Shprintzen–Goldberg syndrome*	Rejected		
HLT primary	*Musculoskeletal and connective tissue disorders of skull congenital*			
SOC primary	*Congenital, familial and genetic disorders*			

MSSO Comment: The proposal to add a new PT Shprintzen–Goldberg syndrome to primary HLT Musculoskeletal and connective tissue disorders of skull congenital in SOC Congenital, familial and genetic disorders and secondary HLT Musculoskeletal and connective tissue disorders congenital in SOC Musculoskeletal and connective tissue disorders is not approved. Shprintzen-Goldberg syndrome recently has been added as a PT in change request 2018291002 for MedDRA version 22.0.

CR Number: 2018320011 **Implementation Date:** 27-Nov-18 Related CR: 2018320011

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Norovirus infection*	Rejected		
HLT primary	*Caliciviral infections*			
SOC primary	*Infections and infestations*			

MSSO Comment: The proposal to add a new PT Norovirus infection to primary HLT Caliciviral infections in SOC Infections and infestations is not approved. Existing MedDRA PT Gastroenteritis norovirus adequately describes norovirus infection, based on pathology and anatomical site of manifestation.

CR Number: 2018320012 **Implementation Date:** 27-Nov-18 Related CR: 2018320012

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Woodhouse-Sakati syndrome*	Approved as Requested	Proposed PT	
HLT primary	*Endocrine disorders congenital NEC*		*Woodhouse-Sakati syndrome*	10082379
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Endocrine disorders congenital NEC	10027671
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Endocrine disorders NEC	10014700
			SOC secondary	
			Endocrine disorders	10014698

MSSO Comment: The proposal to add a new PT Woodhouse-Sakati syndrome to primary HLT Endocrine disorders congenital NEC in SOC Congenital, familial and genetic disorders is approved as requested. Woodhouse–Sakati syndrome, also called hypogonadism, alopecia, diabetes mellitus, intellectual disability and extrapyramidal syndrome, is a rare autosomal recessive multisystem disorder which causes malformations throughout the body, and deficiencies affecting the endocrine system. PT Woodhouse-Sakati syndrome will be additionally linked to secondary HLT Endocrine disorders NEC and secondary HLT Dystonias.

Supplemental Update Report

CR Number: 2018330025 **Implementation Date:** 27-Nov-18 Related CR: 2018320012

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Woodhouse-Sakati syndrome*	Approved as Requested	Proposed PT	
To HLT	*Dystonias*		*Woodhouse-Sakati syndrome*	10082379
			To HLT	
			Dystonias	10013985

MSSO Comment:

CR Number: 2018320013 **Implementation Date:** 27-Nov-18 Related CR: 2018320013

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hypotensive Retinopathy*	Approved Not as Requested	Proposed LLT	
To PT	*Venous stasis retinopathy*		*Hypotensive retinopathy*	10082390 Current
			To PT	
			Venous stasis retinopathy	10065622

MSSO Comment: The proposal to add a new LLT Hypotensive Retinopathy to PT Venous stasis retinopathy is approved but not as requested. Occlusion of the central retinal vein appears to be most commonly caused by venous-stasis retinopathy. Predisposing causes are cardiovascular disease, systemic hypertension, diabetes or raised intraocular pressure. Hypotensive Retinopathy is a term that has been cited in the medical literature synonymous with venous stasis retinopathy, and will be added as a new LLT Hypotensive retinopathy, in accordance with MedDRA capitalization conventions to PT Venous stasis retinopathy.

CR Number: 2018320014 **Implementation Date:** 27-Nov-18 Related CR: 2018320014

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Optic Nerve pigmentation*	Rejected		
HLT primary	*Optic nerve disorders NEC*			
SOC primary	*Nervous system disorders*			

MSSO Comment: The proposal to add a new PT Optic Nerve pigmentation to primary HLT Optic nerve disorders NEC in SOC Nervous system disorders and secondary HLT Visual pathway disorders in SOC Eye disorders is not approved. Pigmentation of the optic disc is a relatively uncommon finding, and can be associated with a variety of etiologies, such as primary eye disorders, melanocytoma, nevus of Ota, hemorrhage, and congenital anomalies such as optic nerve hypoplasia. Pigmentation of the optic nerve is virtually always identified clinically by ophthalmoscopy as pigmentation of the visible part of the optic nerve, the optic disc, during examination of the ocular fundus. Thus, the requested concept can be represented by existing PT Optic disc pigmentation.

Supplemental Update Report

CR Number: 2018320015 **Implementation Date:** 27-Nov-18 Related CR: 2018320015

Change Requested	Add a New PT
Proposed PT	*X-linked intellectual disability, Siderius type*
HLT primary	*Developmental disorders cognitive*
SOC primary	*Nervous system disorders*

Final Disposition
Approved Not as Requested

Final Placement	MedDRA Code #
Proposed PT	
X-linked intellectual disability, Siderius type	10082377
HLT primary	
Congenital disorders NEC	10010445
SOC primary	
Congenital, familial and genetic disorders	10010331
HLT secondary	
Intellectual disabilities	10077548
SOC secondary	
Nervous system disorders	10029205

MSSO Comment: The proposal to add a new PT X-linked intellectual disability, Siderius type to primary HLT Developmental disorders cognitive in SOC Nervous system disorders is approved but not as requested. X-linked intellectual disability, Siderius type is a condition characterized by mild to moderate intellectual disability that affects only males. Affected boys often have delayed development of motor skills such as walking, and their speech may be delayed. Individuals with X-linked intellectual disability, Siderius type frequently also have an opening in the lip (cleft lip) with an opening in the roof of the mouth (cleft palate). A cleft can occur on one or both sides of the upper lip. X-linked intellectual disability, Siderius type will be added as a PT to primary HLT Congenital disorders NEC and secondary HLT Intellectual disabilities.

Supplemental Update Report

CR Number: 2018320016 **Implementation Date:** 27-Nov-18 Related CR: 2018320016

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*SADDAN*	Approved Not as Requested	Proposed PT	
HLT primary	*Congenital disorders NEC*		*SADDAN syndrome*	10082381
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Non-site specific cartilage disorders congenital	10029510
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Non-site specific cartilage disorders congenital	10029510
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new PT SADDAN to primary HLT Congenital disorders NEC in SOC Congenital, familial and genetic disorders is approved but not as requested. SADDAN (severe achondroplasia with developmental delay and acanthosis nigricans) is a rare disorder of bone growth characterized by skeletal, brain, and skin abnormalities. All people with this condition have extremely short stature with particularly short arms and legs. Other features include unusual bowing of the leg bones; a small chest with short ribs and curved collar bones; short, broad fingers; and folds of extra skin on the arms and legs. Structural abnormalities of the brain cause seizures, profound developmental delay, and intellectual disability. Several affected individuals also have had episodes in which their breathing slows or stops for short periods (apnea). Acanthosis nigricans, a progressive skin disorder characterized by thick, dark, velvety skin, is another characteristic feature of SADDAN that develops in infancy or early childhood. The requested term will be added for clarification as SADDAN syndrome and added as a PT to primary bi-axial HLT Non-site specific cartilage disorders congenital (primary SOC Congenital, familial and genetic disorders and secondary SOC Musculoskeletal and connective tissue disorders), secondary HLT Skin hyperplasias and hypertrophies and secondary HLT Intellectual disabilities. In a related change, Severe achondroplasia with developmental delay and acanthosis nigrican, the SADDAN acronym spelled out, will be added as an LLT to PT SADDAN syndrome.

CR Number: 2018330026 **Implementation Date:** 27-Nov-18 Related CR: 2018320016

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*SADDAN syndrome*	Approved as Requested	Proposed PT	
To HLT	*Skin hyperplasias and hypertrophies*		*SADDAN syndrome*	10082381
			To HLT	
			Skin hyperplasias and hypertrophies	10040866

MSSO Comment:

Supplemental Update Report

CR Number: 2018330027 **Implementation Date:** 27-Nov-18 Related CR: 2018320016

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*SADDAN syndrome*	Approved as Requested	Proposed PT	
To HLT	*Intellectual disabilities*		*SADDAN syndrome*	10082381
			To HLT	
			Intellectual disabilities	10077548

MSSO Comment:

CR Number: 2018330028 **Implementation Date:** 27-Nov-18 Related CR: 2018320016

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Severe achondroplasia with developmental delay and acanthosis nigrican*	Approved as Requested	Proposed LLT	
To PT	*SADDAN syndrome*		*Severe achondroplasia with developmental delay and acanthosis nigrican*	10082394 Current
			To PT	
			SADDAN syndrome	10082381

MSSO Comment:

Supplemental Update Report

CR Number: 2018320017 **Implementation Date:** 27-Nov-18 Related CR: 2018320017

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Penta X Syndrome*	Approved Not as Requested	Proposed PT	
HLT primary	*Sex chromosomal abnormalities*		*Penta X syndrome*	10082382
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Sex chromosomal abnormalities	10040453
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Musculoskeletal and connective tissue deformities of skull, face and buccal cavity	10028378
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new PT Penta X Syndrome to primary HLT Sex chromosomal abnormalities in SOC Congenital, familial and genetic disorders is approved but not as requested. This rare chromosomal disorder is characterized by the presence of five X chromosomes leading to short stature, mental retardation, fifth finger clinodactyly, short neck, microcephaly, cardiac anomalies (ventricular septal defect, atrial septal defect, patent ductus arteriosus), and horseshoe kidneys. Onset is during childhood. Penta X Syndrome will be modified in accordance with MedDRA capitalisation conventions to Penta X syndrome and added as a PT to primary HLT Sex chromosomal abnormalities and secondary HLT Musculoskeletal and connective tissue deformities of skull, face and buccal cavity.

CR Number: 2018320018 **Implementation Date:** 27-Nov-18 Related CR: 2018320018

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Lacrimal caruncle*	Rejected		
HLT primary	*Lacrimation disorders*			
SOC primary	*Eye disorders*			

MSSO Comment: The proposal to add a new PT Lacrimal caruncle to primary HLT Lacrimation disorders in SOC Eye disorders is not approved. The lacrimal caruncle is a normal anatomical structure of the eye, and thus out of the scope of MedDRA. Lacrimal caruncle lesions such as inflammation, neoplasms or cysts can be added upon specific requests.

Supplemental Update Report

CR Number: 2018320019 **Implementation Date:** 27-Nov-18 Related CR: 2018320019

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Aberrant aortic arch*	Approved Not as Requested	Proposed PT	
HLT primary	*Congenital aortic anomaly*		*Aberrant aortic arch*	10082380
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Great vessel disorders congenital	10018717
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Vascular malformations and acquired anomalies	10047091
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new PT Aberrant aortic arch to primary HLT Congenital aortic anomaly in SOC Congenital, familial and genetic disorders is approved but not as requested. Congenital anomalies of the aortic arch, which take many forms, result from aberrant development of one or more components of the embryonic pharyngeal arch system. Aberrant aortic arch will be added as a PT to primary HLT Great vessel disorders congenital and secondary HLT Vascular malformations and acquired anomalies. In a related change, non-current LLT Congenital anomalies of aortic arch will be moved from PT Congenital aortic anomaly to the new PT Aberrant aortic arch for better alignment.

CR Number: 2018330029 **Implementation Date:** 27-Nov-18 Related CR: 2018320019

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Congenital anomalies of aortic arch*	Approved as Requested	Proposed LLT	
From PT	*Congenital aortic anomaly*		*Congenital anomalies of aortic arch*	10010338 Non-Current
To PT	*Aberrant aortic arch*		From PT	
			Congenital aortic anomaly	10061052
			To PT	
			Aberrant aortic arch	10082380

MSSO Comment:

Supplemental Update Report

CR Number: 2018320020 **Implementation Date:** 27-Nov-18 Related CR: 2018320020

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Aberrant subclavian artery*	Approved Not as Requested	Proposed LLT	
To PT	*Congenital arterial malformation*		*Aberrant right subclavian artery*	10082388 Current
			To PT	
			Aberrant aortic arch	10082380

MSSO Comment: The proposal to add a new LLT Aberrant subclavian artery to PT Congenital arterial malformation is approved but not as requested. Left aortic arch with aberrant right subclavian artery is usually asymptomatic, but can occasionally result in sophageal compression. Right aortic arch with aberrant left subclavian artery arising from a retroesophageal diverticulum of Kommerell is the second most common cause of a vascular ring after a double aortic arch. Aberrant right subclavian artery will be added as an LLT under new PT Aberrant aortic arch added in change request 2018320019.

CR Number: 2018320021 **Implementation Date:** 27-Nov-18 Related CR: 2018320021

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Orbital Reconstruction*	Approved Not as Requested	Proposed PT	
HLT primary	*Eye therapeutic procedures NEC*		*Orbital reconstruction*	10082385
SOC primary	*Surgical and medical procedures*		HLT primary	
			Orbit and globe therapeutic procedures	10031028
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT Orbital Reconstruction to primary HLT Eye therapeutic procedures NEC in SOC Surgical and medical procedures is approved but not as requested. Orbital reconstruction is the surgical restoration of the anatomy of the orbit in the treatment of orbital pathology and posttraumatic orbital deformities. The procedure usually entails assessment of the bony anatomy and critical neurovascular structures within the orbit, followed by appropriate osteotomy, fracture reduction, and orbital implant placement. Orbital Reconstruction will be modified according to MedDRA capitalization conventions, and added as a PT Orbital reconstruction to HLT Orbit and globe therapeutic procedures, rather than to the proposed HLT Eye therapeutic procedures NEC.

CR Number: 2018320022 **Implementation Date:** 27-Nov-18 Related CR: 2018320022

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Progressive macular hypomelanosis*	Approved Not as Requested	Proposed PT	
To PT	*Skin hypopigmentation*		*Progressive macular hypomelanosis*	10082386
			HLT primary	
			Hypopigmentation disorders	10021064
			SOC primary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment: The proposal to add a new LLT Progressive macular hypomelanosis to PT Skin hypopigmentation is approved but not as requested. Progressive macular hypomelanosis, which refers to a condition typically limited to the trunk, will be added as a PT to HLT Hypopigmentation disorders.

Supplemental Update Report

CR Number: 2018320023 **Implementation Date:** 27-Nov-18 Related CR: 2018320023

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Periocular dermatoses*	Approved Not as Requested	Proposed LLT	
To PT	*Dermatosis*		*Periocular dermatosis*	10082391 Current
			To PT	
			Dermatosis	10048768

MSSO Comment: The proposal to add a new LLT Periocular dermatoses to PT Dermatosis is approved but not as requested. The skin of the periocular area may be affected by dermatoses associated with a variety of etiologies, which include, but are not limited to: infections (bacterial, viral, fungal), urticaria, angioedema, rosacea, atopic dermatitis, contact dermatitis, neoplasms, systemic diseases (e.g., psoriasis, lupus erythematosus, amyloidosis), drug reactions, etc. Periocular dermatoses will be modified to the singular form, Periocular dermatosis and added as anatomical sub-concept LLT to PT Dermatosis.

CR Number: 2018320024 **Implementation Date:** 27-Nov-18 Related CR: 2018320024

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Salzmann nodule*	Rejected		
To PT	*Corneal degeneration*			

MSSO Comment: The proposal to add a new LLT Salzmann nodule to PT Corneal degeneration is not approved. The requested term is represented by existing LLT Salzmann nodular degeneration.

CR Number: 2018320025 **Implementation Date:** 27-Nov-18 Related CR: 2018320025

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Negative dysphotopsia*	Approved Not as Requested	Proposed LLT	
To PT	*Visual field defect*		*Negative dysphotopsia*	10082392 Current
			To PT	
			Dysphotopsia	10082384

MSSO Comment: The proposal to add a new LLT Negative dysphotopsia to PT Visual field defect is approved but not as requested. Negative dysphotopsia, described as an arc-shaped shadow, usually in the temporal field of vision, is a rare condition that can present after in-the-capsule posterior chamber IOL implantation. The precise etiology has not been totally elucidated. Negative dysphotopsia will be added as a sub-concept LLT to PT Dysphotopsia. In a related change, New PT Dysphotopsia will be added to primary HLT Eye and ear procedural complications, secondary HLT Visual disorders NEC and secondary HLT Eye complications associated with device.

Supplemental Update Report

CR Number: 2018330030 **Implementation Date:** 27-Nov-18 Related CR: 2018320025

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Dysphotopsia*	Approved as Requested	Proposed PT	
HLT primary	*Eye and ear procedural complications*		*Dysphotopsia*	10082384
SOC primary	*Injury, poisoning and procedural complications*		HLT primary	
			Eye and ear procedural complications	10015908
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Visual disorders NEC	10047541
			SOC secondary	
			Eye disorders	10015919

MSSO Comment:

CR Number: 2018330031 **Implementation Date:** 27-Nov-18 Related CR: 2018320025

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Dysphotopsia*	Approved as Requested	Proposed PT	
To HLT	*Eye complications associated with device*		*Dysphotopsia*	10082384
			To HLT	
			Eye complications associated with device	10069786

MSSO Comment:

Supplemental Update Report

CR Number: 2018320026 **Implementation Date:** 27-Nov-18 Related CR: 2018320026

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Positive dysphotopsia*	Approved Not as Requested	Proposed LLT	
To PT	*Visual field defect*		*Positive dysphotopsia*	10082389 Current
			To PT	
			Dysphotopsia	10082384

MSSO Comment: The proposal to add a new LLT Positive dysphotopsia to PT Visual field defect is approved but not as requested. Positive dysphotopsia is characterized by undesired light streaks, arcs, and flashes that emanate from obliquely incident sources of light, occurring after uncomplicated extracapsular cataract surgery and intraocular lens implantation. There is evidence that this refractive aberration is related to square-edged intraocular lenses. Positive dysphotopsia will be added as a sub-concept LLT to new PT Dysphotopsia added in change request 2018320025.

CR Number: 2018320027 **Implementation Date:** 27-Nov-18 Related CR: 2018320027

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Waist pain*	Rejected		
To PT	*Pain*			

MSSO Comment: The proposal to add a new LLT Waist pain to PT Pain is not approved. The proposed concept can be coded with the currently available LLT Abdominal pain. In MedDRA, the phrase "waist" is currently limited to the concept of waist circumference measurement.

CR Number: 2018320028 **Implementation Date:** 29-Nov-18 Related CR: 2018320028

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Incontinence*	Rejected After Suspension		
Status	*non-current*			

MSSO Comment: The proposal to change status of LLT Incontinence to non-current is not approved after suspension. The term is well placed with SOC Renal and urinary disorders as the primary SOC since the most common understanding of the term is urinary incontinence. Any changes, whether currency or changing links would have wide reaching effects on legacy data.

Supplemental Update Report

CR Number: 2018320029 **Implementation Date:** 21-Nov-18 Related CR: 2018320029

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Homeopathic aggravation*	Approved as Requested	Proposed PT	
HLT primary	*Therapeutic and nontherapeutic responses*		*Homeopathic aggravation*	10082371
SOC primary	*General disorders and administration site conditions*		HLT primary	
			Therapeutic and nontherapeutic responses	10043409
			SOC primary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Homeopathic aggravation to primary HLT Therapeutic and nontherapeutic responses in SOC General disorders and administration site conditions is approved as requested. Homeopathic aggravation is a temporary worsening of existing symptoms following the administration of a correct homeopathic prescription, and it is the reaction of the organism, as it responds to the gently stimulating action of the medicine. This aggravation may only be a slight worsening of symptoms and may hardly be noticed by the patient. It is important to distinguish homeopathic aggravations from adverse effects derived from homeopathic practice.

CR Number: 2018320030 **Implementation Date:** 21-Nov-18 Related CR: 2018320030

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Initial hoemeopathic aggravation*	Rejected		
To PT	*Homeopathic aggravation*			

MSSO Comment: The proposal to add a new LLT Initial hoemeopathic aggravation to PT Homeopathic aggravation is not approved. Since any homeopathic aggravation is inherently a transitory effect, the requested qualified concept (hardly present in international medical literature) does not seem to be necessary.

CR Number: 2018320031 **Implementation Date:** 21-Nov-18 Related CR: 2018320031

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Homeopathic aggravation*	Rejected		
To PT	*Homeopathic aggravation*			

MSSO Comment: The proposal to add a new LLT Homeopathic aggravation to PT Homeopathic aggravation is not approved. Addition of a new PT in MedDRA automatically comports the addition of the very same term and code number at the LLT level. The proposed change is therefore covered by previous change request 2018320029.

Supplemental Update Report

CR Number: 2018322001 **Implementation Date:** 27-Nov-18 Related CR: 2018322001

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Precursor T-lymphoblastic leukaemia acute*	Approved Not as Requested	Proposed PT	
HLT primary	*Precursor T-lymphoblastic lymphomas/leukaemias*		*Precursor T-lymphoblastic leukaemia acute*	10082373
SOC primary	*Blood and lymphatic system disorders*		HLT primary	
			Precursor T-lymphoblastic lymphomas/leukaemias	10036544
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Precursor T-lymphoblastic lymphomas/leukaemias	10036544
			SOC secondary	
			Blood and lymphatic system disorders	10005329

MSSO Comment: The proposal to add a new PT Precursor T-lymphoblastic leukaemia acute to primary HLT Precursor T-lymphoblastic lymphomas/leukaemias in SOC Blood and lymphatic system disorders is approved but not as requested. Precursor T-lymphoblastic leukemia is an aggressive subtype of T-cell acute lymphoblastic leukemia/lymphoma in which too many T-cell lymphoblasts are found in the bone marrow and blood. Also called T-cell acute lymphoblastic leukemia and T-cell acute lymphocytic leukemia. Precursor T-lymphoblastic leukaemia acute will be added as PT to HLT Precursor T-lymphoblastic lymphomas/leukaemias which primary is linked to SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps)and secondary to SOC Blood and lymphatic system disorders. In a related change, the American English spelled counterpart LLT Precursor T-lymphoblastic leukemia acute will be added to the new PT Precursor T-lymphoblastic leukaemia acute.

CR Number: 2018330032 **Implementation Date:** 27-Nov-18 Related CR: 2018322001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Precursor T-lymphoblastic leukemia acute*	Approved as Requested	Proposed LLT	
To PT	*Precursor T-lymphoblastic leukaemia acute*		*Precursor T-lymphoblastic leukemia acute*	10082374 Current
			To PT	
			Precursor T-lymphoblastic leukaemia acute	10082373

MSSO Comment:

Supplemental Update Report

CR Number: 2018323001 **Implementation Date:** 27-Nov-18 Related CR: 2018323001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Lichenoid dysplasia*	Approved as Requested	Proposed PT	
			Lichenoid dysplasia	10082397
			HLT primary	
			Oral soft tissue disorders NEC	10031015
			SOC primary	
			Gastrointestinal disorders	10017947
			HLT secondary	
			Papulosquamous conditions	10033738
			SOC secondary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment: The proposal to add a new term Lichenoid dysplasia is approved as requested. Lichenoid dysplasia is a lichenoid feature with epithelial dysplasia clinically and histopathologically similar to oral lichen planus. It can be clinically mistaken for oral lichen planus, but has histopathologic features of dysplasia and a true malignant predisposition. The clinician should be able to differentiate between oral lichen planus and lichenoid dysplasia for the proper management. Lichenoid dysplasia will be added as PT to primary HLT Oral soft tissue disorders NEC and secondary HLT Papulosquamous conditions.

CR Number: 2018323002 **Implementation Date:** 27-Nov-18 Related CR: 2018323002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Chromosome 1p36 deletion syndrome*	Approved Not as Requested	Proposed PT	
			1p36 deletion syndrome	10082398
			HLT primary	
			Musculoskeletal disorders congenital NEC	10029513
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Musculoskeletal disorders congenital NEC	10029513
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new LLT Chromosome 1p36 deletion syndrome is approved but not as requested. 1p36 deletion syndrome is a congenital genetic disorder characterized by moderate to severe intellectual disability, delayed growth, hypotonia, seizures, limited speech ability, malformations, hearing and vision impairment, and distinct facial features. The symptoms may vary, depending on the exact location of the chromosomal deletion. The facial features of 1p36 deletion syndrome have been considered to be characteristic, although few patients have been diagnosed solely on the basis of facial appearance. These features may include microcephaly; small, possibly slanted, deep-set eyes; a flat nose and nasal bridge; anomalous, low-set and small ears; a small mouth with down-turned corners; and a pointed chin. The requested term will be shortened and added as PT 1p36 deletion syndrome to bi-axial HLT Musculoskeletal disorders congenital NEC, primary SOC Congenital, familial and genetic disorders and secondary SOC Musculoskeletal and connective tissue disorders and to secondary HLT Intellectual disabilities.

Supplemental Update Report

CR Number: 2018331020 **Implementation Date:** 27-Nov-18 Related CR: 2018323002

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*1p36 deletion syndrome*	Approved as Requested	Proposed PT	
To HLT	*Intellectual disabilities*		*1p36 deletion syndrome*	10082398
			To HLT	
			Intellectual disabilities	10077548

MSSO Comment:

CR Number: 2018323003 **Implementation Date:** 27-Nov-18 Related CR: 2018323003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*PELVIS Syndrome*	Approved Not as Requested	Proposed LLT	
			PELVIS syndrome	10082400 Current
			To PT	
			LUMBAR syndrome	10066910

MSSO Comment: The proposal to add a new LLT PELVIS Syndrome is approved but not as requested. The terms PELVIS Syndrome, the acronym stands for perineal hemangioma, external genitalia malformations, lipomyelomeningocele, vesicorenal abnormalities, imperforate anus, and skin tag) was coined in 2006. In 2010, new discoveries were made, with doctors coining a different term to incorporate all the abnormalities, called LUMBAR syndrome. In 2016, LUMBAR officially replaced PELVIS and SACRAL, as it most accurately describes the current understanding of the affiliated anomalies. The requested term will be modified in accordance to MedDRA capitalization standards and added as an LLT PELVIS syndrome a sub-concept to PT LUMBAR syndrome.

CR Number: 2018323004 **Implementation Date:** 27-Nov-18 Related CR: 2018323004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Anagen effluvium*	Approved as Requested	Proposed LLT	
			Anagen effluvium	10082399 Current
			To PT	
			Diffuse alopecia	10073736

MSSO Comment: The proposal to add a new LLT Anagen effluvium is approved as requested. Anagen effluvium is severe and sudden hair loss that occurs within days or weeks of taking certain drugs (usually chemotherapy drugs). Hair loss is more extensive than telogen effluvium and can include eyebrows, eyelashes, and other areas of the body. In addition re-grown hair may not be as thick as the original hair. Anagen effluvium will be added as LLT to PT Diffuse alopecia, aligned with LLT Telogen effluvium.

Supplemental Update Report

CR Number: 2018323005 **Implementation Date:** 27-Nov-18 Related CR: 2018323005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Non-scarring alopecia*	Approved as Requested	Proposed PT	
			Non-scarring alopecia	10082395
			HLT primary	
			Alopecias	10001769
			SOC primary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment: The proposal to add a new PT Non-scarring alopecia is approved as requested. Non-scarring alopecias are more common than scarring alopecias and include male and female pattern hair loss (also known as androgenetic alopecia), alopecia areata, telogen effluvium, and trichotillomania as well as other less common conditions. Sometimes diseases such as secondary syphilis, thyroid disease, and systemic lupus erythematosus can lead to non-scarring hair loss also. Non-scarring hair thinning can also occur with natural aging, which is known as senescent alopecia. Non-scarring alopecia will be added as PT to HLT Alopecias.

CR Number: 2018323006 **Implementation Date:** 27-Nov-18 Related CR: 2018323006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Enterorrhaphy*	Approved as Requested	Proposed PT	
			Enterorrhaphy	10082396
			HLT primary	
			Gastrointestinal therapeutic procedures NEC	10018013
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Enterorrhaphy is approved as requested. Enterorrhaphy, the surgical procedure of stitching an intestine that has either perforated or been divided during an operation, will be added as PT to HLT Gastrointestinal therapeutic procedures NEC.

Supplemental Update Report

CR Number: 2018323007 **Implementation Date:** 27-Nov-18 Related CR: 2018323007

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Lumbar syndrome*	Approved Not as Requested	LLT to change	
Status	*current*		*Lumbar syndrome*	10066910
			Status	
			Current	

MSSO Comment: The proposal to change status of LLT Lumbar syndrome to current is approved but not as requested. Lumbar Syndrome has been made non-current in v21.0 because of ambiguity and potential confusion with LUMBAR syndrome. Lumbar syndrome also can stand for e.g. LLT Lumbar facet syndrome or LLT Iliolumbar syndrome. The status of LLT Lumbar syndrome will be changed to current. In related changes, LLT Lumbar syndrome will be modified to LUMBAR syndrome. Furthermore, LLT LUMBAR syndrome will be promoted to PT LUMBAR syndrome and linked to primary HLT Vascular anomalies congenital NEC, secondary HLT Cardiovascular neoplasms benign. The most prominent feature of LUMBAR is a large infantile hemangioma on the lower back often extending down to the leg. Other features are urogenital tract malformations, spinal cord defects, bone deformities, anorectal malformations, and arterial anomalies.

CR Number: 2018331018 **Implementation Date:** 27-Nov-18 Related CR: 2018323007

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Lumbar syndrome*	Approved as Requested	Term to modify	
Replacement term	*LUMBAR syndrome*		*Lumbar syndrome*	10066910
			Replacement term	
			LUMBAR syndrome	10066910

MSSO Comment:

Supplemental Update Report

CR Number: 2018331019 **Implementation Date:** 27-Nov-18 Related CR: 2018323007

Change Requested	Promote an LLT
Proposed LLT	*Lumbar syndrome*
From PT	*Back pain*
HLT primary	*Vascular anomalies congenital NEC*

Final Disposition
Approved as Requested

Final Placement	MedDRA Code #
Proposed LLT	
Lumbar syndrome	10066910
From PT	
Back pain	10003988
HLT primary	
Vascular anomalies congenital NEC	10047047
SOC primary	
Congenital, familial and genetic disorders	10010331
HLT secondary	
Cardiovascular neoplasms benign	10007656
SOC secondary	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104

MSSO Comment:

Supplemental Update Report

CR Number: 2018323008 **Implementation Date:** 27-Nov-18 Related CR: 2018323008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Amplified musculoskeletal pain syndrome*	Approved Not as Requested	Proposed PT	
			Amplified musculoskeletal pain syndrome	10082375
			HLT primary	
			Musculoskeletal and connective tissue pain and discomfort	10068757
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395
			HLT secondary	
			Sensory abnormalities NEC	10040021
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new LLT Amplified musculoskeletal pain syndrome is approved but not as requested. Amplified musculoskeletal pain syndrome (AMPS) is a very painful medical condition that can cause pain anywhere in the body. These episodes of pain can be intermittent or constant, can affect the whole body or be localized to one area of the body or affect just a limb. Symptoms include body aches, joint and muscle pain, abnormal sensations of burning, tingling, numbness or pressure, headache, and chronic abdominal pain. In some cases, light touch to the skin causes pain sensations. Amplified musculoskeletal pain syndrome will be added as PT to primary HLT Musculoskeletal and connective tissue pain and discomfort and secondary HLT Sensory abnormalities NEC.

CR Number: 2018323009 **Implementation Date:** 27-Nov-18 Related CR: 2018323009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Bronchus-associated lymphoid tissue lymphoma*	Approved as Requested	Proposed LLT	
To PT	*Extranodal marginal zone B-cell lymphoma (BALT type)*		*Bronchus-associated lymphoid tissue lymphoma*	10082405 Current
			To PT	
			Extranodal marginal zone B-cell lymphoma (BALT type)	10081367

MSSO Comment: The proposal to add a new LLT Bronchus-associated lymphoid tissue lymphoma to PT Extranodal marginal zone B-cell lymphoma (BALT type) is approved as requested. Bronchus-associated lymphoid tissue lymphoma represents the spelled out version of current LLT BALT lymphoma.

Supplemental Update Report

CR Number: 2018323010 **Implementation Date:** 27-Nov-18 Related CR: 2018323010

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Blepharophimosis, ptosis, and epicanthus inversus syndrome type II*	Approved as Requested	Proposed LLT	
			Blepharophimosis, ptosis, and epicanthus inversus syndrome type II	10082406 Current
To PT	*BPES syndrome*		To PT	
			BPES syndrome	10081258

MSSO Comment: The proposal to add a new LLT Blepharophimosis, ptosis, and epicanthus inversus syndrome type II to PT BPES syndrome is approved as requested. For clarification of the acronym expression BPES type II by spelling it out.

CR Number: 2018323011 **Implementation Date:** 27-Nov-18 Related CR: 2018323011

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Blepharophimosis, ptosis, and epicanthus inversus syndrome type I*	Approved as Requested	Proposed LLT	
			Blepharophimosis, ptosis, and epicanthus inversus syndrome type I	10082403 Current
To PT	*BPES syndrome*		To PT	
			BPES syndrome	10081258

MSSO Comment: The proposal to add a new LLT Blepharophimosis, ptosis, and epicanthus inversus syndrome type I to PT BPES syndrome is approved as requested. For clarification of the acronym expression BPES type I by spelling it out.

CR Number: 2018323012 **Implementation Date:** 27-Nov-18 Related CR: 2018323012

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Urinary bladder mapping*	Approved as Requested	Proposed LLT	
To PT	*Bladder mapping*		*Urinary bladder mapping*	10082402 Current
			To PT	
			Bladder mapping	10081498

MSSO Comment: The proposal to add a new LLT Urinary bladder mapping to PT Bladder mapping is approved as requested. Although in the majority of cases in medical literature, the term Bladder mapping refers to the urinary bladder, there are some instances in which the term could refer to gallbladder mapping. Urinary bladder mapping will be added to increase anatomical specificity in avoidance of this potential confusion.

Supplemental Update Report

CR Number: 2018323013 **Implementation Date:** 27-Nov-18 Related CR: 2018323013

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Aspiration bronchial*	Approved Not as Requested	Proposed LLT	
Replacement term	*Aspiration into bronchus*		*Aspiration into bronchus*	10082401 Current
			To PT	
			Aspiration	10003504

MSSO Comment: The proposal to rename PT/LLT Aspiration bronchial to Aspiration into bronchus is approved but not as requested. The term Aspiration into bronchus will be added as an LLT to PT Aspiration to provide an LLT clearly distinct from the investigation term represented by LLT Bronchial aspiration procedure. In a related change, LLT Aspiration bronchial will be flagged non-current to avoid confusion.

CR Number: 2018331021 **Implementation Date:** 27-Nov-18 Related CR: 2018323013

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Aspiration bronchial*	Approved as Requested	LLT to change	
Status	*Non-current*		*Aspiration bronchial*	10050777 Non-Current
			Status	
			Non-current	

MSSO Comment:

CR Number: 2018323014 **Implementation Date:** 27-Nov-18 Related CR: 2018323014

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Aspiration tracheal*	Approved Not as Requested	Proposed LLT	
Replacement term	*Aspiration into trachea*		*Aspiration into trachea*	10082404 Current
			To PT	
			Aspiration	10003504

MSSO Comment: The proposal to rename PT/LLT Aspiration tracheal to Aspiration into trachea is approved but not as requested. The term Aspiration into trachea will be added as LLT to PT Aspiration to provide an LLT clearly distinct from the investigation term represented by LLT Bronchial tracheal procedure. In a related change, LLT Aspiration tracheal will be made non-current to avoid confusion.

Supplemental Update Report

CR Number: 2018331022 **Implementation Date:** 27-Nov-18 Related CR: 2018323014

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Change Status of LLT				
LLT to change	*Aspiration tracheal*	Approved as Requested	LLT to change	
Status	*Non-current*		*Aspiration tracheal*	10003530 Non-Current
			Status	
			Non-current	

MSSO Comment:

CR Number: 2018323015 **Implementation Date:** 29-Nov-18 Related CR: 2018323015

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Rename PT/LLT				
Term to modify	*Monolid eyes*	Rejected After Suspension		
Replacement term	*Monolid eyes disorder*			

MSSO Comment: The proposal to rename PT/LLT Monolid eyes to Monolid eyes disorder is not approved after suspension. The term is clear and grammatically correct as is, and is the common expression in the literature. Adding the word "disorder" is inappropriate since monolid eyes are a normal anatomical variant. As for the conflict with the word "disorder" in the HLT name, Eye disorders congenital, as well as the secondary HLT Lid, lash and lacrimal structural disorders, this is not a concern as MedDRA uses "disorder" throughout (SOC Eye disorders, etc.) even though some of the underlying terms are not strictly disorders. See also PT Prominent epicanthal folds with similar links. This also is not a disorder.

CR Number: 2018323016 **Implementation Date:** 29-Nov-18 Related CR: 2018323016

Change Requested		Final Disposition	Final Placement	MedDRA Code #
Rename PT/LLT				
Term to modify	*Single eyelids*	Rejected After Suspension		
Replacement term	*Single eyelids disorder*			

MSSO Comment: The proposal to rename PT/LLT Single eyelids to Single eyelids disorder is not approved after suspension. The term is clear and grammatically correct as is, and is the common expression in the literature. Adding the word "disorder" is inappropriate since monolid eyes are a normal anatomical variant. As for the conflict with the word "disorder" in the HLT name, Eye disorders congenital, as well as the secondary HLT Lid, lash and lacrimal structural disorders, this is not a concern as MedDRA uses "disorder" throughout (SOC Eye disorders, etc.) even though some of the underlying terms are not strictly disorders. See also PT Prominent epicanthal folds with similar links. This also is not a disorder.

Supplemental Update Report

CR Number: 2018323017 **Implementation Date:** 27-Nov-18 Related CR: 2018323017

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Forced expiratory volume/forced vital capacity ratio decreased*	Approved as Requested	Proposed LLT	
			Forced expiratory volume/forced vital capacity ratio decreased	10082408 Current
To PT	*FEV1/FVC ratio decreased*		To PT	
			FEV1/FVC ratio decreased	10081435

MSSO Comment: The proposal to add a new LLT Forced expiratory volume/forced vital capacity ratio decreased to PT FEV1/FVC ratio decreased is approved as requested. Forced expiratory volume/forced vital capacity ratio decreased represents the expanded form of PT FEV1/FVC ratio decreased, added in version 21.1.

CR Number: 2018323018 **Implementation Date:** 27-Nov-18 Related CR: 2018323018

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Forced expiratory volume/forced vital capacity ratio abnormal*	Approved as Requested	Proposed LLT	
			Forced expiratory volume/forced vital capacity ratio abnormal	10082409 Current
To PT	*FEV1/FVC ratio abnormal*		To PT	
			FEV1/FVC ratio abnormal	10081436

MSSO Comment: The proposal to add a new LLT Forced expiratory volume/forced vital capacity ratio abnormal to PT FEV1/FVC ratio abnormal is approved as requested. Forced expiratory volume/forced vital capacity ratio abnormal represents the expanded form of PT FEV1/FVC ratio abnormal, added in version 21.1.

CR Number: 2018323019 **Implementation Date:** 27-Nov-18 Related CR: 2018323019

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Human Papilloma Virus positive oropharyngeal squamous cell carcinoma*	Approved Not as Requested	Proposed LLT	
			Human papilloma virus positive oropharyngeal squamous cell carcinoma	10082410 Current
To PT	*HPV positive oropharyngeal squamous cell carcinoma*		To PT	
			Oropharyngeal squamous cell carcinoma	10031112

MSSO Comment: The proposal to add a new LLT Human Papilloma Virus positive oropharyngeal squamous cell carcinoma to PT HPV positive oropharyngeal squamous cell carcinoma is approved but not as requested. Human Papilloma Virus positive oropharyngeal squamous cell carcinoma represents the expanded form of LLT HPV positive oropharyngeal squamous cell carcinoma which was added in v21.1 as LLT to PT Oropharyngeal squamous cell carcinoma. Human Papilloma Virus positive oropharyngeal squamous cell carcinoma will be modified in accordance with MedDRA capitalisation conventions and added as LLT Human papilloma virus positive oropharyngeal squamous cell carcinoma to PT Oropharyngeal squamous cell carcinoma.

Supplemental Update Report

CR Number: **2018323020** **Implementation Date:** 27-Nov-18 Related CR: 2018323020

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Thoracic spine subluxation*	Approved as Requested	Proposed LLT	
To PT	*Dislocation of vertebra*		*Thoracic spine subluxation*	10082411 Current
			To PT	
			Dislocation of vertebra	10013183

MSSO Comment: The proposal to add a new LLT Thoracic spine subluxation to PT Dislocation of vertebra is approved as requested. Thoracic spine subluxation is considered to be a misalignment of one vertebra upon the other of the thoracic part or the vertebra column. Thoracic spine subluxations can irritate the nerves of the disc, facet joints, and spinal nerves leaving the spine to cause pain in the mid-back that may even be felt around the sides and into the chest. Even though existing LLT Thoracic subluxation usually defaults to the spine, LLT Thoracic spine subluxation may help to differentiate spinal subluxation from rib subluxation, both in thoracic area.

CR Number: **2018323021** **Implementation Date:** 27-Nov-18 Related CR: 2018323021

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Catheter dysfunction*	Approved as Requested	Proposed LLT	
			Catheter dysfunction	10082407 Current
			To PT	
			Device malfunction	10063829

MSSO Comment: The proposal to add a new term Catheter dysfunction is approved as requested. Catheter dysfunction can be attributed to many causes, and progression of dysfunction to nonfunction varies accordingly. The most common complications are thrombosis and infection. Even with care, fewer than half the catheters placed as “long-term access” are in use a year after their placement, and about a third are removed because they fail to deliver adequate blood flow. Catheter dysfunction will be added as an LLT to PT Device malfunction.

CR Number: **2018324001** **Implementation Date:** 28-Nov-18 Related CR: 2018324001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Allergy to antibiotic*	Approved as Requested	Proposed LLT	
To PT	*Drug hypersensitivity*		*Allergy to antibiotic*	10082424 Current
			To PT	
			Drug hypersensitivity	10013700

MSSO Comment: The proposal to add a new LLT Allergy to antibiotic to PT Drug hypersensitivity is approved as requested. Allergy to an antibiotic is a characteristic of one's immunologic status, while an allergic reaction to an antibiotic/antibiotics represented by existing LLT Allergic reaction to antibiotics is an immune-mediated response to an antibiotic antigen that occurred at a specific time with specific signs and symptoms.

Supplemental Update Report

CR Number: 2018324002 **Implementation Date:** 27-Nov-18 Related CR: 2018324002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Investigation result normal*	Approved Not as Requested	Proposed PT *Investigation normal*	10082416
			HLT primary *Investigations NEC*	10022892
			SOC primary *Investigations*	10022891

MSSO Comment: The proposal to add a new term Investigation result normal is approved but not as requested. Although the proposed term Investigation result normal is nonspecific in nature, it will be rephrased as Investigation normal to conform with related existing terms PT Investigation and PT Investigation abnormal, and added as a PT to HLT Investigations NEC.

CR Number: 2018324003 **Implementation Date:** 27-Nov-18 Related CR: 2018324003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Phelan-McDermid syndrome*	Approved as Requested	Proposed PT *Phelan-McDermid syndrome*	10082417
			HLT primary *Musculoskeletal disorders congenital NEC*	10029513
			SOC primary *Congenital, familial and genetic disorders*	10010331
			HLT secondary *Musculoskeletal disorders congenital NEC*	10029513
			SOC secondary *Musculoskeletal and connective tissue disorders*	10028395

MSSO Comment: The proposal to add a new term Phelan-McDermid syndrome is approved as requested. Phelan-McDermid syndrome is a rare genetic condition caused by a deletion or other structural change of the terminal end of chromosome 22 in the 22q13 region or a disease-causing mutation of the SHANK3 gene. Because the genetic changes vary, the symptoms of Phelan-McDermid syndrome vary too, and can cause a wide range of medical, intellectual, and behavioral challenges. The most common characteristics found in those with PMS are intellectual disability of varying degrees, delayed or absent speech, symptoms of autism spectrum disorder, low muscle tone, motor delays, and epilepsy. There is currently no cure or treatment specifically for PMS. Phelan-McDermid syndrome will be added as a PT to primary bi-axial HLT Musculoskeletal disorders congenital NEC, primary SOC Congenital, familial and genetic disorders, and secondary SOC Musculoskeletal and connective tissue disorders. Furthermore, Phelan-McDermid syndrome will be linked to secondary HLT Seizures and seizure disorders NEC and secondary HLT Developmental motor skills disorders.

Supplemental Update Report

CR Number: 2018331023 **Implementation Date:** 27-Nov-18 Related CR: 2018324003

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Phelan-McDermid syndrome*	Approved as Requested	Proposed PT	
To HLT	*Seizures and seizure disorders NEC*		*Phelan-McDermid syndrome*	10082417
			To HLT	
			Seizures and seizure disorders NEC	10039912

MSSO Comment:

CR Number: 2018331024 **Implementation Date:** 27-Nov-18 Related CR: 2018324003

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Phelan-McDermid syndrome*	Approved as Requested	Proposed PT	
To HLT	*Developmental motor skills disorders*		*Phelan-McDermid syndrome*	10082417
			To HLT	
			Developmental motor skills disorders	10012567

MSSO Comment:

CR Number: 2018324004 **Implementation Date:** 27-Nov-18 Related CR: 2018324004

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Ostomy bag placement*	Approved as Requested	Proposed PT	
			Ostomy bag placement	10082415
			HLT primary	
			Gastrointestinal therapeutic procedures NEC	10018013
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Ostomy bag placement is approved as requested. An ostomy bag is a prosthetic medical pouching device that provides a means for the collection of waste from a surgically diverted biological system (colon, ileum, bladder) and the creation of a stoma. Ostomy bag placement will be added as a new PT to HLT Gastrointestinal therapeutic procedures NEC.

Supplemental Update Report

CR Number: 2018324005 **Implementation Date:** 27-Nov-18 Related CR: 2018324005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Thyroid Cystectomy*	Approved Not as Requested	Proposed PT	
			Thyroid cystectomy	10082412
			HLT primary	
			Thyroid therapeutic procedures	10043755
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT Thyroid Cystectomy is approved but not as requested. A thyroid cystectomy is a surgical excision of a thyroid cyst. Thyroid Cystectomy will be added as PT Thyroid cystectomy, in accordance with MedDRA capitalization conventions, to HLT Thyroid therapeutic procedures.

CR Number: 2018324006 **Implementation Date:** 27-Nov-18 Related CR: 2018324006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Cibophobia*	Approved as Requested	Proposed PT	
			Cibophobia	10082413
			HLT primary	
			Fear symptoms and phobic disorders (incl social phobia)	10068299
			SOC primary	
			Psychiatric disorders	10037175
			HLT secondary	
			General nutritional disorders NEC	10018067
			SOC secondary	
			Metabolism and nutrition disorders	10027433

MSSO Comment: The proposal to add a new term Cibophobia is approved as requested. Cibophobia, an abnormal or morbid aversion to food or to eating, will be added as a PT to primary HLT Fear symptoms and phobic disorders (incl social phobia) and secondary HLT General nutritional disorders NEC.

Supplemental Update Report

CR Number: 2018324007 **Implementation Date:** 27-Nov-18 Related CR: 2018324007

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Respiratory failure type 1*	Approved as Requested	Proposed LLT	
			Respiratory failure type 1	10082414 Current
			To PT	
			Respiratory failure	10038695

MSSO Comment: The proposal to add a new term Respiratory failure type 1 is approved as requested. Respiratory failure type 1 is characterized by an arterial oxygen tension (PaO2) lower than 60 mm Hg with a normal or low arterial carbon dioxide tension (PaCO2). This is the most common form of respiratory failure, and it can be associated with virtually all acute diseases of the lung, which generally involve fluid filling or collapse of alveolar units. Respiratory failure type 1 will be added as an LLT to PT Respiratory failure.

CR Number: 2018324008 **Implementation Date:** 27-Nov-18 Related CR: 2018324008

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Autoimmune myositis*	Approved Not as Requested	Proposed PT	
HLT primary	*Muscular autoimmune disorders*		*Autoimmune myositis*	10082418
SOC primary	*Immune system disorders*		HLT primary	
			Muscle infections and inflammations	10021992
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395
			HLT secondary	
			Muscular autoimmune disorders	10003821
			SOC secondary	
			Immune system disorders	10021428

MSSO Comment: The proposal to add a new PT Autoimmune myositis to primary HLT Muscular autoimmune disorders in SOC Immune system disorders is approved but not as requested. Autoimmune myositis is comprised of systemic rheumatic disorders characterized by inflammatory and degenerative changes in the muscles (polymyositis) or in the skin and muscles (dermatomyositis). Based on MedDRA rules for primary SOC allocations, site of Manifestation prevails over etiology. Therefore, Autoimmune myositis will be added as PT to primary HLT Muscle infections and inflammations and secondary HLT Muscular autoimmune disorders.

Supplemental Update Report

CR Number: 2018324009 **Implementation Date:** 27-Nov-18 Related CR: 2018324009

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pleomorphic leiomyosarcoma*	Approved as Requested	Proposed PT	
HLT primary	*Leiomyosarcomas*		*Pleomorphic leiomyosarcoma*	10082419
SOC primary	*Neoplasms benign, malignant and unspecified (incl cysts and polyps)*		HLT primary	
			Leiomyosarcomas	10024190
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Malignant musculoskeletal and connective tissue neoplasms	10025681
			SOC secondary	
			Musculoskeletal and connective tissue disorders	10028395

MSSO Comment: The proposal to add a new PT Pleomorphic leiomyosarcoma to primary HLT Leiomyosarcomas in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is approved as requested. Pleomorphic leiomyosarcoma is defined as a sarcoma showing typical leiomyosarcomatous fascicles but in which more than two thirds of the tumour is of pleomorphic morphology. Pleomorphic leiomyosarcoma differs from ordinary leiomyosarcoma in its morphology, reduced immunoreactivity for muscle markers, increased proliferative activity and more aggressive behavior. Pleomorphic leiomyosarcoma accounts for about 9% of all leiomyosarcomas. PT Pleomorphic leiomyosarcoma will also be linked to secondary HLT Malignant musculoskeletal and connective tissue neoplasms.

Supplemental Update Report

CR Number: 2018324010 **Implementation Date:** 27-Nov-18 Related CR: 2018324010

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vocal cord telangiectasia*	Approved as Requested	Proposed PT	
HLT primary	*Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)*		*Vocal cord telangiectasia*	10082420
SOC primary	*Respiratory, thoracic and mediastinal disorders*		HLT primary	
			Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	10023819
			SOC primary	
			Respiratory, thoracic and mediastinal disorders	10038738
			HLT secondary	
			Vascular malformations and acquired anomalies	10047091
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new PT Vocal cord telangiectasia to primary HLT Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms) in SOC Respiratory, thoracic and mediastinal disorders is approved as requested. Telangiectasia of the vocal cords is discribed as dilated blood vessels in the area of the vocal fold with the potential for haemorrhage. PT Vocal cord telangiectasia will also be linked to secondary HLT Vascular malformations and acquired anomalies.

CR Number: 2018324011 **Implementation Date:** 28-Nov-18 Related CR: 2018324011

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Cold*	Rejected		
From PT	*Nasopharyngitis*			
To PT	*Upper respiratory tract infection*			

MSSO Comment: The proposal to move the LLT Cold from PT Nasopharyngitis to PT Upper respiratory tract infection is not approved. Based on the final justification of CR2017145007, in MedDRA version 20.0 the common cold concept LLTs (Cold, Cold symptoms, Common cold, Common cold syndrome, Febrile cold (excl flu like illness), Head cold, Pyrexial cold) were moved from PT Nasopharyngitis to PT Viral upper respiratory tract infection. Upon reconsideration these LLTs will be moved back to PT Nasopharyngitis because they have been grouped under Nasopharyngitis since MedDRA version 2.1 and have been used in databases with high frequency with this placement.

Supplemental Update Report

CR Number: **2018324023** **Implementation Date:** 27-Nov-18 Related CR: 2018324023

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Diagnostic device malfunction*	Approved Not as Requested	Proposed LLT	
HLT primary	*Device malfunction events NEC*		*Diagnostic device malfunction*	10082421 Current
SOC primary	*Product issues*		To PT	
			Device malfunction	10063829

MSSO Comment: The proposal to add a new PT Diagnostic device malfunction to primary HLT Device malfunction events NEC in SOC Product issues is approved but not as requested. Diagnostic devices are devices used to identify the nature or cause of a certain phenomenon, usually related to a medical condition. Examples of diagnostic devices are magnetic resonance imaging apparatuses, temperature sensors or pacemakers. Diagnostic device malfunction will be added as a sub-concept LLT to PT Device malfunction.

CR Number: **2018324024** **Implementation Date:** 28-Nov-18 Related CR: 2018324024

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*FDG PET scan*	Approved Not as Requested	Proposed LLT	
To PT	*Radioisotope scan*		*FDG PET scan*	10082422 Current
			To PT	
			Positron emission tomogram	10036220

MSSO Comment: The proposal to add a new LLT FDG PET scan to PT Radioisotope scan is approved but not as requested. FDG (fluorine-18 combined with deoxy-glucose) is a glucose analogue extensively used in oncology for staging, restaging and recently for the evaluation of tumor response to treatment. Cancer cells demonstrate up regulation of glucose metabolism: uptake of glucose or glucose-analogues, as deoxy-glucose is increased. Labeling deoxy-glucose with the positron emitting radionuclide 18F (radionuclide fluorine-18) to form 18F-FDG renders these cells detectable using PET. The abbreviated expression FDG PET scan will be added as an LLT under PT Positron emission tomogram, which is more specific than proposed PT Radioisotope scan. In a related change, the fully worded concept LLT Fluorodeoxyglucose-positron emission tomography will be added to PT Positron emission tomogram. Furthermore, LLT PET scan will be flagged current because it is commonly used and non-ambiguous.

CR Number: **2018331026** **Implementation Date:** 28-Nov-18 Related CR: 2018324024

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Fluorodeoxyglucose-positron emission tomography*	Approved as Requested	Proposed LLT	
To PT	*Positron emission tomogram*		*Fluorodeoxyglucose-positron emission tomography*	10082423 Current
			To PT	
			Positron emission tomogram	10036220

MSSO Comment:

Supplemental Update Report

CR Number: 2018331027 **Implementation Date:** 28-Nov-18 Related CR: 2018324024

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*PET scan*	Approved as Requested	LLT to change	
Status	*Current*		*PET scan*	10034749 Current
			Status	
			Current	

MSSO Comment:

CR Number: 2018324025 **Implementation Date:** 28-Nov-18 Related CR: 2018324025

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pruritic papular eruption associated with HIV*	Approved Not as Requested	Proposed PT	
HLT primary	*Acquired immunodeficiency syndromes*		*Papular pruritic eruption of HIV*	10082425
SOC primary	*Immune system disorders*		HLT primary	
			Retroviral infections	10038997
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Acquired immunodeficiency syndromes	10052740
			SOC secondary	
			Immune system disorders	10021428

MSSO Comment: The proposal to add a new PT Pruritic papular eruption associated with HIV to primary HLT Acquired immunodeficiency syndromes in SOC Immune system disorders is approved but not as requested. Papular pruritic eruption of HIV is considered to be within the spectrum of pruritic papular disorders in HIV, which includes eosinophilic folliculitis and nonspecific pruritus. The primary lesion is a firm urticarial papule, though sterile pustules have been described as well. The eruption is usually symmetric and distributed primarily on the extremities, and less commonly on the trunk and face. Pruritic papular eruption associated with HIV will be modified to more frequently used expression Papular pruritic eruption of HIV and added as PT to primary HLT Retroviral infections (like other non-infectious consequences of HIV infection) and secondary HLT Acquired immunodeficiency syndromes and secondary HLT Papulosquamous conditions.

Supplemental Update Report

CR Number: 2018332022 **Implementation Date:** 28-Nov-18 Related CR: 2018324025

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Papular pruritic eruption of HIV*	Approved as Requested	Proposed PT	
To HLT	*Papulosquamous conditions*		*Papular pruritic eruption of HIV*	10082425
			To HLT	
			Papulosquamous conditions	10033738

MSSO Comment:

CR Number: 2018325001 **Implementation Date:** 28-Nov-18 Related CR: 2018325001

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Dysdiadochokinesis*	Approved as Requested	Proposed LLT	
From PT	*Cerebellar syndrome*		*Dysdiadochokinesis*	10013896
HLT primary	*Coordination and balance disturbances*		From PT	
			Cerebellar syndrome	10008072
			HLT primary	
			Coordination and balance disturbances	10072984
			SOC primary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to promote the LLT Dysdiadochokinesis from PT Cerebellar syndrome to primary HLT Coordination and balance disturbances in SOC Nervous system disorders is approved as requested. Dysdiadochokinesis is one symptom of Cerebellar syndrome - signs and symptoms of a syndrome should not be grouped under the syndrome. Other signs of cerebellar syndrome are also represented on PT level. In related changes, LLT Adiadokokinesis and LLT Dysdiadokokinesis will be moved from PT Cerebellar syndrome to the promoted PT Dysdiadochokinesis for better alignment.

Supplemental Update Report

CR Number: 2018331028 **Implementation Date:** 28-Nov-18 Related CR: 2018325001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Adiadokokinesis*	Approved as Requested	Proposed LLT	
From PT	*Cerebellar syndrome*		*Adiadokokinesis*	10001292 Current
To PT	*Dysdiadochokinesis*		From PT	
			Cerebellar syndrome	10008072
			To PT	
			Dysdiadochokinesis	10013896

MSSO Comment:

CR Number: 2018331029 **Implementation Date:** 28-Nov-18 Related CR: 2018325001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Dysdiadokokinesis*	Approved as Requested	Proposed LLT	
From PT	*Cerebellar syndrome*		*Dysdiadokokinesis*	10013897 Current
To PT	*Dysdiadochokinesis*		From PT	
			Cerebellar syndrome	10008072
			To PT	
			Dysdiadochokinesis	10013896

MSSO Comment:

CR Number: 2018325002 **Implementation Date:** 29-Nov-18 Related CR: 2018325002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Clogged pores*	Approved as Requested	Proposed LLT	
To PT	*Acne*		*Clogged pores*	10082428 Current
			To PT	
			Acne	10000496

MSSO Comment: The proposal to add a new LLT Clogged pores to PT Acne is approved as requested. Clogged pores are a colloquial expression for existing LLT Comedo both terms are subordinate to PT Acne.

Supplemental Update Report

CR Number: 2018325003 **Implementation Date:** 29-Nov-18 Related CR: 2018325003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Genital macule*	Approved as Requested	Proposed PT	
HLT primary	*Reproductive tract disorders NEC (excl neoplasms)*		*Genital macule*	10082427
SOC primary	*Reproductive system and breast disorders*		HLT primary	
			Reproductive tract disorders NEC (excl neoplasms)	10027696
			SOC primary	
			Reproductive system and breast disorders	10038604
			HLT secondary	
			Hyperpigmentation disorders	10020713
			SOC secondary	
			Skin and subcutaneous tissue disorders	10040785

MSSO Comment: The proposal to add a new PT Genital macule to primary HLT Reproductive tract disorders NEC (excl neoplasms) in SOC Reproductive system and breast disorders is approved as requested. Genital melanotic macules are poorly recognized lesions, which appear as isolated discrete macules. Their occurrence, usually as new pigmented lesions in adult life, can cause concern because they can mimic early melanoma. PT Genital macule also will be linked to secondary HLT Hyperpigmentation disorders.

CR Number: 2018325004 **Implementation Date:** 29-Nov-18 Related CR: 2018325004

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Periocular swelling*	Approved as Requested	Proposed LLT	
From PT	*Eye swelling*		*Periocular swelling*	10077364 Current
To PT	*Periorbital swelling*		From PT	
			Eye swelling	10015967
			To PT	
			Periorbital swelling	10056647

MSSO Comment: The proposal to move the LLT Periocular swelling from PT Eye swelling to PT Periorbital swelling is approved as requested for better alignment.

Supplemental Update Report

CR Number: 2018325005 **Implementation Date:** 29-Nov-18 Related CR: 2018325005

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Reaction to food colouring*	Approved as Requested	PT to merge	
To PT	*Reaction to colouring*		*Reaction to food colouring*	10056130 Current
			To PT	
			Reaction to colouring	10037974

MSSO Comment: The proposal to demote the PT Reaction to food colouring under PT Reaction to colouring is approved as requested. PT Reaction to food colouring can be considered a sub-concept of the broader PT Reaction to colouring.

CR Number: 2018325006 **Implementation Date:** 29-Nov-18 Related CR: 2018325006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Hyperaesthesia teeth*	Approved as Requested	Proposed PT	
			Hyperaesthesia teeth	10082426
			HLT primary	
			Dental pain and sensation disorders	10044049
			SOC primary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new term Hyperaesthesia teeth is approved as requested. Hyperesthesia of dental tissues is an increase dental sensitivity caused by different irritants. Usually they are of mechanic, chemical or temperature origin. Hyperaesthesia teeth will be added as a PT to HLT Dental pain and sensation disorders. In related changes, the American English spelled counterpart Hyperesthesia teeth will be added as LLT and the PT Sensitivity of teeth will be merged under the new PT Hyperaesthesia teeth as synonym.

CR Number: 2018332023 **Implementation Date:** 29-Nov-18 Related CR: 2018325006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hyperesthesia teeth*	Approved as Requested	Proposed LLT	
To PT	*Hyperaesthesia teeth*		*Hyperesthesia teeth*	10082429 Current
			To PT	
			Hyperaesthesia teeth	10082426

MSSO Comment:

Supplemental Update Report

CR Number: 2018332024 **Implementation Date:** 29-Nov-18 Related CR: 2018325006

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Sensitivity of teeth*	Approved as Requested	PT to merge	
To PT	*Hyperaesthesia teeth*		*Sensitivity of teeth*	10040012 Current
			To PT	
			Hyperaesthesia teeth	10082426

MSSO Comment:

CR Number: 2018325007 **Implementation Date:** 06-Dec-18 Related CR: 2018325007

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Reaction to food additive*	Approved as Requested	Proposed PT	
To SMQ	*Hypersensitivity (SMQ)*		*Reaction to food additive*	10037977
Term scope	*Narrow*		To SMQ	
			Hypersensitivity (SMQ)	20000214
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Reaction to food additive to Hypersensitivity (SMQ) as a narrow term is approved as requested. Similar PTs, e.g. Reaction to azo-dyes, Reaction to excipient and Reaction to preservatives are included as narrow terms as well.

Supplemental Update Report

CR Number: 2018325008 **Implementation Date:** 29-Nov-18 Related CR: 2018325008

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Post 5-alpha-reductase inhibitor syndrome*	Approved as Requested	Proposed PT	
			Post 5-alpha-reductase inhibitor syndrome	10082430
			HLT primary	
			Endocrine abnormalities of gonadal function NEC	10014691
			SOC primary	
			Endocrine disorders	10014698
			HLT secondary	
			Sexual function and fertility disorders NEC	10013357
			SOC secondary	
			Reproductive system and breast disorders	10038604

MSSO Comment: The proposal to add a new PT Post 5-alpha-reductase inhibitor syndrome is approved as requested. 5-alpha-reductase inhibitors are a group of drugs that are used in the treatment of benign prostatic hyperplasia and male pattern hair loss. Post 5-alpha-reductase inhibitor syndrome is a term recently coined to characterize a constellation of reported undesirable side effects that developed during or after stopping treatment with 5-alpha-reductase inhibitors, and persisted after drug discontinuation. Symptoms included decreased libido, erectile dysfunction, sexual anhedonia, decreased sperm count, gynecomastia, skin changes, cognitive impairment, fatigue, anxiety, depression, and suicidal ideation. Post 5-alpha-reductase inhibitor syndrome will be added as a PT with primary link to HLT Endocrine abnormalities of gonadal function NEC; and secondary links to HLT Sexual function and fertility disorders NEC, secondary HLT Psychiatric symptoms NEC, and secondary HLT Asthenic conditions.

CR Number: 2018332025 **Implementation Date:** 29-Nov-18 Related CR: 2018325008

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Post 5-alpha-reductase inhibitor syndrome*	Approved as Requested	Proposed PT	
To HLT	*Psychiatric symptoms NEC*		*Post 5-alpha-reductase inhibitor syndrome*	10082430
			To HLT	
			Psychiatric symptoms NEC	10037180

MSSO Comment:

Supplemental Update Report

CR Number: 2018332026 **Implementation Date:** 29-Nov-18 Related CR: 2018325008

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Post 5-alpha-reductase inhibitor syndrome*	Approved as Requested	Proposed PT	
To HLT	*Asthenic conditions*		*Post 5-alpha-reductase inhibitor syndrome*	10082430
			To HLT	
			Asthenic conditions	10003550

MSSO Comment:

CR Number: 2018325009 **Implementation Date:** 29-Nov-18 Related CR: 2018325009

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Vocal cord scarring*	Approved as Requested	Proposed PT	
HLT primary	*Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)*		*Vocal cord scarring*	10082431
SOC primary	*Respiratory, thoracic and mediastinal disorders*		HLT primary	
			Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)	10023819
			SOC primary	
			Respiratory, thoracic and mediastinal disorders	10038738

MSSO Comment: The proposal to add a new PT Vocal cord scarring to primary HLT Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms) in SOC Respiratory, thoracic and mediastinal disorders is approved as requested. Vocal cord scarring occurs when scar tissue is formed on the layer of the vocal cord that vibrates. The scarring can be mild or severe, and can occur in an isolated area, or on the entire vocal cord. Symptoms may include difficulty speaking or singing, hoarseness or breathiness, rough voice and voice tiredness.

CR Number: 2018325010 **Implementation Date:** 28-Nov-18 Related CR: 2018325010

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cortical visual impairment*	Approved as Requested	Proposed PT	
From HLT	*Visual disorders NEC*		*Cortical visual impairment*	10076660
To HLT	*Visual impairment and blindness (excl colour blindness)*		From HLT	
			Visual disorders NEC	10047541
			To HLT	
			Visual impairment and blindness (excl colour blindness)	10080708

MSSO Comment: The proposal to move the PT Cortical visual impairment from HLT Visual disorders NEC to HLT Visual impairment and blindness (excl colour blindness) is approved as requested. In CR# 2018263045 the PT Visual impairment was moved from the HLT Visual disorders NEC to HLT Visual impairment and blindness (excl colour blindness) because it is more appropriately aligned with HLT Visual impairment and blindness (excl colour blindness), than with the current link to HLT Visual disorders NEC, by virtue of the wording Visual impairment.

Supplemental Update Report

CR Number: 2018325011 **Implementation Date:** 10-Dec-18 Related CR: 2018325011

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pharyngeal swelling*	Approved as Requested	Proposed PT *Pharyngeal swelling*	10082270
To SMQ	*Anaphylactic reaction (SMQ)*		To SMQ *Anaphylactic reaction (SMQ)*	20000021
Term scope	*Broad*		Term scope *Broad*	
			Term_category *B*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Pharyngeal swelling to Anaphylactic reaction (SMQ) as a broad term is approved as requested. Pharyngeal swelling is a new PT added in v22.0. PT Pharyngeal swelling, similar to included PT Pharyngeal oedema, can be a sign of anaphylaxis. The moved LLT Throat swelling was an LLT under included PT Pharyngeal oedema. PT Pharyngeal swelling will be added to the category B broad search.

CR Number: 2018325012 **Implementation Date:** 10-Dec-18 Related CR: 2018325012

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pharyngeal swelling*	Approved as Requested	Proposed PT *Pharyngeal swelling*	10082270
To SMQ	*Angioedema (SMQ)*		To SMQ *Angioedema (SMQ)*	20000024
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Pharyngeal swelling to Angioedema (SMQ) as a narrow term is approved as requested. Pharyngeal swelling is a new PT added in v22.0. Pharyngeal swelling, similar to included Pharyngeal oedema, can be sign of angioedema. Moved LLT Throat swelling was an LLT under PT Pharyngeal oedema. Oedema/swelling counterparts are narrow in scope.

Supplemental Update Report

CR Number: 2018325013 **Implementation Date:** 10-Dec-18 Related CR: 2018325013

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neonatal sinus bradycardia*	Approved as Requested	Proposed PT	
To SMQ	*Congenital and neonatal arrhythmias (SMQ)*		*Neonatal sinus bradycardia*	10082188
Term scope	*Broad*		To SMQ	
			Congenital and neonatal arrhythmias (SMQ)	20000052
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Neonatal sinus bradycardia to Congenital and neonatal arrhythmias (SMQ) as a broad term is approved as requested. Neonatal sinus bradycardia is a new PT added in v22.0, which fits inclusion criteria for this SMQ as broad in scope; same as for included broader PT Bradycardia neonatal.

CR Number: 2018325014 **Implementation Date:** 10-Dec-18 Related CR: 2018325014

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neonatal sinus tachycardia*	Approved as Requested	Proposed PT	
To SMQ	*Congenital and neonatal arrhythmias (SMQ)*		*Neonatal sinus tachycardia*	10082191
Term scope	*Broad*		To SMQ	
			Congenital and neonatal arrhythmias (SMQ)	20000052
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Neonatal sinus tachycardia to Congenital and neonatal arrhythmias (SMQ) as a broad term is approved as requested. Neonatal sinus tachycardia is a new PT added in v22.0, which fits inclusion criteria for this SMQ as broad in scope, same as for included broader PT Tachycardia neonatal.

Supplemental Update Report

CR Number: 2018325015 **Implementation Date:** 10-Dec-18 Related CR: 2018325015

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pharyngeal swelling*	Approved as Requested	Proposed PT *Pharyngeal swelling*	10082270
To SMQ	*Hypersensitivity (SMQ)*		To SMQ *Hypersensitivity (SMQ)*	20000214
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Pharyngeal swelling to Hypersensitivity (SMQ) as a narrow term is approved as requested. Pharyngeal swelling is a new PT added in v22.0 and, similar to included PT Pharyngeal oedema, can be sign of hypersensitivity. Moved LLT Throat swelling was LLT under PT Pharyngeal oedema. Oedema/swelling counterparts are narrow in scope.

CR Number: 2018325016 **Implementation Date:** 10-Dec-18 Related CR: 2018325016

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Urticarial dermatitis*	Approved as Requested	Proposed PT *Urticarial dermatitis*	10082290
To SMQ	*Hypersensitivity (SMQ)*		To SMQ *Hypersensitivity (SMQ)*	20000214
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Urticarial dermatitis to Hypersensitivity (SMQ) as a narrow term is approved as requested. Urticarial dermatitis is a new PT added in v22.0. The pathogenesis of urticarial dermatitis is incompletely understood. One hypothesis is that urticarial dermatitis is a lymphocyte mediated (type IV) hypersensitivity reaction. PT Urticarial dermatitis will be added to the narrow scope search, same as for PT Dermatitis allergic.

Supplemental Update Report

CR Number: 2018325017 **Implementation Date:** 10-Dec-18 Related CR: 2018325017

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Therapeutic product effect decreased*	Approved as Requested	Proposed PT *Therapeutic product effect decreased*	10082201
To SMQ	*Lack of efficacy/effect (SMQ)*		To SMQ *Lack of efficacy/effect (SMQ)*	20000032
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Therapeutic product effect decreased to Lack of efficacy/effect (SMQ) as a narrow term is approved as requested. Therapeutic product effect decreased is a new PT added in v22.0, which fits inclusion criteria for this SMQ. Demoted PT Drug effect decreased, now an LLT to this broader new PT, was included in this SMQ. All terms in SMQ Lack of efficacy/effect are narrow in scope.

CR Number: 2018325018 **Implementation Date:** 10-Dec-18 Related CR: 2018325018

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Therapeutic product effect delayed*	Approved as Requested	Proposed PT *Therapeutic product effect delayed*	10082202
To SMQ	*Lack of efficacy/effect (SMQ)*		To SMQ *Lack of efficacy/effect (SMQ)*	20000032
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Therapeutic product effect delayed to Lack of efficacy/effect (SMQ) as a narrow term is approved as requested. Therapeutic product effect delayed is a new PT added in v22.0, which fits inclusion criteria for this SMQ. Demoted PT Drug effect delayed, now an LLT to this broader new PT was included in this SMQ. All terms in SMQ Lack of efficacy/effect are narrow in scope.

Supplemental Update Report

CR Number: 2018325019 **Implementation Date:** 10-Dec-18 Related CR: 2018325019

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Therapeutic product effect incomplete*	Approved as Requested	Proposed PT *Therapeutic product effect incomplete*	10082200
To SMQ	*Lack of efficacy/effect (SMQ)*		To SMQ *Lack of efficacy/effect (SMQ)*	20000032
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Therapeutic product effect incomplete to Lack of efficacy/effect (SMQ) as a narrow term is approved as requested. Therapeutic product effect incomplete is a new PT added in v22.0, which fits inclusion criteria for this SMQ. Demoted PT Drug effect incomplete, now LLT to this broader new PT, was included in this SMQ. All terms in SMQ Lack of efficacy/effect are narrow in scope.

CR Number: 2018325020 **Implementation Date:** 10-Dec-18 Related CR: 2018325020

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Therapeutic product effect variable*	Approved as Requested	Proposed PT *Therapeutic product effect variable*	10082204
To SMQ	*Lack of efficacy/effect (SMQ)*		To SMQ *Lack of efficacy/effect (SMQ)*	20000032
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Therapeutic product effect variable to Lack of efficacy/effect (SMQ) as a narrow term is approved as requested. Therapeutic product effect variable is a new PT added in v22.0, which fits inclusion criteria for this SMQ. Demoted PT Drug effect variable, now an LLT to this broader new PT, was included in this SMQ. All terms in SMQ Lack of efficacy/effect are narrow in scope.

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CR Number: 2018325021 **Implementation Date:** 10-Dec-18 Related CR: 2018325021

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Microblepharoexfoliation procedure*	Approved as Requested	Proposed PT *Microblepharoexfoliation procedure*	10082246
To SMQ	*Conjunctival disorders (SMQ)*		To SMQ *Conjunctival disorders (SMQ)*	20000175
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Microblepharoexfoliation procedure to Conjunctival disorders (SMQ) as a narrow term is approved as requested. PT Microblepharoexfoliation procedure, added in V 22.0, is a procedure to treat blepharitis and dry eye disease. The procedure entails removal of accumulated biofilm on the eyelid margin, eliminating the source of inflammation which leads to more comfortable eyelids, and an increase in natural tear production. Because the microblepharoexfoliation procedure may improve conjunctival dryness and inflammation associated with dry eye syndrome, PT Microblepharoexfoliation procedure will be added as a narrow scope term to Conjunctival disorders (SMQ), as all terms are narrow in this SMQ. Please note that PT Dry eye, PT Conjunctival irritation, and PT Xerophthalmia are narrow terms that are currently included in Conjunctival disorders SMQ.

CR Number: 2018325022 **Implementation Date:** 10-Dec-18 Related CR: 2018325022

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Microblepharoexfoliation procedure*	Approved as Requested	Proposed PT *Microblepharoexfoliation procedure*	10082246
To SMQ	*Corneal disorders (SMQ)*		To SMQ *Corneal disorders (SMQ)*	20000156
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Microblepharoexfoliation procedure to Corneal disorders (SMQ) as a broad term is approved as requested. PT Microblepharoexfoliation procedure, added in V 22.0, is a procedure to treat blepharitis and dry eye disease. The procedure entails removal of accumulated biofilm on the eyelid margin, eliminating the source of inflammation which leads to more comfortable eyelids, and an increase in natural tear production. Because dry eye disorders are frequently associated with corneal epithelial abnormalities such as keratitis sicca, PT Microblepharoexfoliation procedure will be added as a broad term to Corneal disorders (SMQ). PT Dry eye, PT Eye irritation, PT Tear break up time decreased, and PT Xerophthalmia are currently broad terms in this SMQ.

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CR Number: 2018325023 **Implementation Date:** 10-Dec-18 Related CR: 2018325023

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Microblepharoexfoliation procedure*	Approved as Requested	Proposed PT *Microblepharoexfoliation procedure*	10082246
To SMQ	*Periorbital and eyelid disorders (SMQ)*		To SMQ *Periorbital and eyelid disorders (SMQ)*	20000179
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Microblepharoexfoliation procedure to Periorbital and eyelid disorders (SMQ) as a narrow term is approved as requested. PT Microblepharoexfoliation procedure, added in V 22.0, is a procedure to treat blepharitis and dry eye disease. The procedure entails removal of accumulated biofilm on the eyelid margin, eliminating the source of inflammation which leads to more comfortable eyelids, and an increase in natural tear production. PT Microblepharoexfoliation procedure will be added to Periorbital and eyelid disorders (SMQ), fulfilling the inclusion criterion: "Terms for eyelid procedures." All terms in this SMQ are narrow in scope.

CR Number: 2018325024 **Implementation Date:** 10-Dec-18 Related CR: 2018325024

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Subretinal hyperreflective exudation*	Approved as Requested	Proposed PT *Subretinal hyperreflective exudation*	10082240
To SMQ	*Retinal disorders (SMQ)*		To SMQ *Retinal disorders (SMQ)*	20000158
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Subretinal hyperreflective exudation to Retinal disorders (SMQ) as a narrow term is approved as requested. PT Subretinal hyperreflective exudation, added in V 22.0, represents a subretinal hyperreflective exudative condition that differs from other types of subretinal hyperreflective material, based on the findings from multimodal imaging. This novel type of subretinal hyperreflective exudation likely represents a sign of active neovascular age-related macular degeneration distinct from subretinal fluid, hemorrhage, neovascular tissue, lipid, pigment hyperplasia, subretinal fibrosis, and the exudation observed with acquired vitelliform lesions. PT Subretinal hyperreflective exudation warrants addition as a narrow scope term to Retinal disorders (SMQ) because it is a retinal disorder, and it fulfills the inclusion criterion: "All terms that contain 'retin'."

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CR Number: 2018325025 **Implementation Date:** 10-Dec-18 Related CR: 2018325025

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pulmonary haemorrhage neonatal*	Approved as Requested	Proposed PT *Pulmonary haemorrhage neonatal*	10082194
To SMQ	*Haemorrhage terms (excl laboratory terms) (SMQ)*		To SMQ *Haemorrhage terms (excl laboratory terms) (SMQ)*	20000039
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Pulmonary haemorrhage neonatal to Haemorrhage terms (excl laboratory terms) (SMQ) as a narrow term is approved as requested. This term, which describes a specific location of hemorrhage, meets the criteria for inclusion in this SMQ which is composed of narrow search terms.

CR Number: 2018325026 **Implementation Date:** 10-Dec-18 Related CR: 2018325026

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pulmonary haemorrhage neonatal*	Approved as Requested	Proposed PT *Pulmonary haemorrhage neonatal*	10082194
To SMQ	*Neonatal disorders (SMQ)*		To SMQ *Neonatal disorders (SMQ)*	20000191
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Pulmonary haemorrhage neonatal to Neonatal disorders (SMQ) as a narrow term is approved as requested. This SMQ contains all terms related to conditions of the neonate. Since the term describes a specific clinical condition (i.e., pulmonary haemorrhage), it will be included in the narrow search terms.

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CR Number: 2018325027 **Implementation Date:** 10-Dec-18 Related CR: 2018325027

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pharyngeal swelling*	Approved as Requested	Proposed PT	
To SMQ	*Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)*		*Pharyngeal swelling*	10082270
Term scope	*Broad*		To SMQ	
			Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)	20000225
			Term scope	
			Broad	
			Term_category	
			B	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Pharyngeal swelling to Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ) as a broad term is approved as requested. This term, which describes a specific type of hypersensitivity-related damage, meets the criteria for inclusion in the Category B broad search terms of this SMQ.

CR Number: 2018325028 **Implementation Date:** 10-Dec-18 Related CR: 2018325028

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*External ear neoplasm malignant*	Approved as Requested	Proposed PT	
To SMQ	*Non-haematological malignant tumours (SMQ)*		*External ear neoplasm malignant*	10082277
Term scope	*Narrow*		To SMQ	
			Non-haematological malignant tumours (SMQ)	20000228
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT External ear neoplasm malignant to Non-haematological malignant tumours (SMQ) as a narrow term is approved as requested. This term describes a specific non-hematological malignancy and meets inclusion criteria for this SMQ composed of narrow search terms.

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CR Number: 2018325029 **Implementation Date:** 10-Dec-18 Related CR: 2018325029

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Velamentous cord insertion*	Approved as Requested	Proposed PT	
To SMQ	*Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)*		*Velamentous cord insertion*	10082174
Term scope	*Narrow*		To SMQ	
			Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)	20000186
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Velamentous cord insertion to Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ) as a narrow term is approved as requested. In velamentous cord insertion, the umbilical cord inserts into the fetal membranes (choriamniotic membranes) and then travels within the membranes to the placenta (between the amnion and the chorion). The exposed vessels are not protected by Wharton's jelly and hence are vulnerable to rupture. Since it is a risk factor for placental hemorrhage, it meets the criteria for inclusion in the narrow search terms of this SMQ.

CR Number: 2018325030 **Implementation Date:** 10-Dec-18 Related CR: 2018325030

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Urticarial dermatitis*	Approved as Requested	Proposed PT	
To SMQ	*Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)*		*Urticarial dermatitis*	10082290
Term scope	*Broad*		To SMQ	
			Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)	20000225
			Term scope	
			Broad	
			Term_category	
			B	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Urticarial dermatitis to Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ) as a broad term is approved as requested. This term, which describes a specific type of hypersensitivity-related damage, meets the criteria for inclusion in the Category B broad search terms of this SMQ. The related PT Urticaria is already included in the Category B search terms of this SMQ.

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CR Number: 2018325031 **Implementation Date:** 10-Dec-18 Related CR: 2018325031

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Squamous cell carcinoma of the parotid gland*	Approved as Requested	Proposed PT	
To SMQ	*Non-haematological malignant tumours (SMQ)*		*Squamous cell carcinoma of the parotid gland*	10082230
Term scope	*Narrow*		To SMQ	
			Non-haematological malignant tumours (SMQ)	20000228
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Squamous cell carcinoma of the parotid gland to Non-haematological malignant tumours (SMQ) as a narrow term is approved as requested. This term describes a specific non-hematological malignancy and meets inclusion criteria for this SMQ composed of narrow search terms.

CR Number: 2018325032 **Implementation Date:** 10-Dec-18 Related CR: 2018325032

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Alpha-thalassaemia-intellectual deficit syndrome*	Approved as Requested	Proposed PT	
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		*Alpha-thalassaemia-intellectual deficit syndrome*	10082291
Term scope	*Narrow*		To SMQ	
			Congenital, familial and genetic disorders (SMQ)	20000077
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Alpha-thalassaemia-intellectual deficit syndrome to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

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CR Number: 2018325033 **Implementation Date:** 10-Dec-18 Related CR: 2018325033

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Congenital nasal septum deviation*	Approved as Requested	Proposed PT *Congenital nasal septum deviation*	10082221
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Congenital nasal septum deviation to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2018325034 **Implementation Date:** 10-Dec-18 Related CR: 2018325034

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gap junction protein beta 2 gene mutation*	Approved as Requested	Proposed PT *Gap junction protein beta 2 gene mutation*	10082218
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Gap junction protein beta 2 gene mutation to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

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CR Number: 2018325035 **Implementation Date:** 10-Dec-18 Related CR: 2018325035

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Shprintzen-Goldberg syndrome*	Approved as Requested	Proposed PT *Shprintzen-Goldberg syndrome*	10082234
To SMQ	*Congenital, familial and genetic disorders (SMQ)*		To SMQ *Congenital, familial and genetic disorders (SMQ)*	20000077
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Shprintzen-Goldberg syndrome to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

CR Number: 2018325036 **Implementation Date:** 10-Dec-18 Related CR: 2018325036

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Administration site reaction neonatal*	Approved as Requested	Proposed PT *Administration site reaction neonatal*	10082193
To SMQ	*Neonatal disorders (SMQ)*		To SMQ *Neonatal disorders (SMQ)*	20000191
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Administration site reaction neonatal to Neonatal disorders (SMQ) as a narrow term is approved as requested. This SMQ contains all terms related to conditions of the neonate. Since the term describes a specific clinical condition, it will be included in the narrow search terms.

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CR Number: 2018325037 **Implementation Date:** 10-Dec-18 Related CR: 2018325037

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Constipation neonatal*	Approved as Requested	Proposed PT	
To SMQ	*Neonatal disorders (SMQ)*		*Constipation neonatal*	10082190
Term scope	*Narrow*		To SMQ	
			Neonatal disorders (SMQ)	20000191
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Constipation neonatal to Neonatal disorders (SMQ) as a narrow term is approved as requested. This SMQ contains all terms related to conditions of the neonate. Since the term describes a specific clinical condition, it will be included in the narrow search terms.

CR Number: 2018325038 **Implementation Date:** 10-Dec-18 Related CR: 2018325038

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Postpartum anxiety*	Approved as Requested	Proposed PT	
To SMQ	*Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)*		*Postpartum anxiety*	10082233
Term scope	*Narrow*		To SMQ	
			Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)	20000186
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Postpartum anxiety to Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ) as a narrow term is approved as requested. Terms for specific postpartum conditions are included in the narrow search terms of this SMQ. The related PT Postpartum stress disorder is already included in this SMQ.

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CR Number: 2018325039 **Implementation Date:** 10-Dec-18 Related CR: 2018325039

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Placenta duplex*	Approved as Requested	Proposed PT	
To SMQ	*Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)*		*Placenta duplex*	10082173
Term scope	*Narrow*		To SMQ	
			Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)	20000186
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Placenta duplex to Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ) as a narrow term is approved as requested. Placenta duplex, also known as bilobed placenta, can increase the risk for postpartum hemorrhage (due to retained placental tissue) and meets the criteria for inclusion in the narrow search terms of this SMQ.

CR Number: 2018325040 **Implementation Date:** 10-Dec-18 Related CR: 2018325040

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neonatal sinus bradycardia*	Approved as Requested	Proposed PT	
To SMQ	*Neonatal disorders (SMQ)*		*Neonatal sinus bradycardia*	10082188
Term scope	*Narrow*		To SMQ	
			Neonatal disorders (SMQ)	20000191
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Neonatal sinus bradycardia to Neonatal disorders (SMQ) as a narrow term is approved as requested. This SMQ contains all terms related to conditions of the neonate. Since the term describes a specific clinical condition (i.e., a specific cardiac rhythm), it will be included in the narrow search terms.

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CR Number: 2018325041 **Implementation Date:** 10-Dec-18 Related CR: 2018325041

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neonatal sinus tachycardia*	Approved as Requested	Proposed PT *Neonatal sinus tachycardia*	10082191
To SMQ	*Neonatal disorders (SMQ)*		To SMQ *Neonatal disorders (SMQ)*	20000191
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Neonatal sinus tachycardia to Neonatal disorders (SMQ) as a narrow term is approved as requested. This SMQ contains all terms related to conditions of the neonate. Since the term describes a specific clinical condition (i.e., a specific cardiac rhythm), it will be included in the narrow search terms.

CR Number: 2018325042 **Implementation Date:** 10-Dec-18 Related CR: 2018325042

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Nasal mucosal blistering*	Approved as Requested	Proposed PT *Nasal mucosal blistering*	10082185
To SMQ	*Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)*		To SMQ *Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)*	20000225
Term scope	*Broad*		Term scope *Broad*	
			Term_category *B*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Nasal mucosal blistering to Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ) as a broad term is approved as requested. This term, which describes a specific type of hypersensitivity-related damage, meets the criteria for inclusion in the Category B broad search terms of this SMQ. The related term, PT Oral mucosal blistering, is already included in this SMQ.

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CR Number: 2018325043 **Implementation Date:** 10-Dec-18 Related CR: 2018325043

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Nasal mucosal blistering*	Approved as Requested	Proposed PT	
To SMQ	*Severe cutaneous adverse reactions (SMQ)*		*Nasal mucosal blistering*	10082185
Term scope	*Broad*		To SMQ	
			Severe cutaneous adverse reactions (SMQ)	20000020
			Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Nasal mucosal blistering to Severe cutaneous adverse reactions (SMQ) as a broad term is approved as requested. This term, which describes a specific type of hypersensitivity-related damage, meets the criteria for inclusion in the broad search terms of this SMQ. The related term, PT Oral mucosal blistering, is already included in this SMQ.

CR Number: 2018325044 **Implementation Date:** 10-Dec-18 Related CR: 2018325044

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Infant irritability*	Approved as Requested	Proposed PT	
To SMQ	*Neonatal disorders (SMQ)*		*Infant irritability*	10082189
Term scope	*Narrow*		To SMQ	
			Neonatal disorders (SMQ)	20000191
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Infant irritability to Neonatal disorders (SMQ) as a narrow term is approved as requested. This SMQ contains all terms related to conditions of the neonate. Since the term describes a specific clinical condition, it will be included in the narrow search terms.

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CR Number: 2018325045 **Implementation Date:** 10-Dec-18 Related CR: 2018325045

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Infant sedation*	Approved as Requested	Proposed PT *Infant sedation*	10082187
To SMQ	*Neonatal disorders (SMQ)*		To SMQ *Neonatal disorders (SMQ)*	20000191
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Infant sedation to Neonatal disorders (SMQ) as a narrow term is approved as requested. This SMQ contains all terms related to conditions of the neonate. Since the term describes a specific clinical condition, it will be included in the narrow search terms.

CR Number: 2018325046 **Implementation Date:** 10-Dec-18 Related CR: 2018325046

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Infant dyschezia*	Approved as Requested	Proposed PT *Infant dyschezia*	10082228
To SMQ	*Neonatal disorders (SMQ)*		To SMQ *Neonatal disorders (SMQ)*	20000191
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Infant dyschezia to Neonatal disorders (SMQ) as a narrow term is approved as requested. This SMQ contains all terms related to conditions of the neonate. Since the term describes a specific clinical condition (i.e., a functional condition characterized by at least 10 minutes of straining and crying before successful or unsuccessful passage of soft stools), it will be included in the narrow search terms.

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CR Number: 2018325047 **Implementation Date:** 10-Dec-18 Related CR: 2018325047

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cancer fatigue*	Approved as Requested	Proposed PT *Cancer fatigue*	10082239
To SMQ	*Malignancy related conditions (SMQ)*		To SMQ *Malignancy related conditions (SMQ)*	20000092
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Cancer fatigue to Malignancy related conditions (SMQ) as a narrow term is approved as requested. This SMQ contains all terms for malignancy related conditions and is composed of narrow search terms only.

CR Number: 2018325048 **Implementation Date:** 10-Dec-18 Related CR: 2018325048

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Chemical burn of genitalia*	Approved as Requested	Proposed PT *Chemical burn of genitalia*	10082269
To SMQ	*Accidents and injuries (SMQ)*		To SMQ *Accidents and injuries (SMQ)*	20000135
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Chemical burn of genitalia to Accidents and injuries (SMQ) as a narrow term is approved as requested. This term meets criteria for inclusion in this SMQ. Related terms for chemical burns of the eye and skin are included in the narrow search terms of this SMQ.

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CR Number: 2018325049 **Implementation Date:** 10-Dec-18 Related CR: 2018325049

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*High-pitched crying*	Approved as Requested	Proposed PT	
To SMQ	*Neonatal disorders (SMQ)*		*High-pitched crying*	10052286
Term scope	*Narrow*		To SMQ	
			Neonatal disorders (SMQ)	20000191
			Term scope	
			Narrow	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT High-pitched crying to Neonatal disorders (SMQ) as a narrow term is approved as requested. This term was promoted from under PT Crying in v22.0. High-pitched crying most often applies to vaccination and is specific to infants/neonates. This SMQ contains all terms related to conditions of the neonate. Since the term describes a specific clinical condition, it will be included in the narrow search terms.

CR Number: 2018325050 **Implementation Date:** 10-Dec-18 Related CR: 2018325050

Change Requested	Change term status in a SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*High-pitched crying*	Approved as Requested	Proposed PT	
To SMQ	*Depression (excl suicide and self injury) (SMQ)*		*High-pitched crying*	10052286
Status	*I*		To SMQ	
			Depression (excl suicide and self injury) (SMQ)	20000167
			Status	
			I	

MSSO Comment: The proposal to change status of the term High-pitched crying in Depression (excl suicide and self injury) (SMQ) to Inactive is approved as requested. LLT High-pitched crying was promoted to a PT in v22.0. It was previously subordinate to PT Crying and was included in the broad search terms of SMQ Depression (excl suicide and self injury). Since high-pitched crying most often applies to vaccination and is specific to infants/neonates, it will be made inactive in the SMQ Depression (excl suicide and self injury).

Supplemental Update Report

CR Number: 2018325051 **Implementation Date:** 10-Dec-18 Related CR: 2018325051

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hypokinetic dysarthria*	Approved as Requested	Proposed PT *Hypokinetic dysarthria*	10082243
To SMQ	*Parkinson-like events (SMQ)*		To SMQ *Parkinson-like events (SMQ)*	20000099
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Hypokinetic dysarthria to Parkinson-like events (SMQ) as a narrow term is approved as requested. Hypokinetic dysarthria is a speech disorder characteristic of Parkinson's disease and is usually caused by degeneration of the substantia nigra. Since it represents a specific clinical sign, it will included in the narrow search terms of this SMQ.

CR Number: 2018325052 **Implementation Date:** 10-Dec-18 Related CR: 2018325052

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Infant dyschezia*	Approved as Requested	Proposed PT *Infant dyschezia*	10082228
To SMQ	*Gastrointestinal nonspecific dysfunction (SMQ)*		To SMQ *Gastrointestinal nonspecific dysfunction (SMQ)*	20000139
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Infant dyschezia to Gastrointestinal nonspecific dysfunction (SMQ) as a broad term is approved as requested. Defecation requires two coordinated events: Pelvic floor relaxation, and an increase in intra-abdominal pressure. Children with infant dyschezia may lack this coordination so they are unable to enjoy easy defecation. Infant dyschezia can be considered a gastrointestinal non-specific functional condition and, like its adult homolog, should be included in the broad scope of this SMQ.

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CR Number: 2018325053 **Implementation Date:** 10-Dec-18 Related CR: 2018325053

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Nonalcoholic fatty liver disease*	Approved as Requested	Proposed PT *Nonalcoholic fatty liver disease*	10082249
To SMQ	*Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ)*		To SMQ *Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ)*	20000013
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Nonalcoholic fatty liver disease to Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ) as a narrow term is approved as requested. Nonalcoholic encompasses a clinical spectrum of liver pathology with different clinical prognoses, from the simple accumulation of triglyceride within hepatocytes (hepatic steatosis) on the most clinically benign extreme, to frank cirrhosis, with nonalcoholic steatohepatitis (NASH) as an intermediate stage. Nonalcoholic fatty liver disease should be added to the narrow scope of this SMQ.

CR Number: 2018325054 **Implementation Date:** 10-Dec-18 Related CR: 2018325054

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Squamous cell carcinoma of the parotid gland*	Approved as Requested	Proposed PT *Squamous cell carcinoma of the parotid gland*	10082230
To SMQ	*Oropharyngeal neoplasms (SMQ)*		To SMQ *Oropharyngeal neoplasms (SMQ)*	20000110
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Squamous cell carcinoma of the parotid gland to Oropharyngeal neoplasms (SMQ) as a narrow term is approved as requested. Malignant salivary gland neoplasms are part of this SMQ, which is only composed of narrow scope terms.

Supplemental Update Report

CR Number: 2018325055 **Implementation Date:** 10-Dec-18 Related CR: 2018325055

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pharyngeal swelling*	Approved as Requested	Proposed PT *Pharyngeal swelling*	10082270
To SMQ	*Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ)*		To SMQ *Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ)*	20000114
Term scope	*Narrow*		Term scope *Narrow*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Pharyngeal swelling to Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ) as a narrow term is approved as requested. Pharyngeal swelling and pharyngeal oedema are not always synonymously used. Swelling may be due to causes other than edema, such as neoplasms, pharyngeal wall thickening or inflammation. Pharyngeal swelling should be added to this SMQ, which is only composed of narrow scope terms.

CR Number: 2018325056 **Implementation Date:** 10-Dec-18 Related CR: 2018325056

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Automatic positive airway pressure*	Approved as Requested	Proposed PT *Automatic positive airway pressure*	10082223
To SMQ	*Acute central respiratory depression (SMQ)*		To SMQ *Acute central respiratory depression (SMQ)*	20000116
Term scope	*Broad*		Term scope *Broad*	
			Term_category *A*	
			Term_weight *0*	

MSSO Comment: The proposal to add PT Automatic positive airway pressure to Acute central respiratory depression (SMQ) as a broad term is approved as requested. This term fits the inclusion criteria for this SMQ for relevant therapeutic procedures. A similar term PT Continuous positive airway pressure is already included as a broad search term.

Supplemental Update Report

CR Number: 2018326001 **Implementation Date:** 29-Nov-18 Related CR: 2018326001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Infusion site itching*	Approved as Requested	Proposed LLT	
To PT	*Infusion site pruritus*		*Infusion site itching*	10082432 Current
			To PT	
			Infusion site pruritus	10053664

MSSO Comment: The proposal to add a new LLT Infusion site itching to PT Infusion site pruritus is approved as requested. Itching is a frequently used synonym of pruritus. The addition of this term facilitates direct coding of a relatively common verbatim term.

CR Number: 2018327001 **Implementation Date:** 29-Nov-18 Related CR: 2018327001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hypocobalaminemia*	Approved as Requested	Proposed LLT	
To PT	*Vitamin B12 deficiency*		*Hypocobalaminemia*	10082435 Current
			To PT	
			Vitamin B12 deficiency	10047609

MSSO Comment: The proposal to add a new LLT Hypocobalaminemia to PT Vitamin B12 deficiency is approved as requested. Vitamin B12 deficiency, also known as cobalamin deficiency, is the medical condition of low blood levels of vitamin B12. Hypocobalaminemia is a synonym of Vitamin B12 deficiency. In a related change, the British spelled counterpart LLT Hypocobalaminaemia will also be added to PT Vitamin B12 deficiency.

CR Number: 2018332029 **Implementation Date:** 29-Nov-18 Related CR: 2018327001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Hypocobalaminaemia*	Approved as Requested	Proposed LLT	
To PT	*Vitamin B12 deficiency*		*Hypocobalaminaemia*	10082438 Current
			To PT	
			Vitamin B12 deficiency	10047609

MSSO Comment:

Supplemental Update Report

CR Number: 2018327002 **Implementation Date:** 29-Nov-18 Related CR: 2018327002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*CISTERNAL PUNCTURE*	Approved Not as Requested	Proposed PT	
To PT	*CSF Test*		*Cisternal puncture*	10082433
			HLT primary	
			Neurologic diagnostic procedures	10029285
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new LLT CISTERNAL PUNCTURE to PT CSF Test is approved but not as requested. A suboccipital puncture or cisternal puncture is a diagnostic procedure that can be performed in order to collect a sample of cerebrospinal fluid (CSF) for biochemical, microbiological, and cytological analysis, or rarely to relieve increased intracranial pressure. The requested term will be modified in accordance with MedDRA capitalisation conventions and added as PT Cisternal puncture to HLT Neurologic diagnostic procedures.

CR Number: 2018327003 **Implementation Date:** 29-Nov-18 Related CR: 2018327003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*EDENTIA*	Approved Not as Requested	Proposed LLT	
To PT	*Anodontia*		*Edentia*	10082434 Current
			To PT	
			Anodontia	10002583

MSSO Comment: The proposal to add a new LLT EDENTIA to PT Anodontia is approved but not as requested. The requested term will be modified in accordance with MedDRA capitalisation conventions to Edentia, the absence of the teeth, and added as synonym LLT to PT Anodontia.

CR Number: 2018327004 **Implementation Date:** 29-Nov-18 Related CR: 2018327004

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*MUSCLE MASS*	Rejected		
Status	*non-current*			

MSSO Comment: The proposal to change status of LLT MUSCLE MASS to non-current is not approved. Please see in the MedDRA Introductory Guide how "mass" concepts are used for MedDRA purposes; i.e. not as a weight but rather as a large body of matter with no definite shape. Mass (non-neoplastic): for MedDRA terms the word “mass” is not considered neoplastic. Terms with “mass” are linked primarily to the SOC that represents the site of manifestation. ”Mass” terms which have no inherent anatomic site (e.g., PT Mass) are linked as primary to SOC General disorders and administration site conditions. However, the MSSO will add PT Muscle mass percentage to HLT Musculoskeletal and soft tissue tests NEC. Muscle mass percentage is the percentage of muscle in the body as compared to the total body weight.

Supplemental Update Report

CR Number: **2018327005** **Implementation Date:** 29-Nov-18 Related CR: 2018327005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*DOUBLE INCONTINENCE,*	Rejected		
HLT primary	*Autonomic nervous system disorders*			
SOC primary	*Nervous system disorders*			

MSSO Comment: The proposal to add a new PT DOUBLE INCONTINENCE, to primary HLT Autonomic nervous system disorders in SOC Nervous system disorders is not approved. Double incontinence, the concomitant presence of urinary and fecal incontinence, can be represented by the combination of existing two single medical concepts, i.e. PT Urinary incontinence and PT Anal incontinence

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CR Number: **2018327006** **Implementation Date:** 29-Nov-18 Related CR: 2018327006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Levator dehiscence*	Approved as Requested	Proposed LLT	
To PT	*Eyelid Ptosis*		*Levator dehiscence*	10082436 Current
			To PT	
			Eyelid Ptosis	10015995

MSSO Comment: The proposal to add a new LLT Levator dehiscence to PT Eyelid Ptosis is approved as requested. Aponeurotic Ptosis is the most common type of acquired ptosis, it´s also called senile or involutional ptosis because it occurs most often in the elderly as an involutional disorder. This entity was fist described by Jones Quickert, and Wobig in 1975 who demonstrated that the levator aponeurosis appeared dehisced or disinserted from the tarsus. LLT Levator dehiscence can be considered a synonym of LLT Aponeurotic ptosis.

CR Number: **2018327007** **Implementation Date:** 29-Nov-18 Related CR: 2018327007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*EPIKERATOPHAKIA*	Approved Not as Requested	Proposed LLT	
HLT primary	*Corneal and scleral therapeutic procedures*		*Epikeratophakia*	10082437 Current
SOC primary	*Surgical and medical procedures*		To PT	
			Corneal transplant	10054846

MSSO Comment: The proposal to add a new PT EPIKERATOPHAKIA to primary HLT Corneal and scleral therapeutic procedures in SOC Surgical and medical procedures is approved but not as requested. Epikeratophakia is the surgical correction of aphakia. It is a refractive surgical procedure in which a donor cornea is transplanted to the anterior surface of the patient's Cornea. Epikeratophakia, with corrected spelling in accordance with MedDRA capitalisation conventions, will be added as sub-concept LLT to PT Corneal transplant.

Supplemental Update Report

CR Number: 2018327008 **Implementation Date:** 29-Nov-18 Related CR: 2018327008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Stretta*	Rejected		
To PT	*Gastrointestinal endoscopic therapy*			

MSSO Comment: The proposal to add a new LLT Stretta to PT Gastrointestinal endoscopic therapy is not approved. Stretta is a trade name for a minimally invasive endoscopic procedure for the treatment gastroesophageal reflux disease. Stretta delivers radiofrequency energy in the form of electromagnetic waves through electrodes at the end of a catheter to the lower esophageal sphincter and the gastric cardia. The requested procedure is represented by PT/LLT Radiofrequency ablation of oesophagus.

CR Number: 2018327009 **Implementation Date:** 30-Nov-18 Related CR: 2018327009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Prothrombin fragment 1.2*	Approved as Requested	Proposed PT	
			Prothrombin fragment 1.2	10082446
			HLT primary	
			Coagulation and bleeding analyses	10009728
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new term Prothrombin fragment 1.2 is approved as requested. This fragment is produced when the patient's coagulation system is activated and it is useful for diagnosing hypercoagulable state and as a marker for disseminated intravascular activation. Prothrombin fragment 1.2 will be added as a PT to HLT Coagulation and bleeding analyses.

CR Number: 2018327010 **Implementation Date:** 30-Nov-18 Related CR: 2018327010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Increased liver stiffness*	Approved as Requested	Proposed PT	
			Increased liver stiffness	10082444
			HLT primary	
			Hepatobiliary signs and symptoms	10019709
			SOC primary	
			Hepatobiliary disorders	10019805

MSSO Comment: The proposal to add a new term Increased liver stiffness is approved as requested. The noninvasive quantitation of liver stiffness by ultrasound based transient elastography, and other recent techniques such as acoustic radiation impulse frequency imaging or magnetic resonance elastography, have turned liver stiffness into a novel objective physical parameter that can be easily followed up. Liver stiffness is not only determined by the degree of fibrosis but also other clinical settings such as inflammation, cholestasis and liver congestion, and consequently Increased liver stiffness will be added as a PT under HLT Hepatobiliary signs and symptoms.

Supplemental Update Report

CR Number: 2018327011 **Implementation Date:** 30-Nov-18 Related CR: 2018327011

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*MRI-PDFF*	Approved as Requested	Proposed LLT *MRI-PDFF*	10082447 Current
			To PT *Magnetic resonance proton density fat fraction measurement*	10082443

MSSO Comment: The proposal to add a new term MRI-PDFF is approved as requested. Proton density fat fraction (PDFF) calculation is a recently described technique based on the use of magnetic resonance images, that offers a promising and readily available method that allows for the simple calculation of fat fraction in any segment of the liver. MRI-PDFF represents an internationally accepted acronym representation of this technique, and will be added as an LLT under the new PT Magnetic resonance proton density fat fraction measurement, which represents the spelled out expression of this procedure. In a related change, PT Magnetic resonance proton density fat fraction measurement will be added under HLT Hepatobiliary imaging procedures.

CR Number: 2018334057 **Implementation Date:** 30-Nov-18 Related CR: 2018327011

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Magnetic resonance proton density fat fraction measurement*	Approved as Requested	Proposed PT *Magnetic resonance proton density fat fraction measurement*	10082443
HLT primary	*Hepatobiliary imaging procedures*		HLT primary *Hepatobiliary imaging procedures*	10019808
SOC primary	*Investigations*		SOC primary *Investigations*	10022891

MSSO Comment:

Supplemental Update Report

CR Number: 2018327012 **Implementation Date:** 30-Nov-18 Related CR: 2018327012

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Placenta growth factor*	Approved as Requested	Proposed PT	
			Placenta growth factor	10082445
			HLT primary	
			Cell marker analyses	10072981
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new term Placenta growth factor is approved as requested. Placental growth factor is a protein-coding gene and a member of the vascular endothelial growth factor (VEGF) family. PGF is ultimately associated with angiogenesis. The main source of PGF during pregnancy is the placental trophoblast. Studies show that maternal serum levels of placental growth factor are lower in women presenting with preeclampsia. Placenta growth factor will be added as a PT to HLT Cell marker analyses.

CR Number: 2018329009 **Implementation Date:** 04-Dec-18 Related CR: 2018329009

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Antibiotic associated colitis*	Approved After Suspension	Proposed LLT	
From PT	*Clostridium difficile colitis*		*Antibiotic associated colitis*	10052815
HLT primary	*Bacterial infections NEC*		From PT	
			Clostridium difficile colitis	10009657
			HLT primary	
			Bacterial infections NEC	10004047
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Intestinal infections	10022678
			SOC secondary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to promote the LLT Antibiotic associated colitis from PT Clostridium difficile colitis to primary HLT Bacterial infections NEC in SOC Infections and infestations and secondary HLT Intestinal infections in SOC Gastrointestinal disorders is approved as requested after suspension. Clostridium difficile is known to account for only for 10 to 25 percent of antibiotic-associated colitis cases. Other pathogens include Clostridium perfringens, Staphylococcus aureus, Klebsiella oxytoca, Candida and Salmonella species. Non-infectious causes include reduced breakdown of primary bile acids, decreased metabolism of carbohydrates, allergic or toxic effects of antibiotics on intestinal mucosa and pharmacological effects on gut motility.

Supplemental Update Report

CR Number: **2018329010** **Implementation Date:** 04-Dec-18 Related CR: 2018329010

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Clostridium difficile colitis*	Rejected After Suspension		
To PT	*Antibiotic associated colitis*			

MSSO Comment: The proposal to demote the PT Clostridium difficile colitis under PT Antibiotic associated colitis is not approved after suspension. Clostridium difficile is the pathogen that is most frequently found in relation to antibiotic associated colitis and warrants representation at the PT level.

CR Number: **2018329011** **Implementation Date:** 04-Dec-18 Related CR: 2018329011

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Klebsiella oxytoca colitis*	Rejected After Suspension		
To PT	*Antibiotic associated colitis*			

MSSO Comment: The proposal to add a new LLT Klebsiella oxytoca colitis to PT Antibiotic associated colitis is not approved after suspension. The concept can be represented by the newly promoted PT Antibiotic associated colitis and the existing LLT Klebsiella oxytoca infection. It is not practical to represent every combination of colitis and the causative organism.

CR Number: **2018330001** **Implementation Date:** 30-Nov-18 Related CR: 2018330001

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Growth abnormal*	Rejected		

MSSO Comment: The proposal to add a new LLT Growth abnormal is not approved. The requested term can be represented by existing PT Growth disorder.

Supplemental Update Report

CR Number: **2018330002** **Implementation Date:** 30-Nov-18 Related CR: 2018330002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ulcerative colitis relapse*	Approved Not as Requested	Proposed LLT	
To PT	*Ulcerative colitis*		*Ulcerative colitis relapse*	10082448 Current
			To PT	
			Colitis ulcerative	10009900

MSSO Comment: The proposal to add a new LLT Ulcerative colitis relapse to PT Ulcerative colitis is approved but not as requested. Ulcerative colitis is a chronic idiopathic inflammatory disease of the large intestine that is characterized by periods of remission and relapse. The requested Ulcerative colitis relapse will be added to the PT Colitis ulcerative.

CR Number: **2018330003** **Implementation Date:** 03-Dec-18 Related CR: 2018330003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Device inappropriate antitachycardia pacing*	Approved Not as Requested	Proposed LLT	
HLT primary	*Device malfunction events NEC*		*Device inappropriate antitachycardia pacing*	10082474 Current
SOC primary	*Product issues*		To PT	
			Device pacing issue	10069864

MSSO Comment: The proposal to add a new PT Device inappropriate antitachycardia pacing to primary HLT Device malfunction events NEC in SOC Product issues is approved but not as requested. Patients with an implantable cardioverter defibrillator (ICD) can undergo inappropriate therapies (shock or antitachycardia pacing) if electrical activity not originating in the ventricle is wrongly recognized as ventricular by the device. Device inappropriate antitachycardia pacing will be added as sub-concept LLT to PT Device pacing issue.

CR Number: **2018330004** **Implementation Date:** 03-Dec-18 Related CR: 2018330004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Noise oversensing*	Approved as Requested	Proposed LLT	
To PT	*Oversensing*		*Noise oversensing*	10082475 Current
			To PT	
			Oversensing	10063834

MSSO Comment: The proposal to add a new LLT Noise oversensing to PT Oversensing is approved as requested. Sensing of electrical signals may be impaired by detection of noise.

Supplemental Update Report

CR Number: 2018330005 **Implementation Date:** 03-Dec-18 Related CR: 2018330005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Device ineffective shock delivery*	Approved as Requested	Proposed PT	
HLT primary	*Device malfunction events NEC*		*Device ineffective shock delivery*	10082473
SOC primary	*Product issues*		HLT primary	
			Device malfunction events NEC	10069795
			SOC primary	
			Product issues	10077536
			HLT secondary	
			Therapeutic and nontherapeutic responses	10043409
			SOC secondary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Device ineffective shock delivery to primary HLT Device malfunction events NEC in SOC Product issues is approved as requested. The intention of delivered ICD (Implantable cardioverter defibrillator) shocks is to terminate a detected ongoing tachycardia. If the shock failed to restore sinus rhythm, the shock was ineffective. Device ineffective shock delivery will will also be secondarily linked HLT Therapeutic and nontherapeutic responses.

CR Number: 2018330006 **Implementation Date:** 30-Nov-18 Related CR: 2018330006

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neisseria test*	Approved as Requested	Proposed PT	
HLT primary	*Bacteria identification and serology (excl mycobacteria)*		*Neisseria test*	10082453
SOC primary	*Investigations*		HLT primary	
			Bacteria identification and serology (excl mycobacteria)	10004000
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Neisseria test to primary HLT Bacteria identification and serology (excl mycobacteria) in SOC Investigations is approved as requested. Neisseria is a genus of bacteria that colonize the mucosal surfaces of many animals. Since investigations without qualifiers are intended to be used to record test names when entering diagnostic test data in the E2B data elements for Results of Tests and Procedures, the unqualified term Neisseria test will be added to complement existing PT Neisseria test positive.

Supplemental Update Report

CR Number: 2018330007 **Implementation Date:** 30-Nov-18 Related CR: 2018330007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Multivisceral transplantation*	Approved as Requested	Proposed PT	
HLT primary	*Gastrointestinal therapeutic procedures NEC*		*Multivisceral transplantation*	10082450
SOC primary	*Surgical and medical procedures*		HLT primary	
			Gastrointestinal therapeutic procedures NEC	10018013
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT Multivisceral transplantation to primary HLT Gastrointestinal therapeutic procedures NEC in SOC Surgical and medical procedures is approved as requested. In a multivisceral transplantation, the stomach, duodenum, pancreas, colon, liver, and spleen may be included during a single transplantation procedure. Multivisceral transplants are considered when the underlying condition significantly compromises other sections of the digestive system, such as intra-abdominal tumors that have not yet metastasized, extensive venous thrombosis or arterial ischemia of the mesentery, and motility syndromes. In a related change, PT Liver and small intestine transplant will be merged under the new PT Multivisceral transplantation.

CR Number: 2018334061 **Implementation Date:** 30-Nov-18 Related CR: 2018330007

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #	
PT to merge	*Liver and small intestine transplant*	Approved as Requested	PT to merge		
To PT	*Multivisceral transplantation*		*Liver and small intestine transplant*	10052280	Current
			To PT		
			Multivisceral transplantation	10082450	

MSSO Comment:

CR Number: 2018330008 **Implementation Date:** 30-Nov-18 Related CR: 2018330008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #	
Proposed LLT	*Infantile nephrotic syndrome*	Approved as Requested	Proposed LLT		
To PT	*Congenital nephrotic syndrome*		*Infantile nephrotic syndrome*	10082454	Current
			To PT		
			Congenital nephrotic syndrome	10060737	

MSSO Comment: The proposal to add a new LLT Infantile nephrotic syndrome to PT Congenital nephrotic syndrome is approved as requested. Congenital nephrotic syndrome is a rare kidney disorder characterized by heavy proteinuria, hypoproteinemia, and edema starting soon after birth. The majority of cases are caused by genetic defects in the components of the glomerular filtration barrier. Congenital nephrotic syndrome is defined as heavy proteinuria starting within three months after birth; nephrotic syndrome appears later during the first year (4–12 months) and is termed infantile nephrotic syndrome; nephrotic syndrome manifesting thereafter is called childhood nephrotic syndrome. Because recent studies have determined that a majority of cases of nephrotic syndrome manifesting in the first year of life can be explained by mutations in 4 genes (NPHS1, NPHS2, WT1, or LAMB2), it is appropriate to place Infantile nephrotic syndrome as a sub-concept LLT of PT Congenital nephrotic syndrome.

Supplemental Update Report

CR Number: 2018330009 **Implementation Date:** 30-Nov-18 Related CR: 2018330009

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Gram-negative sepsis*	Approved Not as Requested	Proposed LLT	
HLT primary	*Sepsis, bacteraemia, viraemia and fungaemia NEC*		*Gram-negative sepsis*	10082456 Current
			To PT	
SOC primary	*Infections and infestations*		*Bacterial sepsis*	10053840

MSSO Comment: The proposal to add a new PT Gram-negative sepsis to primary HLT Sepsis, bacteraemia, viraemia and fungaemia NEC in SOC Infections and infestations is approved but not as requested. Gram-negative sepsis, resulting from gram-negative bacterial infection, is recognized as an increasingly common problem, with up to 300,000 cases occurring each year in the United States alone. Despite the ongoing development of new antibiotics, mortality from gram-negative sepsis remains unacceptably high. Rather than placing Gram-negative sepsis as a new PT, Gram-negative sepsis will be added as a sub-concept LLT to PT Bacterial sepsis.

CR Number: 2018330010 **Implementation Date:** 30-Nov-18 Related CR: 2018330010

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Immune-mediated colitis*	Approved as Requested	Proposed LLT	
			Immune-mediated colitis	10082455 Current
			To PT	
			Immune-mediated enterocolitis	10078961

MSSO Comment: The proposal to add a new term Immune-mediated colitis is approved as requested. Immune-mediated gastrointestinal toxicity in the form of diarrhea and colitis is one of the most common and potentially serious events caused by immunotherapy. Immune-mediated colitis will be added as an LLT to PT Immune-mediated enterocolitis. In a related change, LLT Immune-mediated enterocolitis will be promoted from PT Autoimmune colitis and will be linked to primary HLT Colitis (excl infective) and secondary HLT Immune and associated conditions NEC. Furthermore, LLT Immune-mediated enteritis will be moved from PT Autoimmune enteropathy to the newly promoted PT Immune-mediated enterocolitis.

Supplemental Update Report

CR Number: 2018334062 **Implementation Date:** 30-Nov-18 Related CR: 2018330010

Change Requested	Promote an LLT
Proposed LLT	*Immune-mediated enterocolitis*
From PT	*Autoimmune colitis*
HLT primary	*Colitis (excl infective)*

Final Disposition: Approved as Requested

Final Placement	MedDRA Code #
Proposed LLT	
Immune-mediated enterocolitis	10078961
From PT	
Autoimmune colitis	10075761
HLT primary	
Colitis (excl infective)	10009888
SOC primary	
Gastrointestinal disorders	10017947
HLT secondary	
Immune and associated conditions NEC	10027682
SOC secondary	
Immune system disorders	10021428

MSSO Comment:

CR Number: 2018334063 **Implementation Date:** 30-Nov-18 Related CR: 2018330010

Change Requested	Link (move) an LLT to another PT
Proposed LLT	*Immune-mediated enteritis*
From PT	*Autoimmune enteropathy*
To PT	*Immune-mediated enterocolitis*

Final Disposition: Approved as Requested

Final Placement	MedDRA Code #
Proposed LLT	
Immune-mediated enteritis	10081464 Current
From PT	
Autoimmune enteropathy	10081456
To PT	
Immune-mediated enterocolitis	10078961

MSSO Comment:

Supplemental Update Report

CR Number: 2018330011 **Implementation Date:** 30-Nov-18 Related CR: 2018330011

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Immune-mediated pneumonitis*	Approved as Requested	Proposed PT	
			Immune-mediated pneumonitis	10082452
			HLT primary	
			Lower respiratory tract inflammatory and immunologic conditions	10024972
			SOC primary	
			Respiratory, thoracic and mediastinal disorders	10038738
			HLT secondary	
			Immune and associated conditions NEC	10027682
			SOC secondary	
			Immune system disorders	10021428

MSSO Comment: The proposal to add a new term Immune-mediated pneumonitis is approved as requested. Immune-mediated pneumonitis, a noninfectious inflammation of the lungs, may develop as a side effect of targeted cancer immunotherapies. Precision cancer immunotherapies using immune-checkpoint inhibitors and molecular targeting agents such as immunotherapies such as CTLA4 or PD-1/PD-L1 inhibitors for melanoma or lung cancers, can cause immune-mediated pneumonitis, although the exact mechanism is unknown. Immune-mediated pneumonitis will be added as a new PT to primary HLT Lower respiratory tract inflammatory and immunologic conditions, and to secondary HLT Immune and associated conditions NEC.

CR Number: 2018330012 **Implementation Date:** 30-Nov-18 Related CR: 2018330012

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*External vagal nerve stimulation*	Approved as Requested	Proposed PT	
HLT primary	*Autonomic nerve therapeutic procedures*		*External vagal nerve stimulation*	10082451
SOC primary	*Surgical and medical procedures*		HLT primary	
			Autonomic nerve therapeutic procedures	10003838
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT External vagal nerve stimulation to primary HLT Autonomic nerve therapeutic procedures in SOC Surgical and medical procedures is approved as requested. Vagus nerve stimulation refers to any technique that stimulates the vagus nerve, including manual or electrical stimulation. External vagal nerve stimulation, a noninvasive therapeutic approach to the management of cluster headaches, has recently been introduced, which employs a small handheld device that applies a mild transcutaneous electrical stimulation on the neck. External vagal nerve stimulation will be added as a new PT to HLT Autonomic nerve therapeutic procedures.

Supplemental Update Report

CR Number: 2018330013 **Implementation Date:** 30-Nov-18 Related CR: 2018330013

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ocular postoperative inflammation*	Rejected		
To PT	*Ocular procedural complication*			

MSSO Comment: The proposal to add a new LLT Ocular postoperative inflammation to PT Ocular procedural complication is not approved. Postoperative ocular inflammation is relatively common following ocular procedures, such as cataract surgery, vitrectomy, retinal detachment surgery, trabeculectomy, etc., for which a variety of therapeutic agents and modes of administration are available. The proposed term, Ocular postoperative inflammation, can be represented by split coding with existing terms, such as LLT Post procedural inflammation and LLT Eye inflammation or an alternate appropriate LLT under PT Eye inflammation.

CR Number: 2018330014 **Implementation Date:** 29-Nov-18 Related CR: 2018330014

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Vesicouretral reflux with reflux nephropathy, unilateral*	Approved as Requested	Term to modify *Vesicouretral reflux with reflux nephropathy, unilateral*	
Replacement term	*Vesicoureteral reflux with reflux nephropathy, unilateral*		Replacement term *Vesicoureteral reflux with reflux nephropathy, unilateral*	10047375 Current

MSSO Comment: The proposal to rename PT/LLT Vesicouretral reflux with reflux nephropathy, unilateral to Vesicoureteral reflux with reflux nephropathy, unilateral is approved as requested to correct the misspelling of "Vesicouretral".

CR Number: 2018330015 **Implementation Date:** 29-Nov-18 Related CR: 2018330015

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Vesicouretral reflux with reflux nephropathy, bilateral*	Approved as Requested	Term to modify *Vesicouretral reflux with reflux nephropathy, bilateral*	
Replacement term	*Vesicoureteral reflux with reflux nephropathy, bilateral*		Replacement term *Vesicoureteral reflux with reflux nephropathy, bilateral*	10047374 Current

MSSO Comment: The proposal to rename PT/LLT Vesicouretral reflux with reflux nephropathy, bilateral to Vesicoureteral reflux with reflux nephropathy, bilateral is approved as requested to correct the misspelling of "Vesicouretral".

Supplemental Update Report

CR Number: 2018330016 **Implementation Date:** 29-Nov-18 Related CR: 2018330016

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #	
Term to modify	*Vesicouretral reflux with reflux nephropathy NOS*	Approved as Requested	Term to modify *Vesicouretral reflux with reflux nephropathy NOS*		
Replacement term	*Vesicoureteral reflux with reflux nephropathy NOS*		Replacement term *Vesicoureteral reflux with reflux nephropathy NOS*	10047373	Non-Current

MSSO Comment: The proposal to rename PT/LLT Vesicouretral reflux with reflux nephropathy NOS to Vesicoureteral reflux with reflux nephropathy NOS is approved as requested to correct the misspelling of "Vesicouretral".

CR Number: 2018330017 **Implementation Date:** 29-Nov-18 Related CR: 2018330017

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #	
Term to modify	*Vesicouretral reflux unspecified or without reflux nephropathy*	Approved as Requested	Term to modify *Vesicouretral reflux unspecified or without reflux nephropathy*		
Replacement term	*Vesicoureteral reflux unspecified or without reflux nephropathy*		Replacement term *Vesicoureteral reflux unspecified or without reflux nephropathy*	10047372	Non-Current

MSSO Comment: The proposal to rename PT/LLT Vesicouretral reflux unspecified or without reflux nephropathy to Vesicoureteral reflux unspecified or without reflux nephropathy is approved as requested to correct the misspelling of "Vesicouretral".

CR Number: 2018330018 **Implementation Date:** 03-Dec-18 Related CR: 2018330018

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Anion gap acidosis*	Rejected		
Status	*non-current*			

MSSO Comment: The proposal to change status of LLT Anion gap acidosis to non-current is not approved. Metabolic acidoses are categorized as high or normal anion gap based on the presence or absence of unmeasured anions in serum. However, the imprecise term "Anion gap acidosis" is in MedDRA since version 2.1 and changing the status to non-current would impact legacy data.

Supplemental Update Report

CR Number: 2018330019 **Implementation Date:** 03-Dec-18 Related CR: 2018330019

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Normal anion gap metabolic acidosis*	Approved as Requested	Proposed LLT	
To PT	*Metabolic acidosis*		*Normal anion gap metabolic acidosis*	10082472 Current
			To PT	
			Metabolic acidosis	10027417

MSSO Comment: The proposal to add a new LLT Normal anion gap metabolic acidosis to PT Metabolic acidosis is approved as requested. Metabolic acidoses are categorized as high or normal anion gap based on the presence or absence of unmeasured anions in serum.

CR Number: 2018330020 **Implementation Date:** 30-Nov-18 Related CR: 2018330020

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Type 3 RTA*	Approved Not as Requested	Proposed LLT	
To PT	*Renal tubular acidosis*		*Type 3 (combined proximal and distal) RTA*	10082439 Current
			To PT	
			Renal tubular acidosis	10038535

MSSO Comment: The proposal to add a new LLT Type 3 RTA to PT Renal tubular acidosis is approved but not as requested. RTA - Renal tubular acidosis (RTA) is a group of transport defects in the reabsorption of bicarbonate, the excretion of hydrogen ion (H(+)), or both, resulting in systemic acidosis and hypokalemia with a normal glomerular filtration rate. Although isolated proximal (type 2) or distal (type 1) tubular pathologies are well characterized, a combined pathology leading to type 3 RTA is very rare. The requested term Type 3 RTA will be modified in consistency with other existing types of renal tubular acidosis and added as Type 3 (combined proximal and distal) RTA to PT Renal tubular acidosis.

Supplemental Update Report

CR Number: 2018330021 **Implementation Date:** 30-Nov-18 Related CR: 2018330021

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ocular Surface Squamous Neoplasia*	Approved Not as Requested	Proposed PT	
			Ocular surface squamous neoplasia	10082449
			HLT primary	
			Ocular neoplasms malignancy unspecified	10030053
			SOC primary	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104
			HLT secondary	
			Ocular neoplasms malignancy unspecified	10030053
			SOC secondary	
			Eye disorders	10015919

MSSO Comment: The proposal to add a new LLT Ocular Surface Squamous Neoplasia is approved but not as requested. Ocular surface squamous neoplasia (OSSN) is a broad term encompassing conjunctival, limbal and corneal intraepithelial neoplastic lesions (CIN) and invasive squamous cell carcinoma (SCC) of conjunctiva and cornea. CIN includes varying grades of dysplasia, ranging from mild, moderate, severe dysplasia to carcinoma in situ. Ocular surface squamous neoplasia, corrected in accordance with MedDRA capitalisation conventions, will be added as PT to bi-axial HLT Ocular neoplasms malignancy unspecified (primary SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps), secondary SOC Eye disorders. In a related change, PT Corneoconjunctival intraepithelial neoplasia will be demoted under the new PT Ocular surface squamous neoplasia as sub-concept LLT.

CR Number: 2018334060 **Implementation Date:** 30-Nov-18 Related CR: 2018330021

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Corneoconjunctival intraepithelial neoplasia*	Approved as Requested	PT to merge	
To PT	*Ocular surface squamous neoplasia*		*Corneoconjunctival intraepithelial neoplasia*	10071076 Current
			To PT	
			Ocular surface squamous neoplasia	10082449

MSSO Comment:

Supplemental Update Report

CR Number: 2018331001 **Implementation Date:** 06-Dec-18 Related CR: 2018331001

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Guthrie test*	Approved After Suspension	Proposed LLT	
From PT	*Phenylalanine screen*		*Guthrie test*	10060181
HLT primary	*Foetal and neonatal diagnostic procedures*		From PT	
			Phenylalanine screen	10060127
			HLT primary	
			Foetal and neonatal diagnostic procedures	10053100
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to promote the LLT Guthrie test from PT Phenylalanine screen to primary HLT Foetal and neonatal diagnostic procedures in SOC Investigations is approved as requested after suspension. Guthrie test or "Heel Prick" test is routinely carried out on neonatal (newborn 48-72 hours of age) blood for a variety of known genetic metabolic disorders (e.g. galactosemia, maple syrup urine disease or homocystinuria)and not limited to phenylketonuria. In a related changes, the following LLTs will be promoted to PT level as well and linked to HLT Foetal and neonatal diagnostic procedures: LLT Guthrie test negative from under PT Phenylalanine screen negative; LLT Guthrie test positive from under PT Phenylalanine screen positive. Furthermore, LLT Urine ferric chloride test positive from under PT Phenylalanine screen positive and linked to HLT Foetal and neonatal diagnostic procedures. The ferric chloride test is used to detect metabolites in urine in several inborn error of metabolism, such as, but not limited to phenylketonuria.

CR Number: 2018340037 **Implementation Date:** 06-Dec-18 Related CR: 2018331001

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Guthrie test negative*	Approved as Requested	Proposed LLT	
From PT	*Phenylalanine screen negative*		*Guthrie test negative*	10060183
HLT primary	*Foetal and neonatal diagnostic procedures*		From PT	
			Phenylalanine screen negative	10060151
			HLT primary	
			Foetal and neonatal diagnostic procedures	10053100
			SOC primary	
			Investigations	10022891

MSSO Comment:

Supplemental Update Report

CR Number: 2018340038 **Implementation Date:** 06-Dec-18 Related CR: 2018331001

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Guthrie test positive*	Approved as Requested	Proposed LLT	
From PT	*Phenylalanine screen positive*		*Guthrie test positive*	10060182
HLT primary	*Foetal and neonatal diagnostic procedures*		From PT	
			Phenylalanine screen positive	10060150
			HLT primary	
			Foetal and neonatal diagnostic procedures	10053100
			SOC primary	
			Investigations	10022891

MSSO Comment:

CR Number: 2018340039 **Implementation Date:** 06-Dec-18 Related CR: 2018331001

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Urine ferric chloride test positive*	Approved as Requested	Proposed LLT	
From PT	*Phenylalanine screen positive*		*Urine ferric chloride test positive*	10064439
HLT primary	*Foetal and neonatal diagnostic procedures*		From PT	
			Phenylalanine screen positive	10060150
			HLT primary	
			Foetal and neonatal diagnostic procedures	10053100
			SOC primary	
			Investigations	10022891

MSSO Comment:

Supplemental Update Report

CR Number: 2018331002 **Implementation Date:** 30-Nov-18 Related CR: 2018331002

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Polymyxin antibiotic resistance*	Approved as Requested	Proposed LLT *Polymyxin antibiotic resistance* To PT *Pathogen resistance*	10082440 Current 10034133

MSSO Comment: The proposal to add a new LLT Polymyxin antibiotic resistance is approved as requested. Multidrug resistance in pathogens is an increasingly significant threat for human health. Indeed, some strains are resistant to almost all currently available antibiotics, leaving very limited choices for antimicrobial clinical therapy. In many such cases, polymyxins are the last option available, although their use increases the risk of developing resistant strains. Resistance to the current polymyxins could become a big global health challenge, because this means that virtually no antibiotics will be available for treatment of serious infections caused by polymyxin-resistant “superbugs". Polymyxin antibiotic resistance will be added as an LLT to PT Pathogen resistance.

CR Number: 2018331003 **Implementation Date:** 30-Nov-18 Related CR: 2018331003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Skin test positive delayed / Skin test positive prolonged*	Approved Not as Requested	Proposed LLT *Skin test positive delayed* To PT *Skin test positive*	10082441 Current 10040934
HLT primary	*Immunology skin tests NEC*			
SOC primary	*Investigations*			

MSSO Comment: The proposal to add a new PT Skin test positive delayed / Skin test positive prolonged to primary HLT Immunology skin tests NEC in SOC Investigations is approved but not as requested. Skin test positive delayed represents a positive reaction towards an allergen that occurs after the time period positive test results are normally expected to occur. Skin test positive delayed will be added as a sub-element LLT of PT Skin test positive. A delayed positive skin test and prolonged positive skin test are distinct concepts, and warrant representation by separate terms, therefore, in a related change, the related term Skin test positive prolonged will also be added as LLT to PT Skin test positive to represent a positive skin test reaction that occurs within the expected time frame for allergic reactions, but which persists for a longer than expected in time, up to months in some cases.

CR Number: 2018334056 **Implementation Date:** 30-Nov-18 Related CR: 2018331003

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Skin test positive prolonged*	Approved as Requested	Proposed LLT *Skin test positive prolonged* To PT *Skin test positive*	10082442 Current 10040934
To PT	*Skin test positive*			

MSSO Comment:

Supplemental Update Report

CR Number: 2018331004 **Implementation Date:** 03-Dec-18 Related CR: 2018331004

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Drug exposure before pregnancy*	Approved as Requested	Proposed LLT	
From PT	*Maternal exposure before pregnancy*		*Drug exposure before pregnancy*	10064998
HLT primary	*Exposures associated with pregnancy, delivery and lactation*		From PT	
			Maternal exposure before pregnancy	10071406
			HLT primary	
			Exposures associated with pregnancy, delivery and lactation	10071949
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Exposures associated with pregnancy, delivery and lactation	10071949
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to promote the LLT Drug exposure before pregnancy from PT Maternal exposure before pregnancy to primary HLT Exposures associated with pregnancy, delivery and lactation in SOC Injury, poisoning and procedural complications and secondary HLT Exposures associated with pregnancy, delivery and lactation in SOC Pregnancy, puerperium and perinatal conditions is approved as requested. Drug exposure before pregnancy is not limited to maternal exposure and the general term for unknown cases is better represented as PT.

CR Number: 2018331005 **Implementation Date:** 03-Dec-18 Related CR: 2018331005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Oesophageal inflammation*	Approved as Requested	Proposed LLT	
			Oesophageal inflammation	10082467 Current
			To PT	
			Oesophagitis	10030216

MSSO Comment: The proposal to add a new LLT Oesophageal inflammation is approved as requested. Oesophageal inflammation will be added as a synonym LLT to PT Oesophagitis. In a related change, the American English spelling counterpart LLT Esophageal inflammation will also be added to PT Oesophagitis.

Supplemental Update Report

CR Number: 2018334064 **Implementation Date:** 03-Dec-18 Related CR: 2018331005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Esophageal inflammation*	Approved as Requested	Proposed LLT	
To PT	*Oesophagitis*		*Esophageal inflammation*	10082461 Current
			To PT	
			Oesophagitis	10030216

MSSO Comment:

CR Number: 2018331006 **Implementation Date:** 03-Dec-18 Related CR: 2018331006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Blockage of upper airway by food*	Rejected	Proposed LLT	

MSSO Comment: The proposal to add a new LLT Blockage of upper airway by food is not approved. MedDRA cannot accommodate a specific term for every potential combination of more than one concept. The requested new term LLT Blockage of upper airway by food can be represented by split coding with LLT Food aspiration plus LLT Upper airway obstruction.

CR Number: 2018331007 **Implementation Date:** 03-Dec-18 Related CR: 2018331007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Endocardial bleeding*	Approved Not as Requested	Proposed LLT	
			Subendocardial bleeding	10082468 Current
			To PT	
			Subendocardial haemorrhage	10082459

MSSO Comment: The proposal to add a new LLT Endocardial bleeding is approved but not as requested. Subendocardial hemorrhages occur after cardiac injuries and resuscitation as well as secondary to noncardiac injuries comprising head injuries, infectious diseases, intoxications, hemorrhagic diathesis, abdominal trauma, asthma, and hypovolemic shock. The requested term, Endocardial bleeding, will be modified to Subendocardial bleeding to more specifically reflect the concept, and will be added as a synonym LLT to PT Subendocardial haemorrhage. In a related change, PT Subendocardial haemorrhage will be added to primary HLT Endocardial disorders NEC, and to secondary HLT Haemorrhages NEC. Also, the American English spelling counterpart LLT Subendocardial hemorrhage will be added to the new PT Subendocardial haemorrhage.

Supplemental Update Report

CR Number: 2018334065 **Implementation Date:** 03-Dec-18 Related CR: 2018331007

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Subendocardial haemorrhage*	Approved as Requested	Proposed PT	
HLT primary	*Endocardial disorders NEC*		*Subendocardial haemorrhage*	10082459
SOC primary	*Cardiac disorders*		HLT primary	
			Endocardial disorders NEC	10014660
			SOC primary	
			Cardiac disorders	10007541
			HLT secondary	
			Haemorrhages NEC	10018987
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment:

CR Number: 2018334066 **Implementation Date:** 03-Dec-18 Related CR: 2018331007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Subendocardial hemorrhage*	Approved as Requested	Proposed LLT	
To PT	*Subendocardial haemorrhage*		*Subendocardial hemorrhage*	10082462 Current
			To PT	
			Subendocardial haemorrhage	10082459

MSSO Comment:

CR Number: 2018331008 **Implementation Date:** 03-Dec-18 Related CR: 2018331008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Sudden unexpected death in schizophrenia*	Rejected		

MSSO Comment: The proposal to add a new LLT Sudden unexpected death in schizophrenia is not approved. In general, the MSSO no longer adds new terms that combine a death concept with an underlying potentially related medical condition. Please consider representing the requested term, LLT Sudden unexpected death in schizophrenia by split coding with more than one term, such as LLT Sudden death (or if appropriate, LLT Sudden death unexplained) and LLT Schizophrenia.

Supplemental Update Report

CR Number: 2018331009 **Implementation Date:** 03-Dec-18 Related CR: 2018331009

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Multiple drug toxicity*	Approved as Requested	Proposed LLT	
			Multiple drug toxicity	10082465 Current
			To PT	
			Toxicity to various agents	10070863

MSSO Comment: The proposal to add a new LLT Multiple drug toxicity is approved as requested. Multiple drug toxicity will be added as a sub-concept LLT to PT Toxicity to various agents.

CR Number: 2018331010 **Implementation Date:** 03-Dec-18 Related CR: 2018331010

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Barnes Akathisia Scale*	Approved Not as Requested	Proposed PT	
			Barnes akathisia scale	10082457
			HLT primary	
			Neurologic diagnostic procedures	10029285
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new LLT Barnes Akathisia Scale is approved but not as requested. The Barnes Akathisia Scale is a rating scale that is administered by physicians to assess the severity of akathisia, a syndrome of motor restlessness, principally seen in association with antipsychotic medication. This scale is derived from the findings of studies exploring the clinical features of antipsychotic-induced akathisia, and it has been used extensively in clinical studies worldwide. Proposed LLT Barnes Akathisia Scale will be modified to Barnes akathisia scale to conform with MedDRA capitalization conventions, and added as a new PT to HLT Neurologic diagnostic procedures.

CR Number: 2018331011 **Implementation Date:** 03-Dec-18 Related CR: 2018331011

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Delayed cerebral ischaemia*	Approved as Requested	Proposed LLT	
			Delayed cerebral ischaemia	10082463 Current
			To PT	
			Delayed ischaemic neurological deficit	10078388

MSSO Comment: The proposal to add a new LLT Delayed cerebral ischaemia is approved as requested. Delayed cerebral ischaemia (DCI) is defined as the development of new focal neurological signs and/or deterioration in level of consciousness, lasting for more than 1 hour, or the appearance of new infarctions on CT or MRI. Development of DCI starts on day 3 after Subarachnoid haemorrhage, is maximal at 5–14 days and resolves on day 21. LLT Delayed cerebral ischaemia and the American English spelled counterpart LLT Delayed cerebral ischemia will be added as sub-concepts to PT Delayed ischaemic neurological deficit.

Supplemental Update Report

CR Number: 2018334067 **Implementation Date:** 03-Dec-18 Related CR: 2018331011

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Delayed cerebral ischemia*	Approved as Requested	Proposed LLT	
To PT	*Delayed ischaemic neurological deficit*		*Delayed cerebral ischemia*	10082460 Current
			To PT	
			Delayed ischaemic neurological deficit	10078388

MSSO Comment:

CR Number: 2018331012 **Implementation Date:** 03-Dec-18 Related CR: 2018331012

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Suspected suicide (accomplished)*	Approved Not as Requested	Proposed PT	
			Suspected suicide	10082458
			HLT primary	
			Suicidal and self-injurious behaviour	10042459
			SOC primary	
			Psychiatric disorders	10037175
			HLT secondary	
			Death and sudden death	10011907
			SOC secondary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new LLT Suspected suicide (accomplished) is approved but not as requested. Suspected suicide represents death which was likely self-inflicted. The proposed LLT Suspected suicide (accomplished) will be rephrased as Suspected suicide because the concept implicitly represents a fatal outcome. Suspected suicide will be added as a new PT to primary HLT Suicidal and self-injurious behaviour, and to secondary HLT Death and sudden death.

Supplemental Update Report

CR Number: 2018331013 **Implementation Date:** 03-Dec-18 Related CR: 2018331013

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Advanced gastric carcinoma*	Approved as Requested	Proposed LLT	
			Advanced gastric carcinoma	10082464 Current
			To PT	
			Gastric cancer	10017758

MSSO Comment: The proposal to add a new LLT Advanced gastric carcinoma is approved as requested. Advanced gastric carcinoma encompasses both local neoplastic progression exceeding the anatomical limits of the stomach, and/or metastatic disease. Advanced gastric cancers include the American Joint Committee on Cancer (AJCC) stages IIIb and IV. Advanced gastric carcinoma will be added as a sub-concept LLT to PT Gastric cancer.

CR Number: 2018331014 **Implementation Date:** 03-Dec-18 Related CR: 2018331014

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Stuporous catatonia*	Approved as Requested	Proposed LLT	
			Stuporous catatonia	10082466 Current
			To PT	
			Catatonia	10007776

MSSO Comment: The proposal to add a new LLT Stuporous catatonia is approved as requested. Stuporous catatonia is a motionless, apathetic state in which one is oblivious or does not react to external stimuli. Motor activity is nearly non-existent. Individuals in this state make little or no eye contact with others and may be mute and rigid. One might remain in one position for a long period of time, and then go directly to another position immediately after the first position. Stuporous catatonia is a type of catatonia, and will be added as an LLT to PT Catatonia.

CR Number: 2018331015 **Implementation Date:** 03-Dec-18 Related CR: 2018331015

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Excited catatonia*	Approved as Requested	Proposed LLT	
			Excited catatonia	10082469 Current
			To PT	
			Catatonia	10007776

MSSO Comment: The proposal to add a new LLT Excited catatonia is approved as requested. Excited catatonia, or catatonic excitement, is a state of constant purposeless agitation and excitation. Individuals in this state are extremely hyperactive, although, the activity seems to lack purpose. The individual may also experience delusions or hallucinations. It is commonly cited as one of the most dangerous mental states in psychiatry. Excited catatonia is a sub-type of catatonia and will be added as an LLT to PT Catatonia.

Supplemental Update Report

CR Number: 2018331016 **Implementation Date:** 03-Dec-18 Related CR: 2018331016

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Peripheral artery surgery*	Approved as Requested	Proposed PT	
			Peripheral artery surgery	10082470
			HLT primary	
			Arterial therapeutic procedures (excl aortic)	10003167
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new term Peripheral artery surgery is approved as requested. Peripheral artery surgery will be added as PT to HLT Arterial therapeutic procedures (excl aortic) to provide a broad term for any type of surgical procedure on a peripheral artery.

CR Number: 2018331017 **Implementation Date:** 03-Dec-18 Related CR: 2018331017

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Endoscopic biopsy*	Approved as Requested	Proposed LLT	
			Endoscopic biopsy	10082476 Current
			To PT	
			Biopsy	10004720

MSSO Comment: The proposal to add a new term Endoscopic biopsy is approved as requested. Endoscopic biopsy describes the procedure for obtaining tissue specimen under fiberoptic visualization for histopathology investigation. LLT Endoscopic biopsy will be added as a sub-concept LLT under PT Biopsy.

Supplemental Update Report

CR Number: 2018331025 **Implementation Date:** 10-Dec-18 Related CR: 2018331025

Change Requested	Add term to SMQ	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Automatic positive airway pressure*	Approved as Requested	Proposed PT	
			Automatic positive airway pressure	10082223
To SMQ	*Respiratory failure (SMQ)*		To SMQ	
			Respiratory failure (SMQ)	20000222
Term scope	*Broad*		Term scope	
			Broad	
			Term_category	
			A	
			Term_weight	
			0	

MSSO Comment: The proposal to add PT Automatic positive airway pressure to Respiratory failure (SMQ) as a broad term is approved as requested. This term fits the inclusion criteria for this SMQ for relevant therapeutic procedures. A similar term PT Continuous positive airway pressure is already included as a broad search term.

CR Number: 2018332001 **Implementation Date:** 03-Dec-18 Related CR: 2018332001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Hydrocele operation (female)*	Rejected		

MSSO Comment: The proposal to add a new term Hydrocele operation (female) is not approved. Hydrocele of the canal of Nuck is a rare condition in females. It results from the failure of obliteration of the distal portion of evaginated parietal peritoneum within the inguinal canal which forms a sac containing fluid. Patients generally present with inguinal swelling. MedDRA cannot accommodate a separate term for every possible type of surgical excision or operation. Consequently, the requested term Hydrocele operation (female) can be represented by split coding with more than one term, for example LLT Hydrocele of the canal of Nuck and LLT Female genital operation.

CR Number: 2018332002 **Implementation Date:** 03-Dec-18 Related CR: 2018332002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Vibratory angioedema*	Approved as Requested	Proposed LLT	
			Vibratory angioedema	10082471 Current
			To PT	
			Urticaria vibratory	10052571

MSSO Comment: The proposal to add a new term Vibratory angioedema is approved as requested. Vibratory urticaria, also known as vibratory angioedema, is a rare condition that is characterized by itching, erythema and swelling within minutes of local exposure to vibration. Vibratory angioedema will be added as a synonym LLT to PT Urticaria vibratory.

Supplemental Update Report

CR Number: 2018332003 **Implementation Date:** 03-Dec-18 Related CR: 2018332003

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Chronic cerebrospinal venous insufficiency*	Approved as Requested	Proposed PT	
HLT primary	*Central nervous system vascular disorders NEC*		*Chronic cerebrospinal venous insufficiency*	10082477
SOC primary	*Nervous system disorders*		HLT primary	
			Central nervous system vascular disorders NEC	10007962
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Cerebrovascular and spinal vascular disorders NEC	10008193
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new PT Chronic cerebrospinal venous insufficiency to primary HLT Central nervous system vascular disorders NEC in SOC Nervous system disorders is approved as requested. Chronic cerebrospinal venous insufficiency is characterized by impaired brain venous drainage due to outflow obstruction in the extracranial venous system, mostly related to anomalies in the internal jugular and azygos veins. Cerebral blood flow and brain perfusion are retarded and may result in cerebral atrophy, venous microhemorrhage, and cerebral hypertension. Moreover, stasis may evolve into occlusions of these veins or the dural sinuses. PT Chronic cerebrospinal venous insufficiency will also be linked to secondary HLT Cerebrovascular and spinal vascular disorders NEC.

CR Number: 2018332004 **Implementation Date:** 03-Dec-18 Related CR: 2018332004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Thoracolaparoscopy*	Approved Not as Requested	Proposed PT	
HLT primary	*Gastrointestinal and abdominal imaging procedures*		*Thoracolaparoscopy*	10082478
SOC primary	*Investigations*		HLT primary	
			Abdominal therapeutic procedures NEC	10027653
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT Thoracolaparoscopy to primary HLT Gastrointestinal and abdominal imaging procedures in SOC Investigations is approved but not as requested. Thoracolaparoscopy is a minimally invasive medical procedure involving internal examination, biopsy, and/or resection of disease or masses within the pleural cavity and thoracic cavity, and may be performed either under general anaesthesia or under sedation with local anaesthetic. Thoracolaparoscopy will be added as a PT to HLT Abdominal therapeutic procedures NEC, rather than to the proposed HLT Gastrointestinal and abdominal imaging procedures.

Supplemental Update Report

CR Number: 2018332021 **Implementation Date:** 03-Dec-18 Related CR: 2018332021

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Progression of non-small cell lung cancer*	Rejected		
From PT	*Non-small cell lung cancer*			

MSSO Comment: The proposal to promote the LLT Progression of non-small cell lung cancer from PT Non-small cell lung cancer is not approved. Cancer progression is characterized by increased growth speed and invasiveness of the tumor cells. As a result of the progression, phenotypical changes occur and the tumor becomes more aggressive and acquires greater malignant potential. In MedDRA, progression of a specific type of malignancy is usually represented as a sub-concept of the PT term of the specific cancer. If the progression of a malignancy (in this case a non-small cell lung cancer) needs to be represented at the PT level, to distinguish from a new malignancy, the existing LLT Progression of non-small cell lung cancer can still be used in combination with PT Malignant neoplasm progression.

CR Number: 2018332027 **Implementation Date:** 03-Dec-18 Related CR: 2018332027

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neutrophil Fc gamma RIIIb deficiency*	Approved as Requested	Proposed PT	
HLT primary	*Immune system abnormalities congenital*		*Neutrophil Fc gamma RIIIb deficiency*	10082479
SOC primary	*Congenital, familial and genetic disorders*		HLT primary	
			Immune system abnormalities congenital	10021424
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Primary immunodeficiency syndromes	10036700
			SOC secondary	
			Immune system disorders	10021428

MSSO Comment: The proposal to add a new PT Neutrophil Fc gamma RIIIb deficiency to primary HLT Immune system abnormalities congenital in SOC Congenital, familial and genetic disorders is approved as requested. Fc gamma RIIIb deficiency is a rare defect in which neutrophils do not express Fc gamma RIIIb . Fc gamma RIIIb is a low/intermediate affinity receptor for polyvalent immune-complexed IgG. Neutrophil Fc gamma RIIIb deficiency will also be linked to secondary HLT Primary immunodeficiency syndromes and secondary HLT White blood cell abnormal findings NEC.

Supplemental Update Report

CR Number: 2018337002 **Implementation Date:** 03-Dec-18 Related CR: 2018332027

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neutrophil Fc gamma RIIIb deficiency*	Approved as Requested	Proposed PT	
To HLT	*White blood cell abnormal findings NEC*		*Neutrophil Fc gamma RIIIb deficiency*	10082479
			To HLT	
			White blood cell abnormal findings NEC	10047936

MSSO Comment:

CR Number: 2018332028 **Implementation Date:** 03-Dec-18 Related CR: 2018332028

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Cardiohepatic syndrome*	Approved Not as Requested	Proposed PT	
HLT primary	*Hepatobiliary signs and symptoms*		*Cardiohepatic syndrome*	10082480
SOC primary	*Hepatobiliary disorders*		HLT primary	
			Heart failures NEC	10019281
			SOC primary	
			Cardiac disorders	10007541
			HLT secondary	
			Hepatic failure and associated disorders	10019664
			SOC secondary	
			Hepatobiliary disorders	10019805

MSSO Comment: The proposal to add a new PT Cardiohepatic syndrome to primary HLT Hepatobiliary signs and symptoms in SOC Hepatobiliary disorders and secondary HLT Heart failure signs and symptoms in SOC Cardiac disorders is approved but not as requested. Accumulating evidence shows that acute as well as chronic heart disease can directly contribute to an acute or chronic worsening of liver function and vice versa. This interaction between the heart and the liver, is called "cardiohepatic syndrome". Because this syndrome is primarily a disorder affecting the heart and liver and is not a sign or symptom only, Cardiohepatic syndrome will be added as a PT to primary HLT Heart failures NEC and secondary HLT Hepatic failure and associated disorders.

Supplemental Update Report

CR Number: 2018333002 **Implementation Date:** 06-Dec-18 Related CR: 2018333002

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Behaviour disorder*	Approved as Requested	Proposed LLT	
From PT	*Abnormal behaviour*		*Behaviour disorder*	10004207
HLT primary	*Abnormal behaviour NEC*		From PT	
			Abnormal behaviour	10061422
			HLT primary	
			Abnormal behaviour NEC	10000117
			SOC primary	
			Psychiatric disorders	10037175

MSSO Comment: The proposal to promote the LLT Behaviour disorder from PT Abnormal behaviour to primary HLT Abnormal behaviour NEC in SOC Psychiatric disorders is approved as requested. During a recent MedDRA translation initiative, it was noted that the behavior disorder LLT terms are subordinate to an abnormality PT concept, PT Abnormal behaviour, while the conduct disorder LLT terms are appropriately subordinate to a disorder PT, PT Conduct disorder. In psychiatry and psychology, these concepts are not universally considered to be synonyms. For example, a dictionary definition of behavioral disorder is as follows: “a disorder characterized by displayed behaviors over a long period of time which significantly deviate from socially acceptable norms for a person's age and situation”; whereas a conduct disorder, as described by DSM 5 diagnostic criteria, is “a repetitive and persistent pattern of behavior in which the basic rights of others or major age-appropriate societal norms or rules are violated…”. However, in some languages, “behavior” and “conduct” are virtually synonymous, or closely related and therefore the demotion of PT Conduct disorder under the newly promoted PT Behaviour disorder seem to be appropriate in context of the international use of the two concepts. In related changes, LLT Behavior disorder, LLT Behavioural disorder, and LLT Disorder behavior will be moved from PT Abnormal behaviour to the promoted PT Behaviour disorder for better alignment. Furthermore PT Conduct disorder will be demoted under the newly promoted PT Behaviour disorder for better alignment of related concepts.

CR Number: 2018340022 **Implementation Date:** 06-Dec-18 Related CR: 2018333002

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Behavior disorder*	Approved as Requested	Proposed LLT	
From PT	*Abnormal behaviour*		*Behavior disorder*	10004204 Current
To PT	*Behaviour disorder*		From PT	
			Abnormal behaviour	10061422
			To PT	
			Behaviour disorder	10004207

MSSO Comment:

Supplemental Update Report

CR Number: 2018340023 **Implementation Date:** 06-Dec-18 Related CR: 2018333002

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Behavioural disorder*	Approved as Requested	Proposed LLT	
From PT	*Abnormal behaviour*		*Behavioural disorder*	10004210 Current
To PT	*Behaviour disorder*		From PT	
			Abnormal behaviour	10061422
			To PT	
			Behaviour disorder	10004207

MSSO Comment:

CR Number: 2018340024 **Implementation Date:** 06-Dec-18 Related CR: 2018333002

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Disorder behavior*	Approved as Requested	Proposed LLT	
From PT	*Abnormal behaviour*		*Disorder behavior*	10013190 Current
To PT	*Behaviour disorder*		From PT	
			Abnormal behaviour	10061422
			To PT	
			Behaviour disorder	10004207

MSSO Comment:

CR Number: 2018340025 **Implementation Date:** 06-Dec-18 Related CR: 2018333002

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Conduct disorder*	Approved as Requested	PT to merge	
To PT	*Behaviour disorder*		*Conduct disorder*	10064478 Current
			To PT	
			Behaviour disorder	10004207

MSSO Comment:

Supplemental Update Report

CR Number: 2018333003 **Implementation Date:** 04-Dec-18 Related CR: 2018333003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Mounier-Kuhn syndrome*	Approved as Requested	Proposed LLT	
			Mounier-Kuhn syndrome	10082485 Current
			To PT	
			Tracheobronchomegaly	10044316

MSSO Comment: The proposal to add a new term Mounier-Kuhn syndrome is approved as requested. Mounier-Kuhn syndrome, or tracheobronchomegaly, is a rare congenital disorder characterized by marked tracheobronchial dilation and recurrent lower respiratory tract infections. Diagnosis is typically accomplished with the use of computed tomography and bronchoscopy, as well as pulmonary function testing. Patients may be asymptomatic; however, symptoms can range from minimal with preserved lung function to severe respiratory failure. Mounier-Kuhn syndrome will be added as a synonym LLT to PT Tracheobronchomegaly. In a related change, PT Tracheobronchomegaly will be linked to HLT Respiratory tract disorders congenital NEC and primary SOC will be changed from SOC Respiratory, thoracic and mediastinal disorders to SOC Congenital, familial and genetic disorders because Tracheobronchomegaly is considered to be a congenital disorder.

CR Number: 2018338003 **Implementation Date:** 04-Dec-18 Related CR: 2018333003

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Tracheobronchomegaly*	Approved as Requested	Proposed PT	
To HLT	*Respiratory tract disorders congenital NEC*		*Tracheobronchomegaly*	10044316
			To HLT	
			Respiratory tract disorders congenital NEC	10038726

MSSO Comment:

CR Number: 2018338004 **Implementation Date:** 04-Dec-18 Related CR: 2018333003

Change Requested	Reassign Primary SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Tracheobronchomegaly*	Approved as Requested	Proposed PT	
Old Primary SOC	*Respiratory, thoracic and mediastinal disorders*		*Tracheobronchomegaly*	10044316
			Old Primary SOC	
New Primary SOC	*Congenital, familial and genetic disorders*		*Respiratory, thoracic and mediastinal disorders*	10038738
			New Primary SOC	
			Congenital, familial and genetic disorders	10010331

MSSO Comment:

Supplemental Update Report

CR Number: 2018333004 **Implementation Date:** 04-Dec-18 Related CR: 2018333004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Venous arterialization*	Approved Not as Requested	Proposed LLT	
			Venous arterialization	10082486 Current
			To PT	
			Venous arterialisation	10082482

MSSO Comment: The proposal to add a new PT Venous arterialization is approved but not as requested. Venous arterialization is defined as a surgical alteration of a vein so that it functions as an artery. Such a procedure is a therapeutic option for patients with end stage of peripheral artery disease associated with high amputation and mortality rates and poor quality of life. Venous arterialization will be added as LLT to a new PT Venous arterialisation representing the concept in the British English spelled version. In a related change, Venous arterialisation will be added as PT to HLT Venous therapeutic procedures.

CR Number: 2018338002 **Implementation Date:** 04-Dec-18 Related CR: 2018333004

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Venous arterialisation*	Approved as Requested	Proposed PT	
HLT primary	*Venous therapeutic procedures*		*Venous arterialisation*	10082482
SOC primary	*Surgical and medical procedures*		HLT primary	
			Venous therapeutic procedures	10047231
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment:

CR Number: 2018333005 **Implementation Date:** 04-Dec-18 Related CR: 2018333005

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Arterialisation*	Approved Not as Requested	Proposed LLT	
Status	*non-current*		*Arterialisation*	10056191 Current
			From PT	
			Neovascularisation	10029113
			To PT	
			Venous arterialisation	10082482

MSSO Comment: The proposal to change status of LLT Arterialisation to non-current is approved but not as requested. Arterialisation is used synonymously with venous arterialization. Therefore, instead of changing the status of LLT Arterialisation and LLT Arterialization to non-current, these two LLTs will be moved from PT Neovascularisation to the new PT Venous arterialisation, added in change request 2018333004.

Supplemental Update Report

CR Number: 2018338005 **Implementation Date:** 04-Dec-18 Related CR: 2018333005

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Arterialization*	Approved as Requested	Proposed LLT	
From PT	*Neovascularisation*		*Arterialization*	10003185 Current
To PT	*Venous arterialisation*		From PT	
			Neovascularisation	10029113
			To PT	
			Venous arterialisation	10082482

MSSO Comment:

CR Number: 2018333006 **Implementation Date:** 04-Dec-18 Related CR: 2018333006

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Vertebrobasilar stroke*	Approved as Requested	Proposed PT	
			Vertebrobasilar stroke	10082484
			HLT primary	
			Central nervous system haemorrhages and cerebrovascular accidents	10007948
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Cerebrovascular and spinal necrosis and vascular insufficiency	10008192
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new term Vertebrobasilar stroke is approved as requested. The vertebrobasilar arterial system perfuses the medulla, cerebellum, pons, midbrain, thalamus, and occipital cortex. Occlusion of large vessels in this system usually leads to major disability or death. Vertebrobasilar stroke carries a mortality rate of more than 85%. Because of involvement of the brainstem and cerebellum, most survivors have multisystem dysfunction (eg, quadriplegia or hemiplegia, ataxia, dysphagia, dysarthria, gaze abnormalities, cranial neuropathies). Vertebrobasilar stroke will be added as a PT to primary HLT Central nervous system haemorrhages and cerebrovascular accidents, and to secondary HLT Cerebrovascular and spinal necrosis and vascular insufficiency.

Supplemental Update Report

CR Number: 2018333007 **Implementation Date:** 04-Dec-18 Related CR: 2018333007

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Acute renal failure with lesion of tubular necrosis*	Approved as Requested	LLT to change	
Status	*non-current*		*Acute renal failure with lesion of tubular necrosis*	10001049 Non-Current
			Status	
			non-current	

MSSO Comment: The proposal to change status of LLT Acute renal failure with lesion of tubular necrosis to non-current is approved as requested. Although acute renal failure can result from tubular necrosis secondary to exposure to a toxin or ischemic damage to the tubules, the concepts combined in LLT Acute renal failure with lesion of tubular necrosis can be coded separately. Furthermore, this term, derived from ICD terminology, has been included since the introduction of MedDRA, but all of the other combination terms of this type presently subordinate to PT Acute kidney injury have been changed to non-current status.

CR Number: 2018333008 **Implementation Date:** 04-Dec-18 Related CR: 2018333008

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Posterior tibial tendon dysfunction*	Approved as Requested	Proposed PT	
			Posterior tibial tendon dysfunction	10082483
			HLT primary	
			Tendon disorders	10043234
			SOC primary	
			Musculoskeletal and connective tissue disorders	10028395
			HLT secondary	
			Muscle, tendon and ligament injuries	10028288
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new term Posterior tibial tendon dysfunction is approved as requested. Posterior tibial tendon dysfunction is one of the most common problems of the foot and ankle. It occurs when the posterior tibial tendon becomes inflamed or torn. As a result, the tendon may not be able to provide stability and support for the arch of the foot, resulting in flatfoot. Most patients can be treated using orthotics and braces, or with surgery for more severe, painful cases. Posterior tibial tendon dysfunction will be added as a PT to primary HLT Tendon disorders and secondary HLT Muscle, tendon and ligament injuries.

Supplemental Update Report

CR Number: 2018333009 **Implementation Date:** 03-Dec-18 Related CR: 2018333009

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Obstructive sialadentitis*	Approved as Requested	Proposed LLT	
			Obstructive sialadentitis	10082481 Current
			To PT	
			Sialoadenitis	10040628

MSSO Comment: The proposal to add a new term Obstructive sialadentitis is approved as requested. Sialadenitis is inflammation of the salivary glands. It has several causes, including infections or obstructions. Obstructive sialadentitis will be added as a sub-concept LLT to PT Sialoadenitis.

CR Number: 2018333010 **Implementation Date:** 06-Dec-18 Related CR: 2018333010

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Anaesthesia oral*	Approved as Requested	Proposed PT	
HLT primary	*Oral soft tissue signs and symptoms*		*Anaesthesia oral*	10082548
SOC primary	*Gastrointestinal disorders*		HLT primary	
			Oral soft tissue signs and symptoms	10031021
			SOC primary	
			Gastrointestinal disorders	10017947
			HLT secondary	
			Paraesthesias and dysaesthesias	10033788
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new PT Anaesthesia oral to primary HLT Oral soft tissue signs and symptoms in SOC Gastrointestinal disorders and secondary HLT Paraesthesias and dysaesthesias in SOC Nervous system disorders is approved as requested. Anaesthesia terms need to be represented separate from hypoaesthesias terms. The broad new PT Anaesthesia oral will serve as a grouping PT for several LLTs which at the moment grouped under PT Hypoaesthesia oral. In a related change, the following LLT will be moved from PT Hypoaesthesia oral to the new PT Anaesthesia oral: LLT Anaesthesia lip, LLT Anaesthesia mouth, LLT Anaesthesia oral mucosa, LLT Anaesthesia tongue, LLT Anesthesia lip, LLT Anesthesia mouth, LLT Anesthesia oral mucosa, LLT Anesthesia tongue, LLT Oral mucosal anaesthesia.

Supplemental Update Report

CR Number: 2018340026 **Implementation Date:** 06-Dec-18 Related CR: 2018333010

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Anaesthesia lip*	Approved as Requested	Proposed LLT	
From PT	*Hypoaesthesia oral*		*Anaesthesia lip*	10002094 Current
To PT	*Anaesthesia oral*		From PT	
			Hypoaesthesia oral	10057371
			To PT	
			Anaesthesia oral	10082548

MSSO Comment:

CR Number: 2018340027 **Implementation Date:** 06-Dec-18 Related CR: 2018333010

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Anaesthesia mouth*	Approved as Requested	Proposed LLT	
From PT	*Hypoaesthesia oral*		*Anaesthesia mouth*	10002096 Current
To PT	*Anaesthesia oral*		From PT	
			Hypoaesthesia oral	10057371
			To PT	
			Anaesthesia oral	10082548

MSSO Comment:

CR Number: 2018340028 **Implementation Date:** 06-Dec-18 Related CR: 2018333010

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Anaesthesia oral mucosa*	Approved as Requested	Proposed LLT	
From PT	*Hypoaesthesia oral*		*Anaesthesia oral mucosa*	10002098 Current
To PT	*Anaesthesia oral*		From PT	
			Hypoaesthesia oral	10057371
			To PT	
			Anaesthesia oral	10082548

MSSO Comment:

Supplemental Update Report

CR Number: 2018340029 **Implementation Date:** 06-Dec-18 Related CR: 2018333010

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Anaesthesia tongue*	Approved as Requested	Proposed LLT	
From PT	*Hypoaesthesia oral*		*Anaesthesia tongue*	10002099 Current
To PT	*Anaesthesia oral*		From PT	
			Hypoaesthesia oral	10057371
			To PT	
			Anaesthesia oral	10082548

MSSO Comment:

CR Number: 2018340030 **Implementation Date:** 06-Dec-18 Related CR: 2018333010

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Anesthesia lip*	Approved as Requested	Proposed LLT	
From PT	*Hypoaesthesia oral*		*Anesthesia lip*	10062865 Current
To PT	*Anaesthesia oral*		From PT	
			Hypoaesthesia oral	10057371
			To PT	
			Anaesthesia oral	10082548

MSSO Comment:

CR Number: 2018340031 **Implementation Date:** 06-Dec-18 Related CR: 2018333010

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Anesthesia mouth*	Approved as Requested	Proposed LLT	
From PT	*Hypoaesthesia oral*		*Anesthesia mouth*	10062866 Current
To PT	*Anaesthesia oral*		From PT	
			Hypoaesthesia oral	10057371
			To PT	
			Anaesthesia oral	10082548

MSSO Comment:

Supplemental Update Report

CR Number: 2018340032 **Implementation Date:** 06-Dec-18 Related CR: 2018333010

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Anesthesia oral mucosa*	Approved as Requested	Proposed LLT	
From PT	*Hypoaesthesia oral*		*Anesthesia oral mucosa*	10062867 Current
To PT	*Anaesthesia oral*		From PT	
			Hypoaesthesia oral	10057371
			To PT	
			Anaesthesia oral	10082548

MSSO Comment:

CR Number: 2018340033 **Implementation Date:** 06-Dec-18 Related CR: 2018333010

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Anesthesia tongue*	Approved as Requested	Proposed LLT	
From PT	*Hypoaesthesia oral*		*Anesthesia tongue*	10062868 Current
To PT	*Anaesthesia oral*		From PT	
			Hypoaesthesia oral	10057371
			To PT	
			Anaesthesia oral	10082548

MSSO Comment:

CR Number: 2018340034 **Implementation Date:** 06-Dec-18 Related CR: 2018333010

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Oral mucosal anaesthesia*	Approved as Requested	Proposed LLT	
From PT	*Hypoaesthesia oral*		*Oral mucosal anaesthesia*	10030994 Current
To PT	*Anaesthesia oral*		From PT	
			Hypoaesthesia oral	10057371
			To PT	
			Anaesthesia oral	10082548

MSSO Comment:

Supplemental Update Report

CR Number: 2018333011 **Implementation Date:** 04-Dec-18 Related CR: 2018333011

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Cholangiohepatitis*	Approved Not as Requested	Proposed LLT	
			Oriental cholangiohepatitis	10082488 Current
			To PT	
			Recurrent pyogenic cholangitis	10082487

MSSO Comment: The proposal to add a new term Cholangiohepatitis is approved but not as requested. Recurrent pyogenic cholangitis, also known as Cholangiohepatitis; recurrent attacks of cholangitis with brown pigment gallstones in the common bile duct (choledocholithiasis), ductal stenosis, fever, and jaundice; the highest instances are in eastern and southern Asia, and it is sometimes associated with dietary deficiencies (high carbohydrate, low protein diet) or parasite infection. The proposed term will be renamed to Oriental cholangiohepatitis (which is the most prevalent expression for the human cholangiohepatitis in medical literature) and added as an LLT under a new PT named Recurrent pyogenic cholangitis. In a related change, Recurrent pyogenic cholangitis will be added as a PT to primary HLT Hepatobiliary and spleen infections, and a secondary HLT Bile duct infections and inflammations.

CR Number: 2018338007 **Implementation Date:** 04-Dec-18 Related CR: 2018333011

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Recurrent pyogenic cholangitis*	Approved as Requested	Proposed PT	
HLT primary	*Hepatobiliary and spleen infections*		*Recurrent pyogenic cholangitis*	10082487
SOC primary	*Infections and infestations*		HLT primary	
			Hepatobiliary and spleen infections	10064462
			SOC primary	
			Infections and infestations	10021881
			HLT secondary	
			Bile duct infections and inflammations	10004607
			SOC secondary	
			Hepatobiliary disorders	10019805

MSSO Comment:

Supplemental Update Report

CR Number: 2018333012 **Implementation Date:** 04-Dec-18 Related CR: 2018333012

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*White coat hypertension*	Approved Not as Requested	Proposed LLT	
From PT	*Hypertension*		*White coat hypertension*	10051581
To PT	*Blood pressure increased*		From PT	
			Hypertension	10020772
			HLT primary	
			Vascular hypertensive disorders NEC	10020774
			SOC primary	
			Vascular disorders	10047065

MSSO Comment: The proposal to move the LLT White coat hypertension from PT Hypertension to PT Blood pressure increased is approved but not as requested. Despite its transient nature, White coat hypertension is still a disorder. By MedDRA convention, disorder terms or conditions can not be subordinated to investigations. However, white coat hypertension, more commonly known as white coat syndrome, is a phenomenon in which patients or exhibit a blood pressure level above the normal range, in a clinical setting, though they do not exhibit it in other settings. It is believed that the phenomenon is due to anxiety experienced during a clinic visit. Therefore, LLT White coat hypertension will be promoted from PT Hypertension to a PT and linked to HLT Vascular hypertensive disorders NEC because it does not meet criteria of a real hypertension.

CR Number: 2018333013 **Implementation Date:** 04-Dec-18 Related CR: 2018333013

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Blood pressure high*	Rejected		
From PT	*Hypertension*			
To PT	*Blood pressure increased*			

MSSO Comment: The proposal to move the LLT Blood pressure high from PT Hypertension to PT Blood pressure increased is not approved. As stated in the “6.13.2 Conventions and Exceptions” of the MedDRA Introductory Guide, although “high and “low” are generally considered to be laboratory/investigation type of terms and are found in the SOC Investigations, there are exceptions to this rule in order to comply with the most frequent use of certain expressions in the clinical practice. One of these exceptions is referring to LLT Blood pressure high and LLT Low blood pressure, which are linked to PT Hypertension or PT Hypotension respectively, in SOC Vascular disorders.

CR Number: 2018333014 **Implementation Date:** 07-Dec-18 Related CR: 2018333014

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits*	Rejected		
Status	*non-current*			

MSSO Comment: The proposal to change status of LLT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits to non-current is not approved. This is a technical rejection because demotion of PT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits was not approved. Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits is the internationally recognised concept for on of the two types of Amyloid related imaging abnormality, MRI findings in Alzheimer studies with monoclonal antibodies.

Supplemental Update Report

CR Number: 2018333015 **Implementation Date:** 07-Dec-18 Related CR: 2018333015

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Amyloid related imaging abnormality- superficial siderosis*	Approved Not as Requested	Proposed LLT	
			Amyloid related imaging abnormality-superficial siderosis	10082557 Current
HLT primary	*Central nervous system vascular disorders NEC*			
SOC primary	*Nervous system disorders*		To PT	
			Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits	10072601

MSSO Comment: The proposal to add a new PT Amyloid related imaging abnormality- superficial siderosis to primary HLT Central nervous system vascular disorders NEC in SOC Nervous system disorders and secondary HLT Cerebrovascular and spinal vascular disorders NEC in SOC Vascular disorders is approved but not as requested. Cortical superficial siderosis may have possible causes but it is emerging as a key feature of cerebral amyloid angiopathy. Therefore Amyloid related imaging abnormality-superficial siderosis will be placed, without the space between the hyphen and superficial, and added as an LLT under PT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits.

CR Number: 2018333016 **Implementation Date:** 07-Dec-18 Related CR: 2018333016

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Amyloid related imaging abnormality-microhemorrhages symptomatic*	Rejected		

MSSO Comment: The proposal to add a new LLT Amyloid related imaging abnormality-microhemorrhages symptomatic is not approved. The requested term is represented by existing LLT Symptomatic ARIA-H.

CR Number: 2018333017 **Implementation Date:** 07-Dec-18 Related CR: 2018333017

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Amyloid related imaging abnormality-microhemorrhages asymptomatic*	Rejected		

MSSO Comment: The proposal to add a new LLT Amyloid related imaging abnormality-microhemorrhages asymptomatic is not approved. Please see existing LLT Asymptomatic ARIA-H, which represents the requested term in shortened form.

Supplemental Update Report

CR Number: 2018333018 **Implementation Date:** 07-Dec-18 Related CR: 2018333018

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Amyloid related imaging abnormality-microhaemorrhages*	Approved Not as Requested	Proposed LLT *Amyloid related imaging abnormality-microhaemorrhages*	10082558 Current
HLT primary	*Central nervous system vascular disorders NEC*			
SOC primary	*Nervous system disorders*		To PT *Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits*	10072601

MSSO Comment: The proposal to add a new PT Amyloid related imaging abnormality-microhaemorrhages to primary HLT Central nervous system vascular disorders NEC in SOC Nervous system disorders and secondary HLT Cerebrovascular and spinal vascular disorders NEC in SOC Vascular disorders is approved but not as requested. Amyloid related imaging abnormality-microhaemorrhages and its American English counterpart Amyloid related imaging abnormality-microhemorrhages will be added as sub-concept LLTs to PT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits.

CR Number: 2018341005 **Implementation Date:** 07-Dec-18 Related CR: 2018333018

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Amyloid related imaging abnormality-microhemorrhages*	Approved as Requested	Proposed LLT *Amyloid related imaging abnormality-microhemorrhages*	10082560 Current
To PT	*Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits*		To PT *Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits*	10072601

MSSO Comment:

CR Number: 2018333019 **Implementation Date:** 07-Dec-18 Related CR: 2018333019

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits*	Rejected		
To PT	*Amyloid related imaging abnormality-microhaemorrhages*			

MSSO Comment: The proposal to demote the PT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits under PT Amyloid related imaging abnormality-microhaemorrhages is not approved. Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits is the internationally recognised concept for two types of Amyloid related imaging abnormality, MRI findings in Alzheimer studies with monoclonal antibodies.

Supplemental Update Report

CR Number: 2018333020 **Implementation Date:** 07-Dec-18 Related CR: 2018333020

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Amyloid related imaging abnormality-macrohaemorrhages*	Rejected		
HLT primary	*Central nervous system vascular disorders NEC*			
SOC primary	*Nervous system disorders*			

MSSO Comment: The proposal to add a new PT Amyloid related imaging abnormality-macrohaemorrhages to primary HLT Central nervous system vascular disorders NEC in SOC Nervous system disorders and secondary HLT Cerebrovascular and spinal vascular disorders NEC in SOC Vascular disorders is not approved. Macrohaemorrhages are not a commonly recognized feature of amyloid related imaging abnormalities.

CR Number: 2018333021 **Implementation Date:** 07-Dec-18 Related CR: 2018333021

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Amyloid related imaging abnormality-macrohemorrhages symptomatic*	Rejected		

MSSO Comment: The proposal to add a new LLT Amyloid related imaging abnormality-macrohemorrhages symptomatic is not approved. This is a technical rejection since the proposed PT in change request 2018333020 was not approved.

CR Number: 2018333022 **Implementation Date:** 07-Dec-18 Related CR: 2018333022

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*C.Amyloid related imaging abnormality-macrohemorrhages symptomatic*	Rejected		

MSSO Comment: The proposal to add a new LLT C.Amyloid related imaging abnormality-macrohemorrhages symptomatic is not approved. This is a technical rejection since the proposed PT in change request 2018333020 was not approved.

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CR Number: 2018333023 **Implementation Date:** 07-Dec-18 Related CR: 2018333023

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Amyloid related imaging abnormality-hemosiderin deposits*	Approved as Requested	Proposed LLT *Amyloid related imaging abnormality-hemosiderin deposits* To PT *Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits*	10082555 Current 10072601

MSSO Comment: The proposal to add a new LLT Amyloid related imaging abnormality-hemosiderin deposits is approved as requested. Amyloid related imaging abnormality-hemosiderin deposits together with its British spelled counterpart Amyloid related imaging abnormality-haemosiderin deposits will be added as a sub-concept LLTs to PT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits.

CR Number: 2018341006 **Implementation Date:** 07-Dec-18 Related CR: 2018333023

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Amyloid related imaging abnormality-haemosiderin deposits*	Approved as Requested	Proposed LLT *Amyloid related imaging abnormality-haemosiderin deposits* To PT *Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits*	10082561 Current 10072601
To PT	*Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits*			

MSSO Comment:

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CR Number: 2018333024 **Implementation Date:** 07-Dec-18 Related CR: 2018333024

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Amyloid related imaging abnormality-haemorrhages*	Approved Not as Requested	Proposed LLT *Amyloid related imaging abnormality-haemorrhages*	10082554 Current
HLT primary	*Central nervous system vascular disorders NEC*		To PT *Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits*	10072601
SOC primary	*Nervous system disorders*			

MSSO Comment: The proposal to add a new PT Amyloid related imaging abnormality-haemorrhages to primary HLT Central nervous system vascular disorders NEC in SOC Nervous system disorders and secondary HLT Cerebrovascular and spinal vascular disorders NEC in SOC Vascular disorders is approved but not as requested. Amyloid related imaging abnormality-haemorrhages together with its American English spelled counterpart Amyloid related imaging abnormality-hemorrhages will be added as sub-concept LLTs to PT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits.

CR Number: 2018341007 **Implementation Date:** 07-Dec-18 Related CR: 2018333024

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Amyloid related imaging abnormality-hemorrhages*	Approved as Requested	Proposed LLT *Amyloid related imaging abnormality-hemorrhages*	10082559 Current
To PT	*Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits*		To PT *Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits*	10072601

MSSO Comment:

CR Number: 2018333025 **Implementation Date:** 07-Dec-18 Related CR: 2018333025

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Amyloid related imaging abnormality-hemorrhages symptomatic*	Rejected		

MSSO Comment: The proposal to add a new LLT Amyloid related imaging abnormality-hemorrhages symptomatic is not approved. The requested concept can be represented by existing LLT Symptomatic ARIA-H.

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CR Number: 2018333026 **Implementation Date:** 07-Dec-18 Related CR: 2018333026

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Amyloid related imaging abnormality-hemorrhages asymptomatic*	Rejected		

MSSO Comment: The proposal to add a new LLT Amyloid related imaging abnormality-hemorrhages asymptomatic is not approved. The requested term can be represented by existing LLT Asymptomatic ARIA-H.

CR Number: 2018333027 **Implementation Date:** 07-Dec-18 Related CR: 2018333027

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*ARIA-H*	Rejected		
From PT	*Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits*			
To PT	*Amyloid related imaging abnormality-haemorrhages*			

MSSO Comment: The proposal to move the LLT ARIA-H from PT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits to PT Amyloid related imaging abnormality-haemorrhages is not approved. ARIA-H is appropriately placed under the PT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits as ARIA -H represents a spectrum of MRI findings due to hemosiderin deposits including hemorrhages.

CR Number: 2018333028 **Implementation Date:** 07-Dec-18 Related CR: 2018333028

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*ARIA-microhemorrhages*	Approved as Requested	Proposed LLT	
			ARIA-microhemorrhages	10082556 Current
			To PT	
			Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits	10072601

MSSO Comment: The proposal to add a new LLT ARIA-microhemorrhages is approved as requested. ARIA-microhemorrhages together with British English spelled counterpart ARIA-microhaemorrhages will be added as sub-concept LLTs to PT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits.

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CR Number: 2018341008 **Implementation Date:** 07-Dec-18 Related CR: 2018333028

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*ARIA-microhaemorrhages*	Approved as Requested	Proposed LLT	
To PT	*Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits*		*ARIA-microhaemorrhages*	10082562 Current
			To PT	
			Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits	10072601

MSSO Comment:

CR Number: 2018333029 **Implementation Date:** 07-Dec-18 Related CR: 2018333029

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*ARIA-macrohemorrhages*	Rejected		

MSSO Comment: The proposal to add a new LLT ARIA-macrohemorrhages is not approved. Macrohaemorrhages are not a commonly recognized feature of amyloid related imaging abnormalities.

CR Number: 2018333030 **Implementation Date:** 07-Dec-18 Related CR: 2018333030

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits*	Rejected		
Status	*non-current*			

MSSO Comment: The proposal to change status of LLT Amyloid related imaging abnormality-microhaemorrhages and haemosiderin deposits to non-current is not approved. This change request is a duplication from change request 2018333014.

Supplemental Update Report

CR Number: **2018333031** **Implementation Date:** 04-Dec-18 Related CR: 2018333031

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Muscular back pain*	Rejected		
From PT	*Back pain*			
To PT	*Myalgia*			

MSSO Comment: The proposal to move the LLT Muscular back pain from PT Back pain to PT Myalgia is not approved. Although usually the type of event or condition information has priority over the body site, spinal and paraspinal structures are of very high significance in the clinical practice. Both for grouping and analysis purposes, the proposed term Muscular back pain is better represented in its current position, and would be displaced under general PT Myalgia once separated from the group of pain related conditions gathered under the clinically significant PT Back pain.

CR Number: **2018333032** **Implementation Date:** 06-Dec-18 Related CR: 2018333032

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Tracheal aspiration*	Approved as Requested	LLT to change	
Status	*non-current*		*Tracheal aspiration*	10044281 Non-Current
			Status	
			non-current	

MSSO Comment: The proposal to change status of LLT Tracheal aspiration to non-current is approved as requested. Tracheal aspiration was a PT in the SOC Investigations until Version 21.1 but has been demoted under PT Aspiration on request of a subscriber since. PT Tracheal Aspiration normal and PT Tracheal aspiration abnormal are still terms in the SOC Investigation. This is confusing and flagging non-current is appropriate especially as new LLT Aspiration into trachea recently was added for clarification in change request 2018323014. Also, LLT Tracheal aspiration will be moved from PT Aspiration to PT Tracheal aspiration procedure.

CR Number: **2018340004** **Implementation Date:** 06-Dec-18 Related CR: 2018333032

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Tracheal aspiration*	Approved as Requested	Proposed LLT	
From PT	*Aspiration*		*Tracheal aspiration*	10044281 Non-Current
To PT	*Tracheal aspiration procedure*		From PT	
			Aspiration	10003504
			To PT	
			Tracheal aspiration procedure	10081462

MSSO Comment:

Supplemental Update Report

CR Number: 2018333033 **Implementation Date:** 06-Dec-18 Related CR: 2018333033

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Endotracheal aspiration*	Approved Not as Requested	Proposed LLT	
Status	*non-current*		*Endotracheal aspiration*	10050802 Current
			From PT	
			Aspiration	10003504
			To PT	
			Tracheal aspiration procedure	10081462

MSSO Comment: The proposal to change status of LLT Endotracheal aspiration to non-current is approved but not as requested. Endotracheal aspiration is not an ambiguous term as it relates to a procedure. Therefore, LLT Endotracheal aspiration will be moved from PT Aspiration to new PT Tracheal aspiration procedure added in change request 2018101015.

CR Number: 2018333034 **Implementation Date:** 06-Dec-18 Related CR: 2018333034

Change Requested	Change Status of LLT	Final Disposition	Final Placement	MedDRA Code #
LLT to change	*Nasotracheal aspiration*	Approved Not as Requested	Proposed LLT	
Status	*non-current*		*Nasotracheal aspiration*	10050801 Current
			From PT	
			Aspiration	10003504
			To PT	
			Tracheal aspiration procedure	10081462

MSSO Comment: The proposal to change status of LLT Nasotracheal aspiration to non-current is approved but not as requested. Nasotracheal aspiration is not an ambiguous term but since it relates to a procedure rather than to a disorder, it will be moved from PT Aspiration to PT Tracheal aspiration procedure added in change request 2018101015.

CR Number: 2018333035 **Implementation Date:** 06-Dec-18 Related CR: 2018333035

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Aspiration bronchial*	Approved as Requested	Proposed LLT	
From PT	*Aspiration*		*Aspiration bronchial*	10050777 Non-Current
To PT	*Bronchial aspiration procedure*		From PT	
			Aspiration	10003504
			To PT	
			Bronchial aspiration procedure	10081453

MSSO Comment: The proposal to move the LLT Aspiration bronchial from PT Aspiration to PT Bronchial aspiration procedure is approved as requested. The already non-current LLT Aspiration bronchial, similar to Tracheal aspiration, is a conflicting term as it can refer to a procedure or an act of aspiration of something into the airway tract.

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CR Number: 2018333036 **Implementation Date:** 06-Dec-18 Related CR: 2018333036

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Aspiration tracheal*	Approved as Requested	Proposed LLT	
From PT	*Aspiration*		*Aspiration tracheal*	10003530 Non-Current
To PT	*Tracheal aspiration procedure*		From PT	
			Aspiration	10003504
			To PT	
			Tracheal aspiration procedure	10081462

MSSO Comment: The proposal to move the LLT Aspiration tracheal from PT Aspiration to PT Tracheal aspiration procedure is approved as requested. LLT Aspiration tracheal, the reverse order to Tracheal aspiration, is a conflicting term as it can refer to a procedure or an act of aspiration of something into the the airway tract.

CR Number: 2018333037 **Implementation Date:** 06-Dec-18 Related CR: 2018333037

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ortolani test negative*	Approved as Requested	Proposed PT	
HLT primary	*Physical examination procedures and organ system status*		*Ortolani test negative*	10082549
SOC primary	*Investigations*		HLT primary	
			Physical examination procedures and organ system status	10071941
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Ortolani test negative to primary HLT Physical examination procedures and organ system status in SOC Investigations is approved as requested. The Ortolani test is a physical examination procedure used to evaluate the stability of the hip joints in newborns and infants. A positive Ortolani test is a click or a popping sensation that may be felt if the joint is unstable, caused by the head of the femur moving out of the acetabulum under pressure from the examiner's hands during rotation and abduction. An Ortolani test is negative in the absence of a click or popping sensation. In a related change, PT Barlow test negative and PT Barlow test positive will be added to HLT Physical examination procedures and organ system status. Similar to Ortolani test, Barlow maneuver, a clunk indicates that the head of the femur is moving out of the acetabulum, that means a positive test result. The PT Barlow test negative will be added to represent a term for a test result, where the mentioned clunk does not occur.

Supplemental Update Report

CR Number: 2018340035 **Implementation Date:** 06-Dec-18 Related CR: 2018333037

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Barlow test negative*	Approved as Requested	Proposed PT	
			Barlow test negative	10082552
HLT primary	*Physical examination procedures and organ system status*		HLT primary	
			Physical examination procedures and organ system status	10071941
SOC primary	*Investigations*		SOC primary	
			Investigations	10022891

MSSO Comment:

CR Number: 2018340036 **Implementation Date:** 06-Dec-18 Related CR: 2018333037

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Barlow test positive*	Approved as Requested	Proposed PT	
			Barlow test positive	10082551
HLT primary	*Physical examination procedures and organ system status*		HLT primary	
			Physical examination procedures and organ system status	10071941
SOC primary	*Investigations*		SOC primary	
			Investigations	10022891

MSSO Comment:

Supplemental Update Report

CR Number: 2018333038 **Implementation Date:** 06-Dec-18 Related CR: 2018333038

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ortolani test positive*	Approved as Requested	Proposed PT	
HLT primary	*Physical examination procedures and organ system status*		*Ortolani test positive*	10082550
SOC primary	*Investigations*		HLT primary	
			Physical examination procedures and organ system status	10071941
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Ortolani test positive to primary HLT Physical examination procedures and organ system status in SOC Investigations is approved as requested. The Ortolani test is a physical examination procedure used to evaluate the stability of the hip joints in newborns and infants. A positive Ortolani test is a click or a popping sensation that may be felt if the joint is unstable, caused by the head of the femur moving out of the acetabulum under pressure from the examiner's hands during rotation and abduction.

CR Number: 2018333039 **Implementation Date:** 10-Dec-18 Related CR: 2018333039

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Nodal tachycardia*	Approved as Requested	Proposed LLT	
From PT	*Nodal arrhythmia*		*Nodal tachycardia*	10029471 Current
To PT	*Supraventricular tachycardia*		From PT	
			Nodal arrhythmia	10029458
			To PT	
			Supraventricular tachycardia	10042604

MSSO Comment: The proposal to move the LLT Nodal tachycardia from PT Nodal arrhythmia to PT Supraventricular tachycardia is approved as requested. Nodal tachycardia, tachycardia resulting from a focus in the atrioventricular node, is better represented under PT Supraventricular tachycardia aligned with LLT AV nodal tachycardia.

Supplemental Update Report

CR Number: 2018333040 **Implementation Date:** 10-Dec-18 Related CR: 2018333040

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Tachycardia nodal*	Approved as Requested	Proposed LLT	
From PT	*Nodal arrhythmia*		*Tachycardia nodal*	10043077 Current
To PT	*Supraventricular tachycardia*		From PT	
			Nodal arrhythmia	10029458
			To PT	
			Supraventricular tachycardia	10042604

MSSO Comment: The proposal to move the LLT Tachycardia nodal from PT Nodal arrhythmia to PT Supraventricular tachycardia is approved as requested. Tachycardia nodal, tachycardia resulting from a focus in the atrioventricular node, is better represented under PT Supraventricular tachycardia aligned with LLT AV nodal tachycardia.

CR Number: 2018333041 **Implementation Date:** 10-Dec-18 Related CR: 2018333041

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Nodal arrhythmia*	Approved as Requested	Proposed PT	
From HLT	*Rate and rhythm disorders NEC*		*Nodal arrhythmia*	10029458
To HLT	*Supraventricular arrhythmias*		From HLT	
			Rate and rhythm disorders NEC	10037908
			To HLT	
			Supraventricular arrhythmias	10042600

MSSO Comment: The proposal to move the PT Nodal arrhythmia from HLT Rate and rhythm disorders NEC to HLT Supraventricular arrhythmias is approved as requested. Nodal arrhythmia or Junctional arrhythmia describes an abnormal heart rhythm resulting from impulses coming from a locus of tissue in the area of the atrioventricular node i.e. supraventricular.

CR Number: 2018333042 **Implementation Date:** 10-Dec-18 Related CR: 2018333042

Change Requested	Link (move) a PT to another HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Nodal rhythm*	Approved as Requested	Proposed PT	
From HLT	*Rate and rhythm disorders NEC*		*Nodal rhythm*	10029470
To HLT	*Supraventricular arrhythmias*		From HLT	
			Rate and rhythm disorders NEC	10037908
			To HLT	
			Supraventricular arrhythmias	10042600

MSSO Comment: The proposal to move the PT Nodal rhythm from HLT Rate and rhythm disorders NEC to HLT Supraventricular arrhythmias is approved as requested for better alignment. Nodal rhythm or Junctional rhythm describes an abnormal heart rhythm resulting from impulses coming from a locus of tissue in the area of the atrioventricular node i.e. supraventricular.

Supplemental Update Report

CR Number: 2018333043 **Implementation Date:** 04-Dec-18 Related CR: 2018333043

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Hyperresponsive to stimuli*	Approved as Requested	Proposed PT	
HLT primary	*Neurological signs and symptoms NEC*		*Hyperresponsive to stimuli*	10082489
SOC primary	*Nervous system disorders*		HLT primary	
			Neurological signs and symptoms NEC	10029306
			SOC primary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new PT Hyperresponsive to stimuli to primary HLT Neurological signs and symptoms NEC in SOC Nervous system disorders is approved as requested. This change request arises from a terminology interoperability initiative to map a set of device patient problem codes to MedDRA. This is a counterpart to existing PT Hyporesponsive to stimuli.

CR Number: 2018333044 **Implementation Date:** 04-Dec-18 Related CR: 2018333044

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Taste disorder*	Approved as Requested	Proposed PT	
HLT primary	*Sensory abnormalities NEC*		*Taste disorder*	10082490
SOC primary	*Nervous system disorders*		HLT primary	
			Sensory abnormalities NEC	10040021
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Taste disorders	10043131
			SOC secondary	
			Gastrointestinal disorders	10017947

MSSO Comment: The proposal to add a new PT Taste disorder to primary HLT Sensory abnormalities NEC in SOC Nervous system disorders and secondary HLT Taste disorders in SOC Gastrointestinal disorders is approved as requested. This change request arises from a terminology interoperability initiative to map a set of device patient problem codes to MedDRA. This term represents the general concept of taste disorder and complements the more specific ones already available.

Supplemental Update Report

CR Number: 2018333045 **Implementation Date:** 04-Dec-18 Related CR: 2018333045

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Complete neonatal hearing loss*	Approved as Requested	Proposed LLT	
To PT	*Neonatal deafness*		*Complete neonatal hearing loss*	10082499 Current
			To PT	
			Neonatal deafness	10080897

MSSO Comment: The proposal to add a new LLT Complete neonatal hearing loss to PT Neonatal deafness is approved as requested. This change request arises from a terminology interoperability initiative to map a set of device patient problem codes to MedDRA. There is an existing LLT Complete hearing loss under PT Deafness but there is a need for a similar term specific for neonates.

CR Number: 2018333046 **Implementation Date:** 04-Dec-18 Related CR: 2018333046

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Partial neonatal hearing loss*	Approved as Requested	Proposed LLT	
To PT	*Neonatal hypoacusis*		*Partial neonatal hearing loss*	10082496 Current
			To PT	
			Neonatal hypoacusis	10080902

MSSO Comment: The proposal to add a new LLT Partial neonatal hearing loss to PT Neonatal hypoacusis is approved as requested. This change request arises from a terminology interoperability initiative to map a set of device patient problem codes to MedDRA. There is an existing LLT Partial hearing loss under PT Hypoacusis but there is a need for a similar term specific for neonates.

CR Number: 2018333047 **Implementation Date:** 04-Dec-18 Related CR: 2018333047

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Gastroesophageal burn*	Approved Not as Requested	Proposed LLT	
To PT	*Burn of internal organs*		*Gastroesophageal burn*	10082500 Current
			To PT	
			Burn oesophageal	10006707

MSSO Comment: The proposal to add a new LLT Gastroesophageal burn to PT Burn of internal organs is approved but not as requested. This change request arises from a terminology interoperability initiative to map a set of device patient problem codes to MedDRA. The requested term Gastroesophageal burn will be placed as sub-concept LLT to PT Burn oesophageal.

Supplemental Update Report

CR Number: 2018333048 **Implementation Date:** 04-Dec-18 Related CR: 2018333048

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Intestinal burn*	Approved as Requested	Proposed LLT	
To PT	*Burn of internal organs*		*Intestinal burn*	10082501 Current
			To PT	
			Burn of internal organs	10006712

MSSO Comment: The proposal to add a new LLT Intestinal burn to PT Burn of internal organs is approved as requested. This change request arises from a terminology interoperability initiative to map a set of device patient problem codes to MedDRA. There is a need for a term specific to the intestines. The existing LLT Burn of gastrointestinal tract is too broad.

CR Number: 2018333049 **Implementation Date:** 04-Dec-18 Related CR: 2018333049

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Gastrooesophageal burn*	Approved Not as Requested	Proposed LLT	
To PT	*Burn of internal organs*		*Gastrooesophageal burn*	10082497 Current
			To PT	
			Burn oesophageal	10006707

MSSO Comment: The proposal to add a new LLT Gastrooesophageal burn to PT Burn of internal organs is approved but not as requested. This change request arises from a terminology interoperability initiative to map a set of device patient problem codes to MedDRA. Gastrooesophageal burn, the British English spelled counterpart to LLT Gastroesophageal burn which has been added in change request 2018333047, will also be added as an LLT to PT Burn oesophageal.

CR Number: 2018333050 **Implementation Date:** 04-Dec-18 Related CR: 2018333050

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Nipple sensation changes*	Approved as Requested	Proposed LLT	
To PT	*Sensory disturbance*		*Nipple sensation changes*	10082498 Current
			To PT	
			Sensory disturbance	10040026

MSSO Comment: The proposal to add a new LLT Nipple sensation changes to PT Sensory disturbance is approved as requested. This change request arises from a terminology interoperability initiative to map a set of device patient problem codes to MedDRA. There are existing LLTs for nipple hyperaesthesia and hypoaesthesia but not a more general term for change in sensation.

Supplemental Update Report

CR Number: 2018333051 **Implementation Date:** 04-Dec-18 Related CR: 2018333051

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Neonatal deformity*	Approved as Requested	Proposed PT	
HLT primary	*General signs and symptoms NEC*		*Neonatal deformity*	10082494
SOC primary	*General disorders and administration site conditions*		HLT primary	
			General signs and symptoms NEC	10018072
			SOC primary	
			General disorders and administration site conditions	10018065
			HLT secondary	
			Newborn complications NEC	10010168
			SOC secondary	
			Pregnancy, puerperium and perinatal conditions	10036585

MSSO Comment: The proposal to add a new PT Neonatal deformity to primary HLT General signs and symptoms NEC in SOC General disorders and administration site conditions and secondary HLT Newborn complications NEC in SOC Pregnancy, puerperium and perinatal conditions is approved as requested. This change request arises from a terminology interoperability initiative to map a set of device patient problem codes to MedDRA. There is an existing PT Deformity but there is a need for a term specific to neonates. Please note that this concept refers to an acquired deformity; it is not a congenital concept and therefore there is no link to the congenital SOC.

CR Number: 2018333052 **Implementation Date:** 04-Dec-18 Related CR: 2018333052

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Patient entrapped in device*	Approved as Requested	Proposed PT	
HLT primary	*Complications associated with device NEC*		*Patient entrapped in device*	10082491
SOC primary	*General disorders and administration site conditions*		HLT primary	
			Complications associated with device NEC	10069785
			SOC primary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Patient entrapped in device to primary HLT Complications associated with device NEC in SOC General disorders and administration site conditions is approved as requested. This change request arises from a terminology interoperability initiative to map a set of device patient problem codes to MedDRA. This refers to situations where a patient becomes entangled or caught in a device, such as the side rails or mattress of a bed. Physical entrapment is a commonly reported concept for devices. The wording for this term was agreed with IMDRF.

Supplemental Update Report

CR Number: 2018333053 **Implementation Date:** 04-Dec-18 Related CR: 2018333053

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Increased intraperitoneal volume*	Approved as Requested	Proposed PT	
HLT primary	*Peritoneal and retroperitoneal disorders*		*Increased intraperitoneal volume*	10082492
SOC primary	*Gastrointestinal disorders*		HLT primary	
			Peritoneal and retroperitoneal disorders	10034653
			SOC primary	
			Gastrointestinal disorders	10017947
			HLT secondary	
			Dialysis related complications	10071945
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new PT Increased intraperitoneal volume to primary HLT Peritoneal and retroperitoneal disorders in SOC Gastrointestinal disorders and secondary HLT Dialysis related complications in SOC Injury, poisoning and procedural complications is approved as requested. This change request arises from a terminology interoperability initiative to map a set of device patient problem codes to MedDRA. Increased intraperitoneal volume, also commonly referred to as overfill, is a condition where excess fluid is present in the peritoneal cavity from overfilling or not draining enough effluent during a peritoneal dialysis exchange. In a related change, the frequently used synonym Peritoneal dialysis overfill will be added as an LLT to new PT Increased intraperitoneal volume.

CR Number: 2018338008 **Implementation Date:** 04-Dec-18 Related CR: 2018333053

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Peritoneal dialysis overfill*	Approved as Requested	Proposed LLT	
To PT	*Increased intraperitoneal volume*		*Peritoneal dialysis overfill*	10082502 Current
			To PT	
			Increased intraperitoneal volume	10082492

MSSO Comment:

Supplemental Update Report

CR Number: 2018333054 **Implementation Date:** 04-Dec-18 Related CR: 2018333054

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Breast implant-associated anaplastic large cell lymphoma*	Approved as Requested	Proposed PT	
			Breast implant-associated anaplastic large cell lymphoma	10082495
HLT primary	*Lymphomas unspecified NEC*		HLT primary	
			Lymphomas unspecified NEC	10025324
SOC primary	*Blood and lymphatic system disorders*		SOC primary	
			Blood and lymphatic system disorders	10005329
			HLT secondary	
			Breast complications associated with device	10069783
			SOC secondary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new PT Breast implant-associated anaplastic large cell lymphoma to primary HLT Lymphomas unspecified NEC in SOC Blood and lymphatic system disorders and secondary HLT Breast complications associated with device in SOC General disorders and administration site conditions is approved as requested. This change request arises from a terminology interoperability initiative to map a set of device patient problem codes to MedDRA. BIA-ALCL is a rare lymphoma that can develop around breast implants, and in some cases can spread around the body.

CR Number: 2018333055 **Implementation Date:** 04-Dec-18 Related CR: 2018333055

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Restenosis*	Approved as Requested	Proposed PT	
			Restenosis	10082493
HLT primary	*Non-site specific procedural complications*		HLT primary	
			Non-site specific procedural complications	10029559
SOC primary	*Injury, poisoning and procedural complications*		SOC primary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new PT Restenosis to primary HLT Non-site specific procedural complications in SOC Injury, poisoning and procedural complications is approved as requested. This change request arises from a terminology interoperability initiative to map a set of device patient problem codes to MedDRA. A similar term, PT Reocclusion is already in this HLT.

Supplemental Update Report

CR Number: 2018334001 **Implementation Date:** 06-Dec-18 Related CR: 2018334001

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Congenital arterial blockage NOS*	Approved Not as Requested	Proposed PT	
			Congenital arterial occlusion	10082546
			HLT primary	
			Arterial disorders congenital	10003153
			SOC primary	
			Congenital, familial and genetic disorders	10010331
			HLT secondary	
			Vascular malformations and acquired anomalies	10047091
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new term Congenital arterial blockage NOS is approved but not as requested. Congenital arterial blockage NOS is a very broad concept and will be modified to Congenital arterial occlusion. It will be reworded as the MSSO does not add any new term with the suffix "NOS". Congenital arterial occlusion will be added as PT to primary HLT Arterial disorders congenital and secondary HLT Vascular malformations and acquired anomalies.

CR Number: 2018334002 **Implementation Date:** 06-Dec-18 Related CR: 2018334002

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*COPD assessment test*	Approved as Requested	Proposed PT	
			COPD assessment test	10082547
			HLT primary	
			Investigations NEC	10022892
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new term COPD assessment test is approved as requested. The COPD assessment test (CAT) is a self-administered questionnaire that measures health-related quality of life assessing globally the impact of COPD (cough, sputum, breathlessness, chest tightness, confidence, activity, sleep and energy levels)on health status. COPD assessment test will be added as PT to HLT Investigations NEC.

Supplemental Update Report

CR Number: 2018334003 **Implementation Date:** 06-Dec-18 Related CR: 2018334003

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Tongue thrust*	Approved as Requested	Proposed PT	
			Tongue thrust	10082545
			HLT primary	
			Tongue signs and symptoms	10043985
			SOC primary	
			Gastrointestinal disorders	10017947
			HLT secondary	
			Muscle tone abnormal	10028342
			SOC secondary	
			Nervous system disorders	10029205

MSSO Comment: The proposal to add a new term Tongue thrust is approved as requested. Tongue thrust is the habit of placing the tongue in the wrong position during swallowing, either too far forward or to the sides. The movement is forceful, and is associated with an abnormal increase in muscle tone. Tongue thrust will be added as PT to primary HLT Tongue signs and symptoms and secondary HLT Muscle tone abnormal and HLT Muscle tone abnormalities

CR Number: 2018340021 **Implementation Date:** 06-Dec-18 Related CR: 2018334003

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Tongue thrust*	Approved as Requested	Proposed PT	
To HLT	*Muscle tone abnormalities*		*Tongue thrust*	10082545
			To HLT	
			Muscle tone abnormalities	10028343

MSSO Comment:

CR Number: 2018334004 **Implementation Date:** 05-Dec-18 Related CR: 2018334004

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Product concentrate applied undiluted*	Approved Not as Requested	Proposed LLT	
To PT	*Product preparation error*		*Product concentrate not diluted*	10082542 Current
			To PT	
			Product preparation error	10076869

MSSO Comment: The proposal to add a new LLT Product concentrate applied undiluted to PT Product preparation error is approved but not as requested. The requested Product concentrate applied undiluted represents a combination between preparation error and administration error. To represent the scenario of the report the MSSO will add LLT Product concentrate not diluted to PT Product preparation error. This new LLT together with LLT Administration error represents the original requested concept.

Supplemental Update Report

CR Number: 2018334005 **Implementation Date:** 05-Dec-18 Related CR: 2018334005

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Local anesthtic systemic toxicity*	Approved Not as Requested	Proposed LLT	
To PT	*Systemic toxicity*		*Local anesthetic systemic toxicity*	10082539 Current
			To PT	
			Local anaesthetic systemic toxicity	10082534

MSSO Comment: The proposal to add a new LLT Local anesthtic systemic toxicity to PT Systemic toxicity is approved but not as requested. Local anesthetic systemic toxicity can be life-threatening adverse reaction resulting from local anesthetic reaching significant systemic circulating levels. It is infrequent complication in the use of local anesthesia, and almost always occurs within minutes of injection of the local anesthetic. The proposed term will be added with corrected spelling as LLT Local anesthetic systemic toxicity to a new PT Local anaesthetic systemic toxicity. In a related change, the British spelled counterpart Local anaesthetic systemic toxicity will be added as a PT to HLT Anaesthetic and allied procedural complications.

CR Number: 2018339004 **Implementation Date:** 05-Dec-18 Related CR: 2018334005

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Local anaesthetic systemic toxicity*	Approved as Requested	Proposed PT	
HLT primary	*Anaesthetic and allied procedural complications*		*Local anaesthetic systemic toxicity*	10082534
SOC primary	*Injury, poisoning and procedural complications*		HLT primary	
			Anaesthetic and allied procedural complications	10080709
			SOC primary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment:

CR Number: 2018334006 **Implementation Date:** 05-Dec-18 Related CR: 2018334006

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*LAST*	Rejected		
To PT	*Systemic toxicity*			

MSSO Comment: The proposal to add a new LLT LAST to PT Systemic toxicity is not approved. LAST is a multiple-meaning acronym which does not only represent Local anesthetic systemic toxicity, but also other medical concepts, such as left anterior small thoracotomy, leukocyte-antigen sensitivity testing, or large-area sensing technology

Supplemental Update Report

CR Number: 2018334007 **Implementation Date:** 05-Dec-18 Related CR: 2018334007

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Transnasal humified rapid-insufflation ventilator exchange*	Approved as Requested	Proposed LLT *Transnasal humified rapid-insufflation ventilator exchange*	10082536 Current
To PT	*Mechanical ventilation*		To PT *Mechanical ventilation*	10067221

MSSO Comment: The proposal to add a new LLT Transnasal humified rapid-insufflation ventilator exchange to PT Mechanical ventilation is approved as requested. Transnasal humidified rapid-insufflation ventilatory exchange refers to the use of high-flow nasal cannula to augment the ability to oxygenate and ventilate a patient under general anesthesia, especially for those patients who have diminished or absent respiratory effort. It is also used to improve the safety of airway management during apnoea time before intubation in patients with difficult airways.

CR Number: 2018334008 **Implementation Date:** 05-Dec-18 Related CR: 2018334008

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*THRIVE*	Approved as Requested	Proposed LLT *THRIVE*	10082535 Current
To PT	*Mechanical ventilation*		To PT *Mechanical ventilation*	10067221

MSSO Comment: The proposal to add a new LLT THRIVE to PT Mechanical ventilation is approved as requested. THRIVE is an internationally recognized acronym for Transnasal humidified rapid-insufflation ventilatory exchange.

CR Number: 2018334009 **Implementation Date:** 05-Dec-18 Related CR: 2018334009

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Capnogram*	Approved as Requested	Proposed PT *Capnogram*	10082532
HLT primary	*Respiratory and pulmonary function diagnostic procedures*		HLT primary *Respiratory and pulmonary function diagnostic procedures*	10037385
SOC primary	*Investigations*		SOC primary *Investigations*	10022891

MSSO Comment: The proposal to add a new PT Capnogram to primary HLT Respiratory and pulmonary function diagnostic procedures in SOC Investigations is approved as requested. Capnography (or Capnogram) is the monitoring of the concentration or partial pressure of carbon dioxide (CO2) in the respiratory gases.

Supplemental Update Report

CR Number: 2018334010 **Implementation Date:** 05-Dec-18 Related CR: 2018334010

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Pancreatic cyst drainage*	Approved as Requested	Proposed PT	
HLT primary	*Pancreatic therapeutic procedures*		*Pancreatic cyst drainage*	10082531
SOC primary	*Surgical and medical procedures*		HLT primary	
			Pancreatic therapeutic procedures	10033634
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT Pancreatic cyst drainage to primary HLT Pancreatic therapeutic procedures in SOC Surgical and medical procedures is approved as requested. Pancreatic cyst drainage consists on the evacuation and analysis of a pancreatic cyst content through different techniques (such as percutaneous drainage, transendoscopic approach, and surgery), which is performed following the presence of symptoms, enlargement of cyst, complications (infection, hemorrhage, rupture, and obstruction), and suspicion of malignancy.

CR Number: 2018334011 **Implementation Date:** 05-Dec-18 Related CR: 2018334011

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Skin temperature*	Approved as Requested	Proposed PT	
HLT primary	*Physical examination procedures and organ system status*		*Skin temperature*	10082526
SOC primary	*Investigations*		HLT primary	
			Physical examination procedures and organ system status	10071941
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Skin temperature to primary HLT Physical examination procedures and organ system status in SOC Investigations is approved as requested. The skin keeps body temperature normal (37 °C). Skin temperature depends on air temperature and time spent in that environment, and is a significant variable to measure during physical examination.

Supplemental Update Report

CR Number: 2018334012 **Implementation Date:** 05-Dec-18 Related CR: 2018334012

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Starvation ketoacidosis*	Approved Not as Requested	Proposed PT	
To PT	*Metabolic acidosis*		*Starvation ketoacidosis*	10082528
			HLT primary	
			Metabolic acidoses (excl diabetic acidoses)	10027416
			SOC primary	
			Metabolism and nutrition disorders	10027433

MSSO Comment: The proposal to add a new LLT Starvation ketoacidosis to PT Metabolic acidosis is approved but not as requested. Eating disorders, diabetes, prolonged fasting, severely calorie-restricted diets, restricted access to food (low socioeconomic and elderly patients) may be causes of starvation ketoacidosis. Low insulin levels and high glucagon levels (such as in a fasting state), degrade long chain fatty acids and glycerol from triglycerides resulting in production of ketone bodies and subsequent metabolic acidosis. Starvation ketoacidosis will be added as a PT to HLT Metabolic acidoses (excl diabetic acidoses), consistent with placement of other types of ketoacidosis such PT Alcoholic ketoacidosis.

CR Number: 2018334013 **Implementation Date:** 05-Dec-18 Related CR: 2018334013

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Individual overdose*	Rejected		
To PT	*Overdose*			

MSSO Comment: The proposal to add a new LLT Individual overdose to PT Overdose is not approved. The proposed term does not have a clear definition and is may lead to ambiguity and misunderstanding.

Supplemental Update Report

CR Number: 2018334014 **Implementation Date:** 05-Dec-18 Related CR: 2018334014

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Infusion site eschar*	Approved as Requested	Proposed PT	
			Infusion site eschar	10082533
HLT primary	*Infusion site reactions*		HLT primary	
			Infusion site reactions	10068753
SOC primary	*General disorders and administration site conditions*		SOC primary	
			General disorders and administration site conditions	10018065
			HLT secondary	
			Infusion site reactions	10068753
			SOC secondary	
			Injury, poisoning and procedural complications	10022117

MSSO Comment: The proposal to add a new PT Infusion site eschar to primary HLT Infusion site reactions in SOC General disorders and administration site conditions is approved as requested. Eschar is dead tissue that sheds or falls off from healthy skin. Eschar is typically tan, brown, or black, and may be crusty. The HLGT Administration site reactions which is superior to HLT Infusion site reactions, is bi-axial, with the primary SOC as General disorders and administration site conditions and secondary SOC as Injury, poisoning and procedural complications. PT Infusion site eschar will also linked to secondary HLT Dermal and epidermal conditions NEC.

CR Number: 2018339005 **Implementation Date:** 05-Dec-18 Related CR: 2018334014

Change Requested	Link a PT to a HLT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Infusion site eschar*	Approved as Requested	Proposed PT	
			Infusion site eschar	10082533
To HLT	*Dermal and epidermal conditions NEC*		To HLT	
			Dermal and epidermal conditions NEC	10012424

MSSO Comment:

Supplemental Update Report

CR Number: 2018334015 **Implementation Date:** 05-Dec-18 Related CR: 2018334015

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Aspiration prophylaxis*	Approved as Requested	Proposed LLT *Aspiration prophylaxis* To PT *Respiratory disorder prophylaxis*	 10082537 Current 10081381

MSSO Comment: The proposal to add a new LLT Aspiration prophylaxis is approved as requested. Prevention of perioperative pulmonary aspiration is part of the process of preoperative evaluation and preparation of the patient. The American Society of Anesthesiologists (ASA) has published new “Practice guidelines for preoperative fasting and the use of pharmacologic agents to reduce the risk of pulmonary aspiration. Aspiration prophylaxis will be added as sub-concept LLT to PT Respiratory disorder prophylaxis.

CR Number: 2018334016 **Implementation Date:** 05-Dec-18 Related CR: 2018334016

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Prophylaxis of hypovolaemic shock*	Approved Not as Requested	Proposed PT *Prophylaxis of hypovolaemic shock* HLT primary *Prophylactic procedures NEC* SOC primary *Surgical and medical procedures*	 10082530 10036896 10042613

MSSO Comment: The proposal to add a new LLT Prophylaxis of hypovolaemic shock is approved but not as requested. As in other types of shock, systemic reduction in tissue perfusion leads to decreased oxygen delivery. Unless the initial process is reversed, prolonged oxygen deprivation causes cellular hypoxia and metabolic waste accumulation, leading to multisystem organ failure and death. Fortunately, early recognition of hypovolemic shock and aggressive treatment can dramatically improve the patient’s outcome. Prophylaxis of hypovolaemic shock will be added as PT to HLT Prophylactic procedures NEC. In a related change, the American English counterpart LLT Prophylaxis of hypovolamic shock will be added to the new PT Prophylaxis of hypovolaemic shock.

CR Number: 2018339006 **Implementation Date:** 05-Dec-18 Related CR: 2018334016

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Prophylaxis of hypovolamic shock*	Approved as Requested	Proposed LLT *Prophylaxis of hypovolamic shock* To PT *Prophylaxis of hypovolaemic shock*	 10082530
To PT	*Prophylaxis of hypovolaemic shock*			

MSSO Comment:

Supplemental Update Report

CR Number: 2018334017 **Implementation Date:** 05-Dec-18 Related CR: 2018334017

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Phase separation*	Approved Not as Requested	Proposed LLT	
To PT	*Liquid product physical issue*		*Liquid phase separation*	10082540 Current
			To PT	
			Liquid product physical issue	10069224

MSSO Comment: The proposal to add a new LLT Phase separation to PT Liquid product physical issue is approved but not as requested. Phase separation in amphiphilic systems (surfactants, polymers, drugs, etc.) is an important phenomenon. As the temperature of the solution increases, micellar solutions of some such amphiphilic systems separate into two phases: one surfactant-rich and another surfactant-poor. Phase separation will be renamed for clarification into Liquid phase separation and added as an LLT to PT Liquid product physical issue.

CR Number: 2018334018 **Implementation Date:** 05-Dec-18 Related CR: 2018334018

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Canda auris infection*	Approved Not as Requested	Proposed LLT	
To PT	*Candida infection*		*Candida auris infection*	10082541 Current
			To PT	
			Candida infection	10074170

MSSO Comment: The proposal to add a new LLT Canda auris infection to PT Candida infection is approved but not as requested. Candida auris has emerged as the multi-drug resistant non-albican candida species in critically ill patients admitted to intensive care units (ICU) causing bloodstream and other infections. The requested term Canda auris infection is mispelled and will be corrected to Candida auris infection and added as LLT to PT Candida infection.

CR Number: 2018334019 **Implementation Date:** 05-Dec-18 Related CR: 2018334019

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Lung assist device*	Approved Not as Requested	Proposed PT	
			Lung assist device therapy	10082527
			HLT primary	
			Haematological therapeutic procedures NEC	10052724
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new LLT Lung assist device is approved but not as requested. Artificial lung devices are membranes made of synthetic material that are connected to blood vessels through tubes and cannulas of silicone. The blood passing through the device is oxygenated and cleared of carbon dioxide. The requested term Lung assist device will be modified for clarification of a procedural concept and added PT Lung assist device therapy to HLT Haematological therapeutic procedures NEC. In a related change, PT Extracorporeal membrane oxygenation will be demoted under the new PT Lung assist device therapy as sub-concept LLT.

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CR Number: 2018339007 **Implementation Date:** 05-Dec-18 Related CR: 2018334019

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Extracorporeal membrane oxygenation*	Approved as Requested	PT to merge	
To PT	*Lung assist device therapy*		*Extracorporeal membrane oxygenation*	10053054 Current
			To PT	
			Lung assist device therapy	10082527

MSSO Comment:

CR Number: 2018334020 **Implementation Date:** 05-Dec-18 Related CR: 2018334020

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Bronchial leiomyoma*	Approved Not as Requested	Proposed LLT	
To PT	*Leiomyoma*		*Bronchial leiomyoma*	10082538 Current
			To PT	
			Bronchial neoplasm benign	10052247

MSSO Comment: The proposal to add a new LLT Bronchial leiomyoma to PT Leiomyoma is approved but not as requested. An endobronchial leiomyoma is a rare tumor of the bronchial tree. Very few cases have been reported in literature. Leiomyomas account for less than 2% of all benign lung tumors. Bronchial leiomyoma will be added as an LLT to PT Bronchial neoplasm benign in lieu of the requested PT Leiomyoma for representation in the SOC of manifestation.

CR Number: 2018334021 **Implementation Date:** 05-Dec-18 Related CR: 2018334021

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Blood volume expansion*	Approved Not as Requested	Proposed PT	
HLT primary	*Therapeutic procedures NEC*		*Blood volume expansion*	10082529
SOC primary	*Surgical and medical procedures*		HLT primary	
			Blood and blood product treatment	10019028
			SOC primary	
			Surgical and medical procedures	10042613

MSSO Comment: The proposal to add a new PT Blood volume expansion to primary HLT Therapeutic procedures NEC in SOC Surgical and medical procedures is approved but not as requested. Blood volume expansion refers to the treatment with substances that can be transfused to maintain fluid volume of the blood in event of great necessity, supplemental to the use of whole blood and plasma. Blood volume expansion will be added as a PT to HLT Blood and blood product treatment, the more specific HLT. In a related change, PT Plasma expander transfusion will be demoted under new PT Blood volume expansion as an sub-concept LLT.

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CR Number: 2018339008 **Implementation Date:** 05-Dec-18 Related CR: 2018334021

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Plasma expander transfusion*	Approved as Requested	PT to merge	
To PT	*Blood volume expansion*		*Plasma expander transfusion*	10035288 Current
			To PT	
			Blood volume expansion	10082529

MSSO Comment:

CR Number: 2018334022 **Implementation Date:** 05-Dec-18 Related CR: 2018334022

Change Requested	Promote an LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Tyrosine increased*	Rejected		
From PT	*Amino acid level increased*			

MSSO Comment: The proposal to promote the LLT Tyrosine increased from PT Amino acid level increased is not approved. Promotion of the requested term would be inconsistent with the representation of other amino-acid levels in MedDRA. The differentiation of events of tyrosinemia type I can be obtained by using the disorder related code Tyrosinemia type I

CR Number: 2018334023 **Implementation Date:** 05-Dec-18 Related CR: 2018334023

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Acute toxic metabolic encephalopathy*	Approved as Requested	Proposed LLT	
			Acute toxic metabolic encephalopathy	10082516 Current
			To PT	
			Toxic encephalopathy	10044221

MSSO Comment: The proposal to add a new term Acute toxic metabolic encephalopathy is approved as requested. Acute toxic-metabolic encephalopathy, which encompasses delirium and the acute confusional state, is an acute condition of global cerebral dysfunction in the absence of primary structural brain disease. Exposure to a toxic substance, results in a metabolic encephalopathy. Examples of such toxins include: carbon monoxide or cyanide poisoning, medication side effects or drug ingestions affecting the chemical transmitters in the brain, heavy metals such as manganese; exposure to extreme concentrations of any natural toxin such as cyanotoxins found in shellfish or freshwater cyanobacteria crusts, etc. Acute toxic metabolic encephalopathy will be added as a sub-concept LLT to PT Toxic encephalopathy.

Supplemental Update Report

CR Number: 2018334024 **Implementation Date:** 05-Dec-18 Related CR: 2018334024

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Overflow diarrhea*	Approved as Requested	Proposed LLT *Overflow diarrhea*	10082509 Current
			To PT *Diarrhoea*	10012735

MSSO Comment: The proposal to add a new term Overflow diarrhea is approved as requested. Overflow diarrhea (also called Paradoxical diarrhea, overflow incontinence, spurious diarrhea) may occur in a person who has chronic constipation. In overflow diarrhea, stool fills the rectum, hardens and becomes impacted. Liquid stool leaks around the fecal mass, imitating incontinence. Overflow diarrhea will be added as a sub-concept LLT to PT Diarrhoea. In a related change, the British English spelling counterpart LLT Overflow diarrhoea will be added to PT Diarrhoea.

CR Number: 2018339001 **Implementation Date:** 05-Dec-18 Related CR: 2018334024

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Overflow diarrhoea*	Approved as Requested	Proposed LLT *Overflow diarrhoea*	10082507 Current
To PT	*Diarrhoea*		To PT *Diarrhoea*	10012735

MSSO Comment:

CR Number: 2018334025 **Implementation Date:** 05-Dec-18 Related CR: 2018334025

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Stent graft endoleak type 1*	Approved Not as Requested	Proposed LLT *Stent graft endoleak type I*	10082520 Current
			To PT *Stent-graft endoleak*	10064396

MSSO Comment: The proposal to add a new LLT Stent graft endoleak type 1 is approved but not as requested. A Type I endoleak occurs when there is a gap between the graft and the vessel wall at “seal zones.” The gap allows blood to flow along the side of the graft into the aneurysm sac, which creates pressure within the sac and increases the risk of sac rupture. Stent graft endoleak type I will thus be added, with Roman numeral, as a sub-concept LLT to PT Stent-graft endoleak.

Supplemental Update Report

CR Number: 2018334026 **Implementation Date:** 05-Dec-18 Related CR: 2018334026

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Game keepers thumb*	Approved as Requested	Proposed LLT	
To PT	*Ligament sprain*		*Game keepers thumb*	10082517 Current
			To PT	
			Ligament sprain	10024453

MSSO Comment: The proposal to add a new LLT Game keepers thumb to PT Ligament sprain is approved as requested. Gamekeeper's thumb (also known as skier's thumb or UCL tear) is a type of injury to the ulnar collateral ligament of the thumb. The ulnar collateral ligament may be torn, damaged or in some cases avulsed from its insertion site into the proximal phalanx of the thumb in the vast majority (approximately 90%) of cases.

CR Number: 2018334027 **Implementation Date:** 05-Dec-18 Related CR: 2018334027

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Low grade fever*	Approved as Requested	Proposed LLT	
To PT	*Pyrexia*		*Low grade fever*	10082521 Current
			To PT	
			Pyrexia	10037660

MSSO Comment: The proposal to add a new LLT Low grade fever to PT Pyrexia is approved as requested. Low-grade fever is a common clinical description that is usually classified as an oral temperature that is above 98.6° F (37° C) but lower than 100.4° F (38° C) for a period of 24 hours. Low grade fever will be added as a sub-concept LLT to PT Pyrexia.

CR Number: 2018334028 **Implementation Date:** 05-Dec-18 Related CR: 2018334028

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Tobacco arthritis*	Rejected		

MSSO Comment: The proposal to add a new term Tobacco arthritis is not approved. Heavy cigarette smoking is markedly more prevalent in patients with rheumatoid arthritis who do not have a family history of rheumatoid arthritis. Although smoking tobacco is an established risk factor for rheumatoid arthritis, "tobacco arthritis" is not a universally recognized diagnostic term.

Supplemental Update Report

CR Number: 2018334029 **Implementation Date:** 05-Dec-18 Related CR: 2018334029

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Venous hypertension*	Approved as Requested	Proposed PT	
			Venous hypertension	10082503
			HLT primary	
			Vascular hypertensive disorders NEC	10020774
			SOC primary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new term Venous hypertension is approved as requested. The symptoms associated with varicose veins are caused by an underlying venous circulatory problem and called venous hypertension or high blood pressure inside the vein. Venous hypertension will be added as a PT to HLT Vascular hypertensive disorders NEC.

CR Number: 2018334030 **Implementation Date:** 05-Dec-18 Related CR: 2018334030

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Venous hypertension of legs*	Approved Not as Requested	Proposed LLT	
To PT	*Peripheral Venous Disease*		*Venous hypertension of legs*	10082510 Current
			To PT	
			Venous hypertension	10082503

MSSO Comment: The proposal to add a new LLT Venous hypertension of legs to PT Peripheral Venous Disease is approved but not as requested. The symptoms associated with varicose veins are caused by an underlying venous circulatory problem and called venous hypertension or high blood pressure inside the vein. Venous hypertension of legs will be added as sub-concept LLT to new PT Venous hypertension, added in change request 2018334029.

CR Number: 2018334031 **Implementation Date:** 05-Dec-18 Related CR: 2018334031

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Ischemic wound*	Approved as Requested	Proposed LLT	
			Ischemic wound	10082524 Current
			To PT	
			Ischaemic skin ulcer	10077408

MSSO Comment: The proposal to add a new term Ischemic wound is approved as requested. Ischemic ulcers (wounds) can occur when there is poor blood flow in your legs. Ischemic means reduced blood flow to an area of the body. Poor blood flow causes cells to die and damages tissue. Most ischemic ulcers occur on the feet and legs. These types of wounds can be slow to heal. Ischemic wound will be added as synonym LLT to PT Ischaemic skin ulcer. In a related change, the British English spelled counterpart Ischaemic wound will also be added to PT Ischaemic skin ulcer.

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CR Number: 2018339002 **Implementation Date:** 05-Dec-18 Related CR: 2018334031

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ischaemic wound*	Approved as Requested	Proposed LLT	
To PT	*Ischaemic skin ulcer*		*Ischaemic wound*	10082508 Current
			To PT	
			Ischaemic skin ulcer	10077408

MSSO Comment:

CR Number: 2018334032 **Implementation Date:** 05-Dec-18 Related CR: 2018334032

Change Requested	Add a New Term	Final Disposition	Final Placement	MedDRA Code #
Proposed Term	*Aorta pseudoaneurysm*	Approved Not as Requested	Proposed PT	
			Aortic pseudoaneurysm	10082505
			HLT primary	
			Cardiac and vascular procedural complications	10007602
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Site specific vascular disorders NEC	10057188
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new term Aorta pseudoaneurysm is approved but not as requested. A pseudoaneurysm, also known as a false aneurysm, is a collection of blood that forms between the two outer layers of an artery, the tunica media and the tunica adventitia. The causes of pseudoaneurysms are diverse, and include trauma,3) infection,4) inflammation,5) and various iatrogenic events (e.g., surgery, catheterization, and percutaneous procedures). However, aortic pseudoaneurysms are most frequently associated with postoperative anastomotic complications. Aorta pseudoaneurysm will be phrased as Aortic pseudoaneurysm, the more commonly used term for this concept, and added as a PT to primary HLT Cardiac and vascular procedural complications, and to secondary HLT Site specific vascular disorders NEC.

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CR Number: **2018334033** **Implementation Date:** 05-Dec-18 Related CR: 2018334033

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Ischaemic Wound*	Rejected		

MSSO Comment: The proposal to add a new PT Ischaemic Wound is not approved. Please see change request 2018334031 where the British English spelled LLT Ischaemic wound has been added in a related change to PT Ischaemic skin ulcer.

CR Number: **2018334034** **Implementation Date:** 05-Dec-18 Related CR: 2018334034

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ischaemic wound of limb*	Approved as Requested	Proposed LLT *Ischaemic wound of limb* To PT *Ischaemic skin ulcer*	 10082525 Current 10077408

MSSO Comment: The proposal to add a new LLT Ischaemic wound of limb is approved as requested. Ischaemic wounds and ischaemic ulcers are synonymously used. Therefore, Ischaemic wound of limb will be added as sub-concept LLT to PT Ischaemic skin ulcer. In a related change, American English spelled counterpart LLT Ischemic wound of limb will also be added to PT Ischaemic skin ulcer.

CR Number: **2018339003** **Implementation Date:** 05-Dec-18 Related CR: 2018334034

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ischemic wound of limb*	Approved as Requested	Proposed LLT *Ischemic wound of limb* To PT *Ischaemic skin ulcer*	 10082506 Current 10077408
To PT	*Ischaemic skin ulcer*			

MSSO Comment:

Supplemental Update Report

CR Number: 2018334035 **Implementation Date:** 06-Dec-18 Related CR: 2018334035

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Procedural difficulty*	Rejected After Suspension		

MSSO Comment: The proposal to add a new LLT Procedural difficulty is not approved after suspension. The requested term Procedural difficulty is ambiguous as it can refer to either a difficult procedure or to difficulty (problem) during a procedure.

CR Number: 2018334036 **Implementation Date:** 05-Dec-18 Related CR: 2018334036

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Vessel recoil*	Approved Not as Requested	Proposed PT	
			Elastic vessel recoil complication	10082504
			HLT primary	
			Cardiac and vascular procedural complications	10007602
			SOC primary	
			Injury, poisoning and procedural complications	10022117
			HLT secondary	
			Site specific vascular disorders NEC	10057188
			SOC secondary	
			Vascular disorders	10047065

MSSO Comment: The proposal to add a new LLT Vessel recoil is approved but not as requested. Elastic recoil in any tissue (including arteries) refers to the inherent resistance of a tissue to changes in shape, and the tendency of the tissue to revert to its original shape once deformed. The elasticity in arteries gives rise to Windkessel Effect which helps to maintain a relatively constant pressure in the arteries despite the pulsating nature of the blood flow. Elastic recoil of the arterial wall has been shown to be responsible for a significant loss of luminal area after balloon angioplasty. The requested term will be modified for clarification to Elastic vessel recoil complication and added as PT to primary HLT Cardiac and vascular procedural complications and secondary HLT Site specific vascular disorders NEC.

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CR Number: 2018334037 **Implementation Date:** 05-Dec-18 Related CR: 2018334037

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Coronary vessel recoil*	Approved as Requested	Proposed LLT	
			Coronary vessel recoil	10082511 Current
			To PT	
			Elastic vessel recoil complication	10082504

MSSO Comment: The proposal to add a new LLT Coronary vessel recoil is approved as requested. Elastic recoil of coronary artery is defined as the difference between the maximal diameter of the inflated balloon and the minimal luminal diameter of the dilated segment immediately after the procedure and can be evaluated by quantitative coronary angiography. Elastic recoil of the arterial wall has been shown to be responsible for a significant loss of luminal area after balloon angioplasty in the coronary arteries. Coronary vessel recoil will be added as sub-concept LLT to newly added PT Elastic vessel recoil complication added in change request 2018334036.

CR Number: 2018334038 **Implementation Date:** 05-Dec-18 Related CR: 2018334038

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Peripheral artery recoil*	Approved as Requested	Proposed LLT	
			Peripheral artery recoil	10082518 Current
			To PT	
			Elastic vessel recoil complication	10082504

MSSO Comment: The proposal to add a new LLT Peripheral artery recoil is approved as requested. Elastic recoil in any tissue (including arteries) refers to the inherent resistance of a tissue to changes in shape, and the tendency of the tissue to revert to its original shape once deformed. Elastic recoil of the arterial wall has been shown to be responsible for a significant loss of luminal area after balloon angioplasty in the peripheral arteries. Peripheral artery recoil will be added as sub-concept LLT to the newly added PT Elastic vessel recoil complication added in change request 2018334036.

CR Number: 2018334039 **Implementation Date:** 05-Dec-18 Related CR: 2018334039

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Recurrent stroke*	Approved as Requested	Proposed LLT	
			Recurrent stroke	10082513 Current
			To PT	
			Cerebrovascular accident	10008190

MSSO Comment: The proposal to add a new LLT Recurrent stroke is approved as requested. LLT Recurrent stroke will be added as sub-concept LLT to PT Cerebrovascular accident, complementing existing LLT Recurrent contralateral stroke and LLT Recurrent ipsilateral stroke.

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CR Number: 2018334040 **Implementation Date:** 05-Dec-18 Related CR: 2018334040

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Stroke recrudescence*	Approved as Requested	Proposed LLT	
			Stroke recrudescence	10082519 Current
			To PT	
			Cerebrovascular accident	10008190

MSSO Comment: The proposal to add a new LLT Stroke recrudescence is approved as requested. Stroke recrudescence represents a transient worsening of poststroke neurologic deficits or reemergence of previous stroke-related deficits. Stroke recrudescence will be added as an LLT under PT Cerebrovascular accident.

CR Number: 2018334041 **Implementation Date:** 05-Dec-18 Related CR: 2018334041

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*TIA recrudescence*	Approved as Requested	Proposed LLT	
			TIA recrudescence	10082523 Current
			To PT	
			Transient ischaemic attack	10044390

MSSO Comment: The proposal to add a new LLT TIA recrudescence is approved as requested. Transient ischaemic attack recrudescence represents a worsening of neurologic deficits or reemergence of previous stroke-related ones, which need to be differentiated from a TIA recurrence. TIA recrudescence will be added as an LLT to PT Transient ischaemic attack, in alignment with LLT Recurrent TIA.

CR Number: 2018334042 **Implementation Date:** 05-Dec-18 Related CR: 2018334042

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Typical atrial flutter*	Approved as Requested	Proposed LLT	
			Typical atrial flutter	10082512 Current
			To PT	
			Atrial flutter	10003662

MSSO Comment: The proposal to add a new LLT Typical atrial flutter is approved as requested. Atrial flutter is divided into 2 major categories: cavotricuspid isthmus (CVI) dependent flutter (ie, typical flutter) and atypical flutter (ie, non-CVI dependent). In a Typical atrial flutter the flutter has a macro-reentrant circuit in the right atrium and the direction of propagation is usually counterclockwise around the cavotricuspid isthmus. The propagation can also be clockwise, and as long as it is around the cavotricuspid isthmus, it is still considered a typical flutter. Typical atrial flutter will be added as a sub-element LLT to PT Atrial flutter.

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CR Number: 2018334043 **Implementation Date:** 05-Dec-18 Related CR: 2018334043

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Atypical atrial flutter*	Approved as Requested	Proposed LLT	
			Atypical atrial flutter	10082514 Current
			To PT	
			Atrial flutter	10003662

MSSO Comment: The proposal to add a new LLT Atypical atrial flutter is approved as requested. Atrial flutter is divided into 2 major categories: cavotricuspid isthmus (CVI) dependent flutter (ie, typical flutter) and atypical flutter (ie, non-CVI dependent). Atypical atrial flutter by definition does not involve cavotricuspid isthmus. It usually occurs in structurally abnormal hearts; for example, after cardiac surgery around suture lines or after radiofrequency ablation. It can also occur around scarring in cardiomyopathies. Atypical atrial flutter occurs rarely in normal hearts. Atypical atrial flutter will be added as a sub-element LLT of PT Atrial flutter.

CR Number: 2018334044 **Implementation Date:** 05-Dec-18 Related CR: 2018334044

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Popliteal artery thrombosis*	Approved as Requested	Proposed LLT	
			Popliteal artery thrombosis	10082522 Current
			To PT	
			Peripheral artery thrombosis	10072564

MSSO Comment: The proposal to add a new LLT Popliteal artery thrombosis is approved as requested. The popliteal artery is a relatively short vascular segment but is affected by a unique set of pathologic conditions, including atherosclerosis. An arteriosclerotic plaque may limit blood flow and finally cause thrombosis of the vessel. Acute thrombotic occlusion of the popliteal artery may also result from trauma or following surgery. Popliteal artery thrombosis will be added as sub-concept LLT to PT Peripheral artery thrombosis.

CR Number: 2018334045 **Implementation Date:** 05-Dec-18 Related CR: 2018334045

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Ventricular arrest*	Approved as Requested	Proposed LLT	
			Ventricular arrest	10082515 Current
			To PT	
			Cardiac arrest	10007515

MSSO Comment: The proposal to add a new LLT Ventricular arrest is approved as requested. Since ventricles are the main actors in expelling the blood towards the peripheral beds within the body and lungs, Ventricular arrest can be considered a sub-element LLT of PT Cardiac arrest.

Supplemental Update Report

CR Number: 2018334046 **Implementation Date:** 06-Dec-18 Related CR: 2018334046

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Limbal swelling*	Rejected		
Replacement term	*Limb swelling*			

MSSO Comment: The proposal to rename PT/LLT Limbal swelling to Limb swelling is not approved. PT/LLT Limbal swelling is not synonymous with LLT Swelling of limb and it is appropriately phrased and placed under HLT Ocular infections, inflammations and associated manifestations. The limbus is the junction of conjunctival and corneal tissue at the periphery of the cornea, and can be edematous or swollen in a variety of conditions, such as vernal keratoconjunctivitis.

CR Number: 2018334047 **Implementation Date:** 06-Dec-18 Related CR: 2018334047

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Phantom Limb Syndrome*	Approved Not as Requested	Proposed PT	
			Phantom limb syndrome	10082544
			HLT primary	
			Sensory abnormalities NEC	10040021
			SOC primary	
			Nervous system disorders	10029205
			HLT secondary	
			Pain and discomfort NEC	10033372
			SOC secondary	
			General disorders and administration site conditions	10018065

MSSO Comment: The proposal to add a new LLT Phantom Limb Syndrome is approved but not as requested. Phantom limb syndrome (occurring in 50% to 80% of both traumatic and operative amputees) is characterized by pain, sensory alterations and the feeling that all or a part of the amputated limb is still present. Phantom Limb Syndrome will be corrected according to MedDRA capitalization conventions to PT Phantom limb syndrome and added as a PT to primary HLT Sensory abnormalities NEC and secondary HLT Pain and discomfort NEC. In a related change, the current PT Phantom pain will be demoted underneath new PT Phantom limb syndrome.

Supplemental Update Report

CR Number: 2018339009 **Implementation Date:** 06-Dec-18 Related CR: 2018334047

Change Requested	Demote a PT	Final Disposition	Final Placement	MedDRA Code #
PT to merge	*Phantom pain*	Approved as Requested	PT to merge	
To PT	*Phantom limb syndrome*		*Phantom pain*	10056238 Current
			To PT	
			Phantom limb syndrome	10082544

MSSO Comment:

CR Number: 2018334058 **Implementation Date:** 06-Dec-18 Related CR: 2018334058

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Fracture of astragalus, closed*	Approved as Requested	Proposed LLT	
From PT	*Foot fracture*		*Fracture of astragalus, closed*	10017094 Current
To PT	*Ankle fracture*		From PT	
			Foot fracture	10016970
			To PT	
			Ankle fracture	10002544

MSSO Comment: The proposal to move the LLT Fracture of astragalus, closed from PT Foot fracture to PT Ankle fracture is approved as requested. The proposed move results in better conceptual alignment as astragalus is a synonym of talus or ankle bone.

CR Number: 2018334059 **Implementation Date:** 06-Dec-18 Related CR: 2018334059

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Fracture of astragalus, open*	Approved as Requested	Proposed LLT	
From PT	*Foot fracture*		*Fracture of astragalus, open*	10017095 Current
To PT	*Ankle fracture*		From PT	
			Foot fracture	10016970
			To PT	
			Ankle fracture	10002544

MSSO Comment: The proposal to move the LLT Fracture of astragalus, open from PT Foot fracture to PT Ankle fracture is approved as requested. The proposed move results in better conceptual alignment as astragalus is a synonym of talus or ankle bone.

Supplemental Update Report

CR Number: 2018339010 **Implementation Date:** 06-Dec-18 Related CR: 2018339010

Change Requested	Add a New PT	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Muscle mass percentage*	Approved as Requested	Proposed PT	
HLT primary	*Musculoskeletal and soft tissue tests NEC*		*Muscle mass percentage*	10082553
SOC primary	*Investigations*		HLT primary	
			Musculoskeletal and soft tissue tests NEC	10028394
			SOC primary	
			Investigations	10022891

MSSO Comment: The proposal to add a new PT Muscle mass percentage to primary HLT Musculoskeletal and soft tissue tests NEC in SOC Investigations is approved as requested. Muscle mass percentage is the percentage of muscle in the body as compared to the total body weight.

CR Number: 2018340001 **Implementation Date:** 07-Dec-18 Related CR: 2018340001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Taste disturbance*	Approved as Requested	Proposed LLT	
From PT	*Dysgeusia*		*Taste disturbance*	10043132 Current
To PT	*Taste disorder*		From PT	
			Dysgeusia	10013911
			To PT	
			Taste disorder	10082490

MSSO Comment: The proposal to move the LLT Taste disturbance from PT Dysgeusia to PT Taste disorder is approved as requested. Taste disturbance is broader than Dysgeusia and better represented under newly added PT Taste disorder see change request 2018333044. In related change and for a similiar reason, the following LLTs will be moved from PT Dysgeusia to PT Taste disorder: LLT Taste abnormality, LLT Taste alteration, LLT Taste altered, and LLT Taste changed.

CR Number: 2018341001 **Implementation Date:** 07-Dec-18 Related CR: 2018340001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Taste abnormality*	Approved as Requested	Proposed LLT	
From PT	*Dysgeusia*		*Taste abnormality*	10043123 Current
To PT	*Taste disorder*		From PT	
			Dysgeusia	10013911
			To PT	
			Taste disorder	10082490

MSSO Comment:

Supplemental Update Report

CR Number: 2018341002 **Implementation Date:** 07-Dec-18 Related CR: 2018340001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Taste alteration*	Approved as Requested	Proposed LLT	
From PT	*Dysgeusia*		*Taste alteration*	10043125 Current
To PT	*Taste disorder*		From PT	
			Dysgeusia	10013911
			To PT	
			Taste disorder	10082490

MSSO Comment:

CR Number: 2018341003 **Implementation Date:** 07-Dec-18 Related CR: 2018340001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Taste altered*	Approved as Requested	Proposed LLT	
From PT	*Dysgeusia*		*Taste altered*	10043126 Current
To PT	*Taste disorder*		From PT	
			Dysgeusia	10013911
			To PT	
			Taste disorder	10082490

MSSO Comment:

CR Number: 2018341004 **Implementation Date:** 07-Dec-18 Related CR: 2018340001

Change Requested	Link (move) an LLT to another PT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Taste changed*	Approved as Requested	Proposed LLT	
From PT	*Dysgeusia*		*Taste changed*	10043129 Current
To PT	*Taste disorder*		From PT	
			Dysgeusia	10013911
			To PT	
			Taste disorder	10082490

MSSO Comment:

Supplemental Update Report

CR Number: 2018341009 **Implementation Date:** 12-Dec-18 Related CR: 2018341009

Change Requested	Rename PT/LLT	Final Disposition	Final Placement	MedDRA Code #
Term to modify	*Prophylaxis of hypovolamic shock*	Approved as Requested	Term to modify	
Replacement term	*Prophylaxis of hypovolemic shock*		*Prophylaxis of hypovolamic shock*	
			Replacement term	
			Prophylaxis of hypovolemic shock	10082543 Current

MSSO Comment: The proposal to rename PT/LLT Prophylaxis of hypovolamic shock to Prophylaxis of hypovolemic shock is approved as requested. In change request 2018339006 the LLT Prophylaxis of hypovolamic shock was added as the US spelling counterpart to the new British PT Prophylaxis of hypovolaemic shock. This is misspelled and should instead be spelled as Prophylaxis of hypovolemic shock.

CR Number: 2018341010 **Implementation Date:** 12-Dec-18 Related CR: 2018341010

Change Requested	Add a New LLT	Final Disposition	Final Placement	MedDRA Code #
Proposed LLT	*Anesthesia oral*	Approved as Requested	Proposed LLT	
To PT	*Anaesthesia oral*		*Anesthesia oral*	10082563 Current
			To PT	
			Anaesthesia oral	10082548

MSSO Comment: The proposal to add a new LLT Anesthesia oral to PT Anaesthesia oral is approved as requested. LLT Anesthesia oral is the US spelling counterpart to the British spelling PT Anaesthesia oral added in change request 2018333010.

CR Number: 2018341011 **Implementation Date:** 11-Dec-18 Related CR: 2018341011

Change Requested	Reassign Primary SOC	Final Disposition	Final Placement	MedDRA Code #
Proposed PT	*Breast implant-associated anaplastic large cell lymphoma*	Approved as Requested	Proposed PT	
			Breast implant-associated anaplastic large cell lymphoma	10082495
Old Primary SOC	*Blood and lymphatic system disorders*		Old Primary SOC	
			Blood and lymphatic system disorders	10005329
New Primary SOC	*Neoplasms benign, malignant and unspecified (incl cysts and polyps)*		New Primary SOC	
			Neoplasms benign, malignant and unspecified (incl cysts and polyps)	10029104

MSSO Comment: The proposal to reassign the primary SOC of PT Breast implant-associated anaplastic large cell lymphoma from current SOC Blood and lymphatic system disorders to SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is approved as requested. The primary SOC of PT Breast implant-associated anaplastic large cell lymphoma should be SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps).