

# Supplemental Update Report

CR Number: 2019121002      Implementation Date: 29-May-19      Related CR: 2019121002

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT      Add a New PT <i>Alexander disease</i>	Approved After Suspension	Proposed PT <i>Alexander disease</i>	10083059
		HLT primary <i>Central nervous system disorders congenital NEC</i>	10009713
		SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
		HLT secondary <i>Leukodystrophies</i>	10068202
		SOC secondary <i>Nervous system disorders</i>	10029205

MSSO Comment: The proposal to add a new PT Alexander disease is approved as requested after suspension. Alexander disease is a type of leukodystrophy that is histologically characterized by eosinophilic (abnormal protein deposits) material known as Rosenthal fibers at the surface of the brain and around its blood vessels. Its most common infantile form may result in hydrocephaly, megalencephaly, seizures, stiffness in the arms and/or legs (spasticity/ spastic quadriparesis), intellectual disability, developmental delay, and progressive psychomotor retardation. Less frequently, onset occurs later in childhood (juvenile form) or in adulthood. Alexander disease will be added as a PT to primary HLT Central nervous system disorders congenital NEC and secondary HLT Leukodystrophies. In a related change, PT Leukodystrophy will be moved from HLT Demyelinating disorders NEC to HLT Leukodystrophies for better alignment.

CR Number: 2019148024      Implementation Date: 29-May-19      Related CR: 2019121002

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT      Link (move) a PT to another HLT <i>Leukodystrophy</i>	Approved as Requested	Proposed PT <i>Leukodystrophy</i>	10024381
From HLT <i>Demyelinating disorders NEC</i>		From HLT <i>Demyelinating disorders NEC</i>	10012302
To HLT <i>Leukodystrophies</i>		To HLT <i>Leukodystrophies</i>	10068202

MSSO Comment:

# Supplemental Update Report

CR Number: 2019121003 Implementation Date: 29-May-19 Related CR: 2019121003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
LLT to change	<i>Lepromatous leprosy (type I)</i>	Approved After Suspension	LLT to change	
Status	<i>non-current</i>		<i>Lepromatous leprosy (type I)</i>	10024228 Non-Current
			Status	
			<i>non-current</i>	

MSSO Comment: The proposal to change status of LLT Lepromatous leprosy (type I) to non-current is approved as requested after suspension. LLT Lepromatous leprosy (type I) is ambiguous and not consistent with classifications (can refer to Indeterminate - I leprosy Preclinical state- Lepromatous usually is LL - the "types" refer to Tuberculoid leprosy vs. lepromatous leprosy vs. borderline leprosy (Ridley and Jopling; TT, BB, BL, LL).

CR Number: 2019121004 Implementation Date: 29-May-19 Related CR: 2019121004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Rhinobronchial syndrome</i>	Approved Not as Requested After Suspension	Proposed LLT	
HLT primary	<i>Respiratory tract disorders NEC</i>		<i>Rhinobronchial syndrome</i>	10083062 Current
SOC primary	<i>Respiratory, thoracic and mediastinal disorders</i>		To PT	
			<i>Upper-airway cough syndrome</i>	10070488

MSSO Comment: The proposal to add a new PT Rhinobronchial syndrome to primary HLT Respiratory tract disorders NEC in SOC Respiratory, thoracic and mediastinal disorders is approved but not as requested after suspension. Rhinobronchial syndrome, synonym of post nasal drip, will be added as an LLT to PT Upper-airway cough syndrome.

# Supplemental Update Report

CR Number: 2019121005 Implementation Date: 29-May-19 Related CR: 2019121005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Near death experience</i>	Approved Not as Requested After Suspension	Proposed LLT	
From PT	<i>Apparent death</i>		<i>Near death experience</i>	10068111
HLT primary	<i>Perception disturbances NEC</i>		From PT	
			<i>Apparent death</i>	10067476
			HLT primary	
			<i>Disturbances in consciousness NEC</i>	10013509
			SOC primary	
			<i>Nervous system disorders</i>	10029205
			HLT secondary	
			<i>Perception disturbances NEC</i>	10082213
			SOC secondary	
			<i>Psychiatric disorders</i>	10037175

MSSO Comment: The proposal to promote the LLT Near death experience from PT Apparent death to primary HLT Perception disturbances NEC in SOC Psychiatric disorders is approved but not as requested after suspension. Near death experience will be promoted from PT Apparent death to a PT Level, but primarily linked to primary HLT Disturbances in consciousness NEC and secondary HLT Perception disturbances NEC.

CR Number: 2019121006 Implementation Date: 29-May-19 Related CR: 2019121006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Viral load abnormal</i>	Approved After Suspension	Proposed PT	
HLT primary	<i>Virus identification and serology</i>		<i>Viral load abnormal</i>	10083060
SOC primary	<i>Investigations</i>		HLT primary	
			<i>Virus identification and serology</i>	10047490
			SOC primary	
			<i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Viral load abnormal to primary HLT Virus identification and serology in SOC Investigations is approved as requested after suspension. Viral load is usually used to describe the amount of HIV in a body fluid either quantitatively, or qualitatively as high, medium, or low. It does not appear to commonly be reported as abnormal.

# Supplemental Update Report

CR Number: 2019121007 Implementation Date: 29-May-19 Related CR: 2019121007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Exposure to Fungi</i>	Approved Not as Requested After Suspension	Proposed PT <i>Exposure to fungus</i>	10083061
HLT primary	<i>Exposures to agents or circumstances NEC</i>		HLT primary <i>Exposures to agents or circumstances NEC</i>	10073304
SOC primary	<i>Injury, poisoning and procedural complications</i>		SOC primary <i>Injury, poisoning and procedural complications</i>	10022117

MSSO Comment: The proposal to add a new PT Exposure to Fungi to primary HLT Exposures to agents or circumstances NEC in SOC Injury, poisoning and procedural complications is approved but not as requested after suspension. The requested concept will be added as PT Exposure to fungus in accordance to MedDRA capitalization conventions and in singular form, to HLT Exposures to agents or circumstances NEC. In a related change PT Exposure to mould will demoted under new PT Exposure to fungus as a sub-concept LLT.

CR Number: 2019148025 Implementation Date: 29-May-19 Related CR: 2019121007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	Demote a PT <i>Exposure to mould</i>	Approved as Requested	PT to merge <i>Exposure to mould</i>	10072074 Current
To PT	<i>Exposure to fungus</i>		To PT <i>Exposure to fungus</i>	10083061

MSSO Comment:

# Supplemental Update Report

CR Number: 2019133002      Implementation Date: 29-May-19      Related CR: 2019133002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Promote an LLT <i>Drug delivery system issue</i>	Approved After Suspension	Proposed LLT <i>Drug delivery system issue</i>	10074961
From PT	<i>Device issue</i>		From PT <i>Device issue</i>	10069868
			HLT primary <i>Product quality issues NEC</i>	10069324
			SOC primary <i>Product issues</i>	10077536

MSSO Comment: The proposal to promote the LLT Drug delivery system issue from PT Device issue is approved as requested after suspension. Drug delivery system issues are not always device related and are therefore represented at PT level. Drug delivery system issue will be promoted from PT Device issue to a PT level and linked to HLT Product quality issues NEC. In a related change, for the same reason LLT Drug delivery system malfunction will be promoted from PT Device malfunction to a PT level and linked to HLT Product quality issues NEC.

CR Number: 2019148023      Implementation Date: 29-May-19      Related CR: 2019133002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Promote an LLT <i>Drug delivery system malfunction</i>	Approved as Requested	Proposed LLT <i>Drug delivery system malfunction</i>	10068383
From PT	<i>Device malfunction</i>		From PT <i>Device malfunction</i>	10063829
HLT primary	<i>Product quality issues NEC</i>		HLT primary <i>Product quality issues NEC</i>	10069324
			SOC primary <i>Product issues</i>	10077536

MSSO Comment:

# Supplemental Update Report

CR Number: 2019135004      Implementation Date: 29-May-19      Related CR: 2019135004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Habit cough</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Respiratory, thoracic and mediastinal disorders</i>		<i>Habit cough</i>	10082913
New Primary SOC	<i>Psychiatric disorders</i>		Old Primary SOC	
			<i>Respiratory, thoracic and mediastinal disorders</i>	10038738
			New Primary SOC	
			<i>Psychiatric disorders</i>	10037175

**MSSO Comment:** The proposal to reassign the primary SOC of PT Habit cough from current SOC Respiratory, thoracic and mediastinal disorders to SOC Psychiatric disorders is approved as requested. Following an internal review, the “somatic” and “psychogenic” concepts are classified per Diagnostic and Statistical Manual of Mental Disorders (DSM-5) as psychiatric disorders and as a result were primarily linked to SOC Psychiatric disorders rather than to the site of manifestation. The changes in this batch number 20110549 are based on the reversal of the primary SOC changes made in batch number 20110451 to restore the primary link of the “somatic” and “psychogenic” concepts to SOC Psychiatric disorders. These changes maintain consistency with the modifications made in MedDRA version 19.0 to better align MedDRA with the latest version of DSM-5. In a related change for a similar reason, the primary SOC for the following PTs will be changed from site of manifestation to SOC Psychiatric disorders. PT Aphonia psychogenic, PT Dysphonia psychogenic, and PT Psychogenic pseudosyncope will each have its primary SOC reassigned from SOC Nervous system disorders to SOC Psychiatric disorders. Also, PT Blindness hysterical will have its primary SOC reassigned from SOC Eye disorders to SOC Psychiatric disorders. Then PT Colitis psychogenic will have its primary SOC reassigned from SOC Gastrointestinal disorders to SOC Psychiatric disorders.

CR Number: 2019144017      Implementation Date: 29-May-19      Related CR: 2019135004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Colitis psychogenic</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Gastrointestinal disorders</i>		<i>Colitis psychogenic</i>	10053397
New Primary SOC	<i>Psychiatric disorders</i>		Old Primary SOC	
			<i>Gastrointestinal disorders</i>	10017947
			New Primary SOC	
			<i>Psychiatric disorders</i>	10037175

**MSSO Comment:**

# Supplemental Update Report

CR Number: 2019144018 Implementation Date: 29-May-19 Related CR: 2019135004

<u>Change Requested</u>	Reassign Primary SOC	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Dysphonia psychogenic</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Nervous system disorders</i>		<i>Dysphonia psychogenic</i>	10013953
New Primary SOC	<i>Psychiatric disorders</i>		Old Primary SOC	
			<i>Nervous system disorders</i>	10029205
			New Primary SOC	
			<i>Psychiatric disorders</i>	10037175

MSSO  
Comment:

CR Number: 2019144020 Implementation Date: 29-May-19 Related CR: 2019135004

<u>Change Requested</u>	Reassign Primary SOC	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Blindness hysterical</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Eye disorders</i>		<i>Blindness hysterical</i>	10005179
New Primary SOC	<i>Psychiatric disorders</i>		Old Primary SOC	
			<i>Eye disorders</i>	10015919
			New Primary SOC	
			<i>Psychiatric disorders</i>	10037175

MSSO  
Comment:

CR Number: 2019144021 Implementation Date: 29-May-19 Related CR: 2019135004

<u>Change Requested</u>	Reassign Primary SOC	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Psychogenic pseudosyncope</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Nervous system disorders</i>		<i>Psychogenic pseudosyncope</i>	10075190
New Primary SOC	<i>Psychiatric disorders</i>		Old Primary SOC	
			<i>Nervous system disorders</i>	10029205
			New Primary SOC	
			<i>Psychiatric disorders</i>	10037175

MSSO  
Comment:

# Supplemental Update Report

CR Number: 2019144022 Implementation Date: 29-May-19 Related CR: 2019135004

<u>Change Requested</u>	Reassign Primary SOC	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Aphonia psychogenic</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Nervous system disorders</i>		<i>Aphonia psychogenic</i>	10002954
New Primary SOC	<i>Psychiatric disorders</i>		Old Primary SOC	
			<i>Nervous system disorders</i>	10029205
			New Primary SOC	
			<i>Psychiatric disorders</i>	10037175

MSSO  
Comment:

CR Number: 2019135005 Implementation Date: 29-May-19 Related CR: 2019135005

<u>Change Requested</u>	Reassign Primary SOC	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Cardiovascular somatic symptom disorder</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Cardiac disorders</i>		<i>Cardiovascular somatic symptom disorder</i>	10078078
New Primary SOC	<i>Psychiatric disorders</i>		Old Primary SOC	
			<i>Cardiac disorders</i>	10007541
			New Primary SOC	
			<i>Psychiatric disorders</i>	10037175

MSSO  
Comment: The proposal to reassign the primary SOC of PT Cardiovascular somatic symptom disorder from current SOC Cardiac disorders to SOC Psychiatric disorders is approved as requested. Following an internal review, the “somatic” and “psychogenic” concepts are classified per Diagnostic and Statistical Manual of Mental Disorders (DSM-5) as psychiatric disorders and as a result were primarily linked to SOC Psychiatric disorders rather than to the site of manifestation. The changes in this batch number 2019135005 are based on the reversal of the primary SOC changes made in batch number 20110451 to restore the primary link of the “somatic” and “psychogenic” concepts to SOC Psychiatric disorders. These changes maintain consistency with the modifications made in MedDRA version 19.0 to better align MedDRA with the latest version of DSM-5.

# Supplemental Update Report

CR Number: 2019135006      Implementation Date: 29-May-19      Related CR: 2019135006

<u>Change Requested</u>	Reassign Primary SOC	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Chronic idiopathic pain syndrome</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Nervous system disorders</i>		<i>Chronic idiopathic pain syndrome</i>	10078098
New Primary SOC	<i>Psychiatric disorders</i>		Old Primary SOC	
			<i>Nervous system disorders</i>	10029205
			New Primary SOC	
			<i>Psychiatric disorders</i>	10037175

**MSSO Comment:** The proposal to reassign the primary SOC of PT Chronic idiopathic pain syndrome from current SOC Nervous system disorders to SOC Psychiatric disorders is approved as requested. Following an internal review, the “somatic” and “psychogenic” concepts are classified per Diagnostic and Statistical Manual of Mental Disorders (DSM-5) as psychiatric disorders and as a result were primarily linked to SOC Psychiatric disorders rather than to the site of manifestation. The changes in this batch number 20110549 are based on the reversal of the primary SOC changes made in batch number 20110451 to restore the primary link of the “somatic” and “psychogenic” concepts to SOC Psychiatric disorders. These changes maintain consistency with the modifications made in MedDRA version 19.0 to better align MedDRA with the latest version of DSM-5.

CR Number: 2019135007      Implementation Date: 29-May-19      Related CR: 2019135007

<u>Change Requested</u>	Reassign Primary SOC	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Cutaneous somatic symptom disorder</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Skin and subcutaneous tissue disorders</i>		<i>Cutaneous somatic symptom disorder</i>	10078081
New Primary SOC	<i>Psychiatric disorders</i>		Old Primary SOC	
			<i>Skin and subcutaneous tissue disorders</i>	10040785
			New Primary SOC	
			<i>Psychiatric disorders</i>	10037175

**MSSO Comment:** The proposal to reassign the primary SOC of PT Cutaneous somatic symptom disorder from current SOC Skin and subcutaneous tissue disorders to SOC Psychiatric disorders is approved as requested. Following an internal review, the “somatic” and “psychogenic” concepts are classified per Diagnostic and Statistical Manual of Mental Disorders (DSM-5) as psychiatric disorders and as a result were primarily linked to SOC Psychiatric disorders rather than to the site of manifestation. The changes in this batch number 20110549 are based on the reversal of the primary SOC changes made in batch number 20110451 to restore the primary link of the “somatic” and “psychogenic” concepts to SOC Psychiatric disorders. These changes maintain consistency with the modifications made in MedDRA version 19.0 to better align MedDRA with the latest version of DSM-5.

# Supplemental Update Report

CR Number: 2019135008      Implementation Date: 29-May-19      Related CR: 2019135008

<u>Change Requested</u>	Reassign Primary SOC	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Gastrointestinal somatic symptom disorder</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Gastrointestinal disorders</i>		<i>Gastrointestinal somatic symptom disorder</i>	10078079
New Primary SOC	<i>Psychiatric disorders</i>		Old Primary SOC	
			<i>Gastrointestinal disorders</i>	10017947
			New Primary SOC	
			<i>Psychiatric disorders</i>	10037175

**MSSO Comment:** The proposal to reassign the primary SOC of PT Gastrointestinal somatic symptom disorder from current SOC Gastrointestinal disorders to SOC Psychiatric disorders is approved as requested. Following an internal review, the “somatic” and “psychogenic” concepts are classified per Diagnostic and Statistical Manual of Mental Disorders (DSM-5) as psychiatric disorders and as a result were primarily linked to SOC Psychiatric disorders rather than to the site of manifestation. The changes in this batch number 20110549 are based on the reversal of the primary SOC changes made in batch number 20110451 to restore the primary link of the “somatic” and “psychogenic” concepts to SOC Psychiatric disorders. These changes maintain consistency with the modifications made in MedDRA version 19.0 to better align MedDRA with the latest version of DSM-5.

CR Number: 2019135009      Implementation Date: 29-May-19      Related CR: 2019135009

<u>Change Requested</u>	Reassign Primary SOC	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Neurologic somatic symptom disorder</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Nervous system disorders</i>		<i>Neurologic somatic symptom disorder</i>	10078080
New Primary SOC	<i>Psychiatric disorders</i>		Old Primary SOC	
			<i>Nervous system disorders</i>	10029205
			New Primary SOC	
			<i>Psychiatric disorders</i>	10037175

**MSSO Comment:** The proposal to reassign the primary SOC of PT Neurologic somatic symptom disorder from current SOC Nervous system disorders to SOC Psychiatric disorders is approved as requested. Following an internal review, the “somatic” and “psychogenic” concepts are classified per Diagnostic and Statistical Manual of Mental Disorders (DSM-5) as psychiatric disorders and as a result were primarily linked to SOC Psychiatric disorders rather than to the site of manifestation. The changes in this batch number 20110549 are based on the reversal of the primary SOC changes made in batch number 20110451 to restore the primary link of the “somatic” and “psychogenic” concepts to SOC Psychiatric disorders. These changes maintain consistency with the modifications made in MedDRA version 19.0 to better align MedDRA with the latest version of DSM-5.

# Supplemental Update Report

CR Number: 2019135010      Implementation Date: 29-May-19      Related CR: 2019135010

<u>Change Requested</u>	Reassign Primary SOC	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Polydipsia psychogenic</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Metabolism and nutrition disorders</i>		<i>Polydipsia psychogenic</i>	10036069
New Primary SOC	<i>Psychiatric disorders</i>		Old Primary SOC	
			<i>Metabolism and nutrition disorders</i>	10027433
			New Primary SOC	
			<i>Psychiatric disorders</i>	10037175

**MSSO Comment:** The proposal to reassign the primary SOC of PT Polydipsia psychogenic from current SOC Metabolism and nutrition disorders to SOC Psychiatric disorders is approved as requested. Following an internal review, the "somatic" and "psychogenic" concepts are classified per Diagnostic and Statistical Manual of Mental Disorders (DSM-5) as psychiatric disorders and as a result were primarily linked to SOC Psychiatric disorders rather than to the site of manifestation. The changes in this batch number 20110549 are based on the reversal of the primary SOC changes made in batch number 20110451 to restore the primary link of the "somatic" and "psychogenic" concepts to SOC Psychiatric disorders. These changes maintain consistency with the modifications made in MedDRA version 19.0 to better align MedDRA with the latest version of DSM-5.

CR Number: 2019135011      Implementation Date: 29-May-19      Related CR: 2019135011

<u>Change Requested</u>	Reassign Primary SOC	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Psychogenic dysuria</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Renal and urinary disorders</i>		<i>Psychogenic dysuria</i>	10037195
New Primary SOC	<i>Psychiatric disorders</i>		Old Primary SOC	
			<i>Renal and urinary disorders</i>	10038359
			New Primary SOC	
			<i>Psychiatric disorders</i>	10037175

**MSSO Comment:** The proposal to reassign the primary SOC of PT Psychogenic dysuria from current SOC Renal and urinary disorders to SOC Psychiatric disorders is approved as requested. Following an internal review, the "somatic" and "psychogenic" concepts are classified per Diagnostic and Statistical Manual of Mental Disorders (DSM-5) as psychiatric disorders and as a result were primarily linked to SOC Psychiatric disorders rather than to the site of manifestation. The changes in this batch number 20110549 are based on the reversal of the primary SOC changes made in batch number 20110451 to restore the primary link of the "somatic" and "psychogenic" concepts to SOC Psychiatric disorders. These changes maintain consistency with the modifications made in MedDRA version 19.0 to better align MedDRA with the latest version of DSM-5.

# Supplemental Update Report

CR Number: 2019135012      Implementation Date: 29-May-19      Related CR: 2019135012

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Psychogenic movement disorder</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Nervous system disorders</i>		<i>Psychogenic movement disorder</i>	10072376
New Primary SOC	<i>Psychiatric disorders</i>		Old Primary SOC	
			<i>Nervous system disorders</i>	10029205
			New Primary SOC	
			<i>Psychiatric disorders</i>	10037175

**MSSO Comment:** The proposal to reassign the primary SOC of PT Psychogenic movement disorder from current SOC Nervous system disorders to SOC Psychiatric disorders is approved as requested. Following an internal review, the "somatic" and "psychogenic" concepts are classified per Diagnostic and Statistical Manual of Mental Disorders (DSM-5) as psychiatric disorders and as a result were primarily linked to SOC Psychiatric disorders rather than to the site of manifestation. The changes in this batch number 20110549 are based on the reversal of the primary SOC changes made in batch number 20110451 to restore the primary link of the "somatic" and "psychogenic" concepts to SOC Psychiatric disorders. These changes maintain consistency with the modifications made in MedDRA version 19.0 to better align MedDRA with the latest version of DSM-5.

CR Number: 2019135013      Implementation Date: 29-May-19      Related CR: 2019135013

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Psychogenic respiratory distress</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Respiratory, thoracic and mediastinal disorders</i>		<i>Psychogenic respiratory distress</i>	10072630
New Primary SOC	<i>Psychiatric disorders</i>		Old Primary SOC	
			<i>Respiratory, thoracic and mediastinal disorders</i>	10038738
			New Primary SOC	
			<i>Psychiatric disorders</i>	10037175

**MSSO Comment:** The proposal to reassign the primary SOC of PT Psychogenic respiratory distress from current SOC Respiratory, thoracic and mediastinal disorders to SOC Psychiatric disorders is approved as requested. Following an internal review, the "somatic" and "psychogenic" concepts are classified per Diagnostic and Statistical Manual of Mental Disorders (DSM-5) as psychiatric disorders and as a result were primarily linked to SOC Psychiatric disorders rather than to the site of manifestation. The changes in this batch number 20110549 are based on the reversal of the primary SOC changes made in batch number 20110451 to restore the primary link of the "somatic" and "psychogenic" concepts to SOC Psychiatric disorders. These changes maintain consistency with the modifications made in MedDRA version 19.0 to better align MedDRA with the latest version of DSM-5.

# Supplemental Update Report

CR Number: 2019135014      Implementation Date: 29-May-19      Related CR: 2019135014

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Psychogenic tremor</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Nervous system disorders</i>		<i>Psychogenic tremor</i>	10072377
New Primary SOC	<i>Psychiatric disorders</i>		Old Primary SOC	
			<i>Nervous system disorders</i>	10029205
			New Primary SOC	
			<i>Psychiatric disorders</i>	10037175

**MSSO Comment:** The proposal to reassign the primary SOC of PT Psychogenic tremor from current SOC Nervous system disorders to SOC Psychiatric disorders is approved as requested. Following an internal review, the "somatic" and "psychogenic" concepts are classified per Diagnostic and Statistical Manual of Mental Disorders (DSM-5) as psychiatric disorders and as a result were primarily linked to SOC Psychiatric disorders rather than to the site of manifestation. The changes in this batch number 20110549 are based on the reversal of the primary SOC changes made in batch number 20110451 to restore the primary link of the "somatic" and "psychogenic" concepts to SOC Psychiatric disorders. These changes maintain consistency with the modifications made in MedDRA version 19.0 to better align MedDRA with the latest version of DSM-5.

CR Number: 2019135015      Implementation Date: 29-May-19      Related CR: 2019135015

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Somatoform genitourinary disorder</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Renal and urinary disorders</i>		<i>Somatoform genitourinary disorder</i>	10077253
New Primary SOC	<i>Psychiatric disorders</i>		Old Primary SOC	
			<i>Renal and urinary disorders</i>	10038359
			New Primary SOC	
			<i>Psychiatric disorders</i>	10037175

**MSSO Comment:** The proposal to reassign the primary SOC of PT Somatoform genitourinary disorder from current SOC Renal and urinary disorders to SOC Psychiatric disorders is approved as requested. Following an internal review, the "somatic" and "psychogenic" concepts are classified per Diagnostic and Statistical Manual of Mental Disorders (DSM-5) as psychiatric disorders and as a result were primarily linked to SOC Psychiatric disorders rather than to the site of manifestation. The changes in this batch number 20110549 are based on the reversal of the primary SOC changes made in batch number 20110451 to restore the primary link of the "somatic" and "psychogenic" concepts to SOC Psychiatric disorders. These changes maintain consistency with the modifications made in MedDRA version 19.0 to better align MedDRA with the latest version of DSM-5.

# Supplemental Update Report

CR Number: 2019135016      Implementation Date: 29-May-19      Related CR: 2019135016

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Torticollis psychogenic</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Musculoskeletal and connective tissue disorders</i>		<i>Torticollis psychogenic</i>	10044076
New Primary SOC	<i>Psychiatric disorders</i>		<i>Musculoskeletal and connective tissue disorders</i>	10028395
			<i>Psychiatric disorders</i>	10037175

**MSSO Comment:** The proposal to reassign the primary SOC of PT Torticollis psychogenic from current SOC Musculoskeletal and connective tissue disorders to SOC Psychiatric disorders is approved as requested. Following an internal review, the “somatic” and “psychogenic” concepts are classified per Diagnostic and Statistical Manual of Mental Disorders (DSM-5) as psychiatric disorders and as a result were primarily linked to SOC Psychiatric disorders rather than to the site of manifestation. The changes in this batch number 20110549 are based on the reversal of the primary SOC changes made in batch number 20110451 to restore the primary link of the “somatic” and “psychogenic” concepts to SOC Psychiatric disorders. These changes maintain consistency with the modifications made in MedDRA version 19.0 to better align MedDRA with the latest version of DSM-5.

CR Number: 2019135017      Implementation Date: 29-May-19      Related CR: 2019135017

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Vomiting psychogenic</i>	Approved as Requested	Proposed PT	
Old Primary SOC	<i>Gastrointestinal disorders</i>		<i>Vomiting psychogenic</i>	10047709
New Primary SOC	<i>Psychiatric disorders</i>		<i>Gastrointestinal disorders</i>	10017947
			<i>Psychiatric disorders</i>	10037175

**MSSO Comment:** The proposal to reassign the primary SOC of PT Vomiting psychogenic from current SOC Gastrointestinal disorders to SOC Psychiatric disorders is approved as requested. Following an internal review, the “somatic” and “psychogenic” concepts are classified per Diagnostic and Statistical Manual of Mental Disorders (DSM-5) as psychiatric disorders and as a result were primarily linked to SOC Psychiatric disorders rather than to the site of manifestation. The changes in this batch number 20110549 are based on the reversal of the primary SOC changes made in batch number 20110451 to restore the primary link of the “somatic” and “psychogenic” concepts to SOC Psychiatric disorders. These changes maintain consistency with the modifications made in MedDRA version 19.0 to better align MedDRA with the latest version of DSM-5.

# Supplemental Update Report

CR Number: 2019140004      Implementation Date: 24-May-19      Related CR: 2019140004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Stereognosis</i>	Rejected		

**MSSO Comment:** The proposal to add a new term Stereognosis is not approved. Stereognosis is the ability to recognize and identify common objects through tactile manipulation without the use of visual cues and it is normal physiological function which is out of the scope of MedDRA. The absence of this ability is called Astereognosis (or tactile object agnosia), which manifests with difficulty in recognizing items by touch when primary sensory modalities (e.g., pain, temperature, and vibration) are intact. Astereognosis already exists in MedDRA as an LLT under the PT Agnosia.

CR Number: 2019141001      Implementation Date: 24-May-19      Related CR: 2019141001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>CARDIA LIGATION THERAPY</i>	Approved Not as Requested	Proposed LLT <i>Cardia variceal ligation</i>	10083017 Current
			To PT <i>Gastric variceal ligation</i>	10076238

**MSSO Comment:** The proposal to add a new LLT CARDIA LIGATION THERAPY is approved but not as requested. Endoscopic variceal ligation therapy is often performed in the collateral vessels at the vicinity of the gastric cardia to treat or prevent variceal bleeding. Eradication of such collateral vessels may lead to longer recurrence-free status of esophageal varices. The proposed term has been renamed to Cardia variceal ligation, which appears to be more used in medical literature and in accordance with MedDRA capitalization conventions, and will be added as a sub-concept LLT to PT Gastric variceal ligation.

CR Number: 2019141002      Implementation Date: 24-May-19      Related CR: 2019141002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Vascular ligation</i>	Approved Not as Requested	Proposed PT <i>Vascular ligation</i>	10083018
			HLT primary <i>Vascular therapeutic procedures NEC</i>	10047094
			SOC primary <i>Surgical and medical procedures</i>	10042613

**MSSO Comment:** The proposal to add a new LLT Vascular ligation is approved but not as requested. The proposed term represents a broad concept encompassing a very diverse and heterogeneous types of vascular interventions, such as LLT Arterial ligation, LLT Venous ligation, etc... Vascular ligation will be added as PT to HLT Vascular therapeutic procedures NEC.

# Supplemental Update Report

CR Number: 2019141003 Implementation Date: 24-May-19 Related CR: 2019141003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Cardiac ligation	Rejected		

MSSO Comment: The proposal to add a new term Cardiac ligation is not approved. The proposed intervention can be represented by the new LLT Cardia variceal ligation which has been added in change request 2019141001.

CR Number: 2019141016 Implementation Date: 24-May-19 Related CR: 2019141016

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Infusion reaction	Approved as Requested	Proposed LLT Infusion reaction	10083019 Current
To PT			Infusion related reaction	10051792

MSSO Comment: The proposal to add a new LLT Infusion reaction is approved as requested. Infusion related reactions include hypersensitivity reactions and cytokine release syndromes. These reactions are often experienced by patients during the infusion of cytotoxic or monoclonal antibody therapy (uniphasic reaction) and/or within hours of an infusion (biphasic/delayed reaction). Infusion reaction will be added as an LLT to PT Infusion related reaction as the two terms are used synonymously.

CR Number: 2019142001 Implementation Date: 28-May-19 Related CR: 2019142001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Application site burning sensation	Rejected		
To PT	Burning sensation			

MSSO Comment: The proposal to add a new LLT Application site burning sensation to PT Burning sensation is not approved. The requested term can be represented by LLT Application site burning under PT Application site pain. Burning or Burning sensation are used in general interchangeably in meaning and if not represented as single PT terms are subordinated in MedDRA under pain, irritation, discomfort PTs depending on context and relevance.

# Supplemental Update Report

CR Number: 2019142002 Implementation Date: 28-May-19 Related CR: 2019142002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Drug toxicity due to polymorphism</i>	Rejected		

MSSO Comment: The proposal to add a new term Drug toxicity due to polymorphism 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 MSSO considers this concept to be represented in MedDRA by LLT Drug toxicity and LLT Genetic polymorphism. Please note that 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.

CR Number: 2019142005 Implementation Date: 24-May-19 Related CR: 2019142005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Prothrombin fragment 1.2 level increased</i>	Approved Not as Requested	Proposed PT <i>Prothrombin fragment 1.2 increased</i>	10083020
			HLT primary <i>Coagulation and bleeding analyses</i>	10009728
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new term Prothrombin fragment 1.2 level increased is approved but not as requested. When prothrombin is converted to thrombin, the prothrombin fragment 1.2 is released from prothrombin. An increase in the level of prothrombin fragment 1.2 may be useful in the assessment of ongoing coagulation activation as may occur in thrombosis or disseminated intravascular coagulation. Prothrombin fragment 1.2 increased will be added as a new PT to HLT Coagulation and bleeding analyses to pair existing PT Prothrombin fragment 1.2.

CR Number: 2019142006 Implementation Date: 24-May-19 Related CR: 2019142006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Bone necrosis excision</i>	Approved as Requested	Proposed LLT <i>Bone necrosis excision</i>	10083022 Current
			To PT <i>Bone debridement</i>	10057612

MSSO Comment: The proposal to add a new term Bone necrosis excision is approved as requested. Bone necrosis, or osteonecrosis is a condition where an insufficient supply of blood to bone results in bone tissue death, and excision of bone necrosis is one of the therapeutic approaches to this condition. Bone necrosis excision will be added as a sub-concept LLT to PT Bone debridement.

# Supplemental Update Report

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CR Number: 2019142007      Implementation Date: 24-May-19      Related CR: 2019142007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Drug-induced high blood glucose</i>	Rejected		

MSSO Comment: The proposal to add a new term Drug-induced high blood glucose is not approved. The proposed term can be represented by LLT/PT Drug-induced hyperglycaemia.

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CR Number: 2019142008      Implementation Date: 24-May-19      Related CR: 2019142008

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Basal cell carcinoma face</i>	Approved as Requested	Proposed LLT <i>Basal cell carcinoma face</i>	10083025 Current
			To PT <i>Basal cell carcinoma</i>	10004146

MSSO Comment: The proposal to add a new term Basal cell carcinoma face is approved as requested. The face is an important anatomical location of special relevance for basal cell carcinomas. Therefore, Basal cell carcinoma face will be added as a sub-concept LLT to PT Basal cell carcinoma.

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CR Number: 2019142009      Implementation Date: 24-May-19      Related CR: 2019142009

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Amygdalolith</i>	Approved as Requested	Proposed LLT <i>Amygdalolith</i>	10083023 Current
			To PT <i>Tonsillolith</i>	10063957

MSSO Comment: The proposal to add a new term Amygdalolith is approved as requested. Tonsilloliths, also known as amygdaloliths and tonsil stones, are white to yellowish pea-sized calcified collections of mucus, organic debris, and anaerobic bacteria. Amygdalolith will be added as a synonym LLT to PT Tonsillolith.

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# Supplemental Update Report

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CR Number: 2019142010      Implementation Date: 24-May-19      Related CR: 2019142010

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Acute-on-chronic subdural hematoma</i>	Approved Not as Requested	Proposed LLT <i>Acute on chronic subdural hematoma</i>	10083024 Current
			To PT <i>Subdural haematoma</i>	10042361

MSSO Comment: The proposal to add a new term Acute-on-chronic subdural hematoma is approved but not as requested. An acute on chronic subdural hematoma is often noted to have developed following head trauma in an individual with an underlying chronic subdural hematoma. Acute on chronic subdural hematoma, without hyphenation, will be added as a sub-concept LLT to PT Subdural haematoma. In a related change, the British English spelling counterpart LLT Acute on chronic subdural haematoma will also be added to PT Subdural haematoma.

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CR Number: 2019144014      Implementation Date: 24-May-19      Related CR: 2019142010

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Acute on chronic subdural haematoma</i>	Approved as Requested	Proposed LLT <i>Acute on chronic subdural haematoma</i>	10083026 Current
To PT	<i>Subdural haematoma</i>		To PT <i>Subdural haematoma</i>	10042361

MSSO Comment:

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# Supplemental Update Report

CR Number: 2019142011      Implementation Date: 24-May-19      Related CR: 2019142011

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term <i>Congenital ureteropelvic junction obstruction</i>	Approved as Requested	Proposed PT <i>Congenital ureteropelvic junction obstruction</i>	10083021
		HLT primary <i>Renal and urinary tract disorders congenital NEC</i>	10038361
		SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
		HLT secondary <i>Renal obstructive disorders</i>	10038488
		SOC secondary <i>Renal and urinary disorders</i>	10038359

**MSSO Comment:** The proposal to add a new term Congenital ureteropelvic junction obstruction is approved as requested. Congenital ureteropelvic junction obstruction is a partial or intermittent total blockage of the flow of urine that occurs where the ureter enters the kidney. The obstruction is caused by anatomic lesions or functional disturbances that restrict urinary flow across the ureteropelvic junction, resulting in hydronephrosis. It is the main cause of end stage renal disease in children. Congenital ureteropelvic junction obstruction will be added as a new PT to primary HLT Renal and urinary tract disorders congenital NEC and to secondary HLT Renal obstructive disorders.

CR Number: 2019142012      Implementation Date: 28-May-19      Related CR: 2019142012

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT <i>Intramyelinic oedema</i>	Approved as Requested	Proposed PT <i>Intramyelinic oedema</i>	10083038
SOC primary <i>Nervous system disorders</i>		HLT primary <i>Demyelinating disorders NEC</i>	10012302
		SOC primary <i>Nervous system disorders</i>	10029205
		HLT secondary <i>Poisoning and toxicity</i>	10035777
		SOC secondary <i>Injury, poisoning and procedural complications</i>	10022117

**MSSO Comment:** The proposal to add a new PT Intramyelinic oedema in SOC Nervous system disorders is approved as requested. Intramyelinic edema is a form of cytotoxic edema within the white matter of the brain defined by electron microscopy as "white matter spongiosis" or "white matter vacuolation." The neuroparenchyma has a spongy appearance and microvacuolation is characterized by fluid accumulation and separation/ splitting of the outer layers of myelin. Intramyelinic oedema will be added as a PT to primary HLT Demyelinating disorders NEC and secondary HLT Poisoning and toxicity. In a related change, the American English spelled counterpart Intramyelinic edema will be add as an LLT to PT Intramyelinic oedema. Furthermore, synonym LLT White matter vacuolation will be moved from PT White matter lesion to the new PT Intramyelinic oedema.

# Supplemental Update Report

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CR Number: 2019148009

Implementation Date: 28-May-19

Related CR: 2019142012

Change Requested

Add a New LLT

Final Disposition

Final Placement

MedDRA  
Code #

Proposed LLT *Intramyelinic edema*  
To PT *Intramyelinic oedema*

Approved as Requested

Proposed LLT  
*Intramyelinic edema*  
To PT  
*Intramyelinic oedema*

10083039 Current

10083038

MSSO

Comment:

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CR Number: 2019148010

Implementation Date: 28-May-19

Related CR: 2019142012

Change Requested

Link (move) an LLT to another PT

Final Disposition

Final Placement

MedDRA  
Code #

Proposed LLT *White matter vacuolation*  
From PT *White matter lesion*  
To PT *Intramyelinic oedema*

Approved as Requested

Proposed LLT  
*White matter vacuolation*  
From PT  
*White matter lesion*  
To PT  
*Intramyelinic oedema*

10079757 Current

10072731

10083038

MSSO

Comment:

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# Supplemental Update Report

CR Number: 2019142013      Implementation Date: 28-May-19      Related CR: 2019142013

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Injection site panniculitis</i>	Approved as Requested	Proposed PT <i>Injection site panniculitis</i>	10083040
HLT primary	<i>injection site reactions</i>		HLT primary <i>Injection site reactions</i>	10022097
SOC primary	<i>General disorders and administration site conditions</i>		SOC primary <i>General disorders and administration site conditions</i>	10018065
			HLT secondary <i>Allergic conditions NEC</i>	10027654
			SOC secondary <i>Immune system disorders</i>	10021428

MSSO Comment: The proposal to add a new PT Injection site panniculitis to primary HLT injection site reactions in SOC General disorders and administration site conditions is approved as requested. Panniculitis is an inflammatory process of subcutaneous adipose tissue. Symptoms include tender skin nodules and systemic signs such as weight loss and fatigue. Injection site panniculitis will also secondarily linked to HLT Allergic conditions NEC, and HLT Panniculitides.

CR Number: 2019148011      Implementation Date: 28-May-19      Related CR: 2019142013

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link a PT to a HLT <i>Injection site panniculitis</i>	Approved as Requested	Proposed PT <i>Injection site panniculitis</i>	10083040
To HLT	<i>Panniculitides</i>		To HLT <i>Panniculitides</i>	10033674

MSSO Comment:

# Supplemental Update Report

**CR Number:** 2019142014      **Implementation Date:** 28-May-19      **Related CR:** 2019142014

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Lichenoid drug reaction</i>	Approved Not as Requested	Proposed LLT <i>Lichenoid drug reaction</i>	10083041 Current
HLT primary	<i>Dermatitis ascribed to specific agent</i>		To PT <i>Drug eruption</i>	10013687
SOC primary	<i>Skin and subcutaneous tissue disorders</i>			

**MSSO Comment:** The proposal to add a new PT Lichenoid drug reaction to primary HLT Dermatitis ascribed to specific agent in SOC Skin and subcutaneous tissue disorders is approved but not as requested. Lichenoid drug eruption, also called drug-induced lichen planus, is an uncommon cutaneous adverse effect of several drugs. It is characterized by a symmetric eruption of flat-topped, erythematous or violaceous papules resembling lichen planus on the trunk and extremities. Histologic examination reveals lichenoid interface dermatitis. Lichenoid drug reaction will be added as a sub-concept LLT to PT Drug eruption, aligned with LLT Lichen planus-like eruption.

**CR Number:** 2019142015      **Implementation Date:** 24-May-19      **Related CR:** 2019142015

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Vesiculectomy</i>	Approved as Requested	Proposed PT <i>Vesiculectomy</i>	10083029
			HLT primary <i>Male genital tract therapeutic procedures NEC</i>	10038591
			SOC primary <i>Surgical and medical procedures</i>	10042613

**MSSO Comment:** The proposal to add a new term Vesiculectomy is approved as requested. Vesiculectomy is defined as resection of a portion or all of each of the seminal vesicles and will be added as PT to HLT Male genital tract therapeutic procedures NEC. In a related change, PT Seminal vesicle operation will be moved from HLT Epididymal therapeutic procedures to HLT Male genital tract therapeutic procedures NEC for better alignment.

**CR Number:** 2019144015      **Implementation Date:** 24-May-19      **Related CR:** 2019142015

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link (move) a PT to another HLT <i>Seminal vesicle operation</i>	Approved as Requested	Proposed PT <i>Seminal vesicle operation</i>	10062161
From HLT	<i>Epididymal therapeutic procedures</i>		From HLT <i>Epididymal therapeutic procedures</i>	10014997
To HLT	<i>Male genital tract therapeutic procedures NEC</i>		To HLT <i>Male genital tract therapeutic procedures NEC</i>	10038591

**MSSO Comment:**

# Supplemental Update Report

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<b>CR Number:</b> 2019142016	<b>Implementation Date:</b> 24-May-19	<b>Related CR:</b> 2019142016	
<u>Change Requested</u>	Demote a PT	<u>Final Disposition</u>	<u>Final Placement</u>
PT to merge	<i>Cow's milk intolerance</i>	Approved Not as Requested	Proposed PT
To PT	<i>Dairy intolerance</i>		<i>Cow's milk intolerance</i>
			10011241 Current
			With LLT
			<i>Dairy intolerance</i>
			10011852

MSSO Comment: The proposal to demote the PT Cow's milk intolerance under PT Dairy intolerance is approved but not as requested. PT Cow's milk intolerance will be swapped with LLT Dairy intolerance as Dairy intolerance is the broader concept including all products containing animal milk.

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<b>CR Number:</b> 2019142017	<b>Implementation Date:</b> 24-May-19	<b>Related CR:</b> 2019142017	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Stress fecal incontinence</i>	Approved as Requested	Proposed LLT
			<i>Stress fecal incontinence</i>
			10083030 Current
			To PT
			<i>Anal incontinence</i>
			10077605

MSSO Comment: The proposal to add a new LLT Stress fecal incontinence is approved as requested. Stress fecal or anal incontinence is observed in cases of sneezing, coughing, laughing and picking up heavy things. It occurs when the anal sphincter muscle is weak and can't control the bowel movements. Anal stress incontinence is a result of physical and not mental stress. Stress fecal incontinence and its British English spelled counterpart Stress faecal incontinence will be added as sub-concept LLTs under PT Anal incontinence.

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<b>CR Number:</b> 2019144016	<b>Implementation Date:</b> 24-May-19	<b>Related CR:</b> 2019142017	
<u>Change Requested</u>	Add a New LLT	<u>Final Disposition</u>	<u>Final Placement</u>
Proposed LLT	<i>Stress faecal incontinence</i>	Approved as Requested	Proposed LLT
To PT	<i>Anal incontinence</i>		<i>Stress faecal incontinence</i>
			10083031 Current
			To PT
			<i>Anal incontinence</i>
			10077605

MSSO Comment:

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# Supplemental Update Report

CR Number: 2019142018 Implementation Date: 24-May-19 Related CR: 2019142018

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Facial injury	Rejected		

MSSO Comment: The proposal to add a new term Facial injury is not approved. The proposed term can be represented by existing LLT/PT Face injury.

CR Number: 2019142019 Implementation Date: 24-May-19 Related CR: 2019142019

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Physical examination of joints abnormal	Approved as Requested	Proposed PT Physical examination of joints abnormal	10083028
			HLT primary Physical examination procedures and organ system status	10071941
			SOC primary Investigations	10022891

MSSO Comment: The proposal to add a new term Physical examination of joints abnormal is approved as requested. Physical examination of joints abnormal will be added as PT to HLT Physical examination procedures and organ system status aligned with the unqualified PT Physical examination of joints.

CR Number: 2019142020 Implementation Date: 24-May-19 Related CR: 2019142020

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Physical examination of joints normal	Approved as Requested	Proposed PT Physical examination of joints normal	10083027
			HLT primary Physical examination procedures and organ system status	10071941
			SOC primary Investigations	10022891

MSSO Comment: The proposal to add a new term Physical examination of joints normal is approved as requested. Physical examination of joints normal will be added as PT to HLT Physical examination procedures and organ system status aligned with the unqualified PT Physical examination of joints.

# Supplemental Update Report

**CR Number:** 2019142021      **Implementation Date:** 24-May-19      **Related CR:** 2019142021

<a href="#">Change Requested</a>		<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Post procedural infection bacterial</i>	Rejected		

**MSSO Comment:** The proposal to add a new term Post procedural infection bacterial is not approved. MedDRA cannot provide a term for all possible combinations between a postoperative or post procedural complication such as infection and a given organism class. Please consider split coding with LLT Post procedural infection or LLT Postoperative infection and LLT Bacterial infection.

**CR Number:** 2019142022      **Implementation Date:** 24-May-19      **Related CR:** 2019142022

<a href="#">Change Requested</a>		<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed Term	<i>Post procedural infection fungal</i>	Rejected		

**MSSO Comment:** The proposal to add a new term Post procedural infection fungal is not approved. MedDRA cannot provide a term for all possible combinations between a postoperative or post procedural complication such as infection and a given organism class. Please consider split coding with LLT Post procedural infection or LLT Postoperative infection and LLT Fungal infection.

**CR Number:** 2019142023      **Implementation Date:** 28-May-19      **Related CR:** 2019142023

<a href="#">Change Requested</a>		<a href="#">Final Disposition</a>	<a href="#">Final Placement</a>	<a href="#">MedDRA Code #</a>
Proposed PT	<i>Monocyte chemotactic protein-2 increased</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Immune response protein analyses NEC</i>		<i>Monocyte chemotactic protein-2 increased</i>	10083043
SOC primary	<i>Investigations</i>		HLT primary	
			<i>Immune response protein analyses NEC</i>	10021421
			SOC primary	
			<i>Investigations</i>	10022891

**MSSO Comment:** The proposal to add a new PT Monocyte chemotactic protein-2 increased to primary HLT Immune response protein analyses NEC in SOC Investigations is approved as requested. Monocyte Chemoattractant Protein 2 (MCP-2), also known as CCL8, is implicated in allergic responses through its ability to activate mast cells, eosinophils, and basophils. Its biological activity is determined by the ability to chemoattract human peripheral blood mononuclear cells and is typically in the range of 10-100 ng/mL. In a related change, both the non-qualified test name, Monocyte chemotactic protein-2, and the counterpart result Monocyte chemotactic protein-2 decreased will be added as PTs under HLT Immune response protein analyses NEC.

# Supplemental Update Report

CR Number: 2019148014 Implementation Date: 28-May-19 Related CR: 2019142023

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Monocyte chemotactic protein-2</i>	Approved as Requested	Proposed PT <i>Monocyte chemotactic protein-2</i>	10083046
HLT primary	<i>Immune response protein analyses NEC</i>		HLT primary <i>Immune response protein analyses NEC</i>	10021421
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891

MSSO  
Comment:

CR Number: 2019148015 Implementation Date: 28-May-19 Related CR: 2019142023

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Monocyte chemotactic protein-2 decreased</i>	Approved as Requested	Proposed PT <i>Monocyte chemotactic protein-2 decreased</i>	10083047
HLT primary	<i>Immune response protein analyses NEC</i>		HLT primary <i>Immune response protein analyses NEC</i>	10021421
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891

MSSO  
Comment:

# Supplemental Update Report

CR Number: 2019142024 Implementation Date: 28-May-19 Related CR: 2019142024

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT	Approved as Requested	Proposed PT	
HLT primary	<i>Macrophage inflammatory protein - 1 alpha</i>		<i>Macrophage inflammatory protein - 1 alpha</i>	10083042
SOC primary	<i>Immune response protein analyses NEC</i>		HLT primary	
	<i>Investigations</i>		<i>Immune response protein analyses NEC</i>	10021421
			SOC primary	
			<i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new PT Macrophage inflammatory protein - 1 alpha to primary HLT Immune response protein analyses NEC in SOC Investigations is approved as requested. Macrophage inflammatory protein 1-alpha (MIP-1-alpha), also known as Chemokine (C-C motif) ligand 3 (CCL3), is a protein that in humans is encoded by the CCL3 gene. Macrophage inflammatory protein 1-alpha is involved in the acute inflammatory state by the recruitment and activation of polymorphonuclear leukocytes through specific binding receptors. In a related change, both qualified related test outcome terms Macrophage inflammatory protein 1-alpha increased and Macrophage inflammatory protein 1-alpha decreased will be added as PTs under HLT Immune response protein analyses NEC.

CR Number: 2019148016 Implementation Date: 28-May-19 Related CR: 2019142024

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT	Approved as Requested	Proposed PT	
HLT primary	<i>Macrophage inflammatory protein 1-alpha increased</i>		<i>Macrophage inflammatory protein 1-alpha increased</i>	10083049
SOC primary	<i>Immune response protein analyses NEC</i>		HLT primary	
	<i>Investigations</i>		<i>Immune response protein analyses NEC</i>	10021421
			SOC primary	
			<i>Investigations</i>	10022891

MSSO Comment:

# Supplemental Update Report

CR Number: 2019148017 Implementation Date: 28-May-19 Related CR: 2019142024

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Macrophage inflammatory protein 1-alpha decreased</i>	Approved as Requested	Proposed PT <i>Macrophage inflammatory protein 1-alpha decreased</i>	10083045
HLT primary	<i>Immune response protein analyses NEC</i>		HLT primary <i>Immune response protein analyses NEC</i>	10021421
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891

MSSO  
Comment:

CR Number: 2019142025 Implementation Date: 28-May-19 Related CR: 2019142025

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Interferon beta level</i>	Approved as Requested	Proposed PT <i>Interferon beta level</i>	10083044
HLT primary	<i>Immune response protein analyses NEC</i>		HLT primary <i>Immune response protein analyses NEC</i>	10021421
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891

MSSO  
Comment: The proposal to add a new PT Interferon beta level to primary HLT Immune response protein analyses NEC in SOC Investigations is approved as requested. Interferon beta (IFN $\beta$ ) is a cytokine that is naturally produced by the immune system in response to biological and chemical stimuli. Its determination is important in the treatment of various diseases such as hepatitis C infection and multiple sclerosis. In a related change, both qualified related test outcome terms Interferon beta level increased and Interferon beta level decreased will be added as PTs under HLT Immune response protein analyses NEC.

# Supplemental Update Report

CR Number: 2019148018 Implementation Date: 28-May-19 Related CR: 2019142025

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Interferon beta level increased</i>	Approved as Requested	Proposed PT <i>Interferon beta level increased</i>	10083048
HLT primary	<i>Immune response protein analyses NEC</i>		HLT primary <i>Immune response protein analyses NEC</i>	10021421
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891

MSSO  
Comment:

CR Number: 2019148019 Implementation Date: 28-May-19 Related CR: 2019142025

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Interferon beta level decreased</i>	Approved as Requested	Proposed PT <i>Interferon beta level decreased</i>	10083050
HLT primary	<i>Immune response protein analyses NEC</i>		HLT primary <i>Immune response protein analyses NEC</i>	10021421
SOC primary	<i>Investigations</i>		SOC primary <i>Investigations</i>	10022891

MSSO  
Comment:

# Supplemental Update Report

CR Number: 2019142026      Implementation Date: 28-May-19      Related CR: 2019142026

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Paralytic scoliosis</i>	Approved as Requested	Proposed PT <i>Paralytic scoliosis</i>	10083051
HLT primary	<i>Spine and neck deformities</i>		HLT primary <i>Spine and neck deformities</i>	10012140
SOC primary	<i>Musculoskeletal and connective tissue disorders</i>		SOC primary <i>Musculoskeletal and connective tissue disorders</i>	10028395
			HLT secondary <i>Paralysis and paresis (excl cranial nerve)</i>	10033800
			SOC secondary <i>Nervous system disorders</i>	10029205

MSSO Comment: The proposal to add a new PT Paralytic scoliosis to primary HLT Spine and neck deformities in SOC Musculoskeletal and connective tissue disorders is approved as requested. Paralytic scoliosis is a modality of scoliosis consisting on lateral curvature of the spine due to paralysis of spinal muscles associated to conditions such as muscular dystrophy, arthrogyposis or other muscular disorders. Paralytic scoliosis will also be linked to secondary HLT Paralysis and paresis (excl cranial nerve) and secondary HLT Thoracic musculoskeletal disorders.

CR Number: 2019148020      Implementation Date: 28-May-19      Related CR: 2019142026

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Link a PT to a HLT <i>Paralytic scoliosis</i>	Approved as Requested	Proposed PT <i>Paralytic scoliosis</i>	10083051
To HLT	<i>Thoracic musculoskeletal disorders</i>		To HLT <i>Thoracic musculoskeletal disorders</i>	10043475

MSSO Comment:

# Supplemental Update Report

CR Number: 2019142027 Implementation Date: 28-May-19 Related CR: 2019142027

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Muehrcke lines</i>	Approved Not as Requested	Proposed LLT <i>Muehrcke lines</i>	10083052 Current
			To PT <i>Leukonychia</i>	10050658

**MSSO Comment:** The proposal to add a new PT Muehrcke lines is approved but not as requested. Muehrcke's lines (ML) are rare presentation of apparent leukonychia (static white discoloration bands secondary to nail bed pathology) ML are a strong indicator of hypoalbuminemia, which can result from a variety of different causes are usually associated with periods of metabolic stress and hypoalbuminemia, such as those secondary to infections, severe malnutrition, chronic diseases and chemotherapy drugs. ML typically fade with digital compression and are expected to disappear as long as the serum albumin levels increase. Muehrcke lines will be added as subconcept LLT to PT Leukonychia, a recently added PT for MedDRA version 22.1.

CR Number: 2019142028 Implementation Date: 28-May-19 Related CR: 2019142028

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Primary intimal tear false lumen perfusion</i>	Approved as Requested	Proposed LLT <i>Primary intimal tear false lumen perfusion</i>	10083057 Current
			To PT <i>Stent-graft endoleak</i>	10064396

**MSSO Comment:** The proposal to add a new term Primary intimal tear false lumen perfusion is approved as requested. Continued patency of the false lumen in aortic dissection has an essential adverse influence on aortic enlargement and long-term survival. Primary intimal tear false lumen perfusion will be added as a sub-concept LLT to PT Stent-graft endoleak aligned with LLT Persistent blood flow in false lumen of aortic dissection.

CR Number: 2019142029 Implementation Date: 28-May-19 Related CR: 2019142029

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Proximal aorta false lumen perfusion</i>	Approved as Requested	Proposed LLT <i>Proximal aorta false lumen perfusion</i>	10083056 Current
			To PT <i>Stent-graft endoleak</i>	10064396

**MSSO Comment:** The proposal to add a new term Proximal aorta false lumen perfusion is approved as requested. Proximal aorta false lumen perfusion more directly describes flow from an aortic source distal to the endovascular stent-graft, through fenestrations in the dissection septum, secondary aortic tears, or re-entry points, into the aortic false lumen. Proximal aorta false lumen perfusion will be added as a sub-concept LLT to PT Stent-graft endoleak aligned with LLT Persistent blood flow in false lumen of aortic dissection.

# Supplemental Update Report

CR Number: 2019142030 Implementation Date: 28-May-19 Related CR: 2019142030

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Add a New Term			
Proposed Term <i>Distal aorta false lumen perfusion</i>	Approved as Requested	Proposed LLT <i>Distal aorta false lumen perfusion</i>	10083055 Current
		To PT <i>Stent-graft endoleak</i>	10064396

MSSO Comment: The proposal to add a new term Distal aorta false lumen perfusion is approved as requested. Distal aorta false lumen perfusion more directly describes flow from an aortic source distal to the endovascular stent-graft, through fenestrations in the dissection septum, secondary aortic tears, or re-entry points, into the aortic false lumen. Distal aorta false lumen perfusion will be added as a sub-concept LLT to PT Stent-graft endoleak aligned with LLT Persistent blood flow in false lumen of aortic dissection.

CR Number: 2019142031 Implementation Date: 28-May-19 Related CR: 2019142031

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Add a New Term			
Proposed Term <i>Proximal branch false lumen perfusion</i>	Approved as Requested	Proposed LLT <i>Proximal branch false lumen perfusion</i>	10083053 Current
		To PT <i>Stent-graft endoleak</i>	10064396

MSSO Comment: The proposal to add a new term Proximal branch false lumen perfusion is approved as requested. Proximal branch false lumen perfusion more directly describes flow into the aortic false lumen via retrograde flow from aortic arch branch vessels. Proximal branch false lumen perfusion will be added as a sub-concept LLT to PT Stent-graft endoleak aligned with LLT Persistent blood flow in false lumen of aortic dissection.

CR Number: 2019142032 Implementation Date: 28-May-19 Related CR: 2019142032

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Add a New Term			
Proposed Term <i>Distal branch false lumen perfusion</i>	Approved as Requested	Proposed LLT <i>Distal branch false lumen perfusion</i>	10083054 Current
		To PT <i>Stent-graft endoleak</i>	10064396

MSSO Comment: The proposal to add a new term Distal branch false lumen perfusion is approved as requested. Distal branch false lumen perfusion more directly describes flow into the aortic false lumen via retrograde flow from distal branch vessels in the chest (intercostals), abdomen (e.g., mesenteric, renal), or pelvis (iliac). Distal branch false lumen perfusion will be added as a sub-concept LLT to PT Stent-graft endoleak aligned with other specific types of stent-graft complications.

# Supplemental Update Report

CR Number: 2019142033      Implementation Date: 28-May-19      Related CR: 2019142033

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Rib contusion</i>	Approved as Requested	Proposed LLT	
From PT	<i>Contusion</i>		<i>Rib contusion</i>	10081170 Current
To PT	<i>Bone contusion</i>		From PT	
			<i>Contusion</i>	10050584
			To PT	
			<i>Bone contusion</i>	10066251

MSSO Comment: The proposal to move the LLT Rib contusion from PT Contusion to PT Bone contusion is approved as requested for better alignment of the concept.

CR Number: 2019142034      Implementation Date: 28-May-19      Related CR: 2019142034

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Cerebral venous sinus thrombosis</i>	Approved Not as Requested	Proposed PT	
			<i>Cerebral venous sinus thrombosis</i>	10083037
			HLT primary	
			<i>Cerebrovascular venous and sinus thrombosis</i>	10008209
			SOC primary	
			<i>Nervous system disorders</i>	10029205
			HLT secondary	
			<i>Cerebrovascular embolism and thrombosis</i>	10008205
			SOC secondary	
			<i>Vascular disorders</i>	10047065

MSSO Comment: The proposal to add a new LLT Cerebral venous sinus thrombosis is approved but not as requested. Cerebral venous sinus thrombosis (CVST) occurs when a blood clot forms in the brain's venous sinuses. Cerebral venous sinus thrombosis will be added as a PT to primary HLT Cerebrovascular venous and sinus thrombosis and secondary HLT Cerebrovascular embolism and thrombosis. In a related change, Intracranial venous sinus thrombosis will be demoted under the new PT Cerebral venous sinus thrombosis, which is the more prevalent expression.

# Supplemental Update Report

CR Number: 2019148008 Implementation Date: 28-May-19 Related CR: 2019142034

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	Demote a PT <i>Intracranial venous sinus thrombosis</i>	Approved as Requested	PT to merge <i>Intracranial venous sinus thrombosis</i>	10061251 Current
To PT	<i>Cerebral venous sinus thrombosis</i>		To PT <i>Cerebral venous sinus thrombosis</i>	10083037

MSSO  
Comment:

CR Number: 2019143001 Implementation Date: 28-May-19 Related CR: 2019143001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Drug use for misdiagnosis</i>	Rejected		
To PT	<i>Product selection error</i>			

MSSO Comment: The proposal to add a new LLT Drug use for misdiagnosis to PT Product selection error is not approved. Please consider to code to LLT Wrong drug administered. The underlying causality "misdiagnosis" cannot be represented because medical errors such as diagnostic errors are outside of the scope of MedDRA.

CR Number: 2019143002 Implementation Date: 28-May-19 Related CR: 2019143002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Cervical papilloma</i>	Approved Not as Requested	Proposed LLT <i>Cervix papilloma</i>	10083058 Current
HLT primary	<i>Cervix neoplasms benign</i>		To PT <i>Cervix warts</i>	10063815
SOC primary	<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>			

MSSO Comment: The proposal to add a new PT Cervical papilloma to primary HLT Cervix neoplasms benign in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) and secondary HLT Papilloma viral infections in SOC Infections and infestations is approved but not as requested. Cervical papilloma will be re-worded based on MedDRA conventions for general word usage as stated in the MedDRA Introductory Guide, section 5.1 and added as LLT Cervix papilloma to PT Cervix warts.

# Supplemental Update Report

CR Number: 2019143003 Implementation Date: 29-May-19 Related CR: 2019143003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Receptive language disorder	Approved as Requested	Proposed LLT	
To PT	Language disorder		Receptive language disorder	10083085 Current
			To PT	
			Language disorder	10074869

MSSO Comment: The proposal to add a new LLT Receptive language disorder to PT Language disorder is approved as requested. Receptive language disorder occurs when there is a lack of ability to understand words, sentences, and speech acts. These patients may rely on reading facial expressions and have particular trouble with complex sentences.

CR Number: 2019143004 Implementation Date: 29-May-19 Related CR: 2019143004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Alternating bulbar syndrome	Approved as Requested	Proposed LLT	
To PT	Brain stem syndrome		Alternating bulbar syndrome	10083084 Current
			To PT	
			Brain stem syndrome	10063292

MSSO Comment: The proposal to add a new LLT Alternating bulbar syndrome to PT Brain stem syndrome is approved as requested. Alternating bulbar syndrome is a type of alternating hemiplegia characterized by a set of clinical features resulting from occlusion of the anterior spinal artery.

CR Number: 2019143005 Implementation Date: 29-May-19 Related CR: 2019143005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Alternating peduncular syndrome	Approved as Requested	Proposed LLT	
To PT	Brain stem syndrome		Alternating peduncular syndrome	10083086 Current
			To PT	
			Brain stem syndrome	10063292

MSSO Comment: The proposal to add a new LLT Alternating peduncular syndrome to PT Brain stem syndrome is approved as requested. Peduncular syndrome, also called alternating oculomotor hemiplegia and Weber's syndrome in the basal midbrain, involves nerve III and portions of the cerebral peduncle. There is a nerve III palsy on the side of the lesion and a contralateral hemiparesis.

# Supplemental Update Report

CR Number: 2019143006 Implementation Date: 29-May-19 Related CR: 2019143006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Subdural abscess</i>	Approved as Requested	Proposed PT <i>Subdural abscess</i>	10083083
HLT primary	<i>Central nervous system and spinal infections</i>		HLT primary <i>Central nervous system and spinal infections</i>	10007935
SOC primary	<i>Infections and infestations</i>		SOC primary <i>Infections and infestations</i>	10021881
			HLT secondary <i>Central nervous system abscesses</i>	10000319
			SOC secondary <i>Nervous system disorders</i>	10029205

MSSO Comment: The proposal to add a new PT Subdural abscess to primary HLT Central nervous system and spinal infections in SOC Infections and infestations is approved as requested. Subdural empyema (ie, abscess) is an intracranial focal collection of purulent material located between the dura mater and the arachnoid mater. Subdural abscess will also be secondarily linked to HLT Central nervous system abscesses. In a related change, PT Subdural empyema will be demoted to the new PT Subdural abscess as they are synonymously used. Furthermore, for similar reason PT Epidural empyema will be demoted under PT Extradural abscess.

CR Number: 2019150620 Implementation Date: 29-May-19 Related CR: 2019143006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	Demote a PT <i>Subdural empyema</i>	Approved as Requested	PT to merge <i>Subdural empyema</i>	10042360 Current
To PT	<i>Subdural abscess</i>		To PT <i>Subdural abscess</i>	10083083

MSSO Comment:

# Supplemental Update Report

CR Number: 2019150621 Implementation Date: 29-May-19 Related CR: 2019143006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Epidural empyema</i>	Approved as Requested	PT to merge	
To PT	<i>Extradural abscess</i>		<i>Epidural empyema</i>	10072822 Current
			To PT	
			<i>Extradural abscess</i>	10061846

MSSO  
Comment:

CR Number: 2019143007 Implementation Date: 28-May-19 Related CR: 2019143007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Migration of renal calculi</i>	Approved Not as Requested	Proposed PT	
To PT	<i>nephrolithiasis</i>		<i>Retrograde migration of renal calculi</i>	10083032
			HLT primary	
			<i>Renal lithiasis</i>	10038478
			SOC primary	
			<i>Renal and urinary disorders</i>	10038359
			HLT secondary	
			<i>Urinary tract procedural complications</i>	10046588
			SOC secondary	
			<i>Injury, poisoning and procedural complications</i>	10022117

MSSO  
Comment: The proposal to add a new LLT Migration of renal calculi to PT nephrolithiasis is approved but not as requested. Migration of a renal stone or stone fragments may be spontaneous or happen as a complication during endoscopic lithotripsy and a different concept from nephrolithiasis. Migration of renal calculi will be re-worded for clarification to Retrograde migration of renal calculi and added as PT to primary HLT Renal lithiasis and secondary HLT Urinary tract procedural complications. In a related change, the synonym LLT Upward migration of renal calculi will be added to new PT Retrograde migration of renal calculi.

# Supplemental Update Report

CR Number: 2019148005 Implementation Date: 28-May-19 Related CR: 2019143007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Upward migration of renal calculi</i>	Approved as Requested	Proposed LLT <i>Upward migration of renal calculi</i>	10083033 Current
To PT	<i>Retrograde migration of renal calculi</i>		To PT <i>Retrograde migration of renal calculi</i>	10083032

MSSO  
Comment:

CR Number: 2019143055 Implementation Date: 29-May-19 Related CR: 2019143055

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Omentoplasty</i>	Approved as Requested	Proposed PT <i>Omentoplasty</i>	10083067
			HLT primary <i>Abdominal therapeutic procedures NEC</i>	10027653
			SOC primary <i>Surgical and medical procedures</i>	10042613

MSSO Comment: The proposal to add a new term Omentoplasty is approved as requested. Omentoplasty is a surgical procedure in which part of the greater omentum is used to cover or fill a defect, augment arterial or portal venous circulation, absorb effusions, or increase lymphatic drainage. Omentoplasty will be added as a new PT to HLT Abdominal therapeutic procedures NEC. In a related change, PT Omental flap operation, PT Omental implantation, and PT Omentopexy will be demoted and added as sub-concept LLTs to PT Omentoplasty.

CR Number: 2019149992 Implementation Date: 29-May-19 Related CR: 2019143055

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	Demote a PT <i>Omental flap operation</i>	Approved as Requested	PT to merge <i>Omental flap operation</i>	10075297 Current
To PT	<i>Omentoplasty</i>		To PT <i>Omentoplasty</i>	10083067

MSSO  
Comment:

# Supplemental Update Report

CR Number: 2019149993 Implementation Date: 29-May-19 Related CR: 2019143055

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Omentopexy</i>	Approved as Requested	PT to merge <i>Omentopexy</i>	10069422 Current
To PT	<i>Omentoplasty</i>		To PT <i>Omentoplasty</i>	10083067

MSSO  
Comment:

CR Number: 2019149994 Implementation Date: 29-May-19 Related CR: 2019143055

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Omental implantation</i>	Approved as Requested	PT to merge <i>Omental implantation</i>	10069434 Current
To PT	<i>Omentoplasty</i>		To PT <i>Omentoplasty</i>	10083067

MSSO  
Comment:

CR Number: 2019143056 Implementation Date: 29-May-19 Related CR: 2019143056

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Radiation osteomyelitis</i>	Approved as Requested	Proposed LLT <i>Radiation osteomyelitis</i>	10083068 Current
			To PT <i>Osteoradionecrosis</i>	10067352

MSSO  
Comment: The proposal to add a new term Radiation osteomyelitis is approved as requested. Radiation therapy may cause osteoradionecrosis of exposed bone tissue, leading to radiation osteomyelitis with a source of infection. Radiation osteomyelitis will be added as an LLT to PT Osteoradionecrosis.

# Supplemental Update Report

CR Number: 2019143057      Implementation Date: 29-May-19      Related CR: 2019143057

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Rhinocerebral mucormycosis</i>	Approved as Requested	Proposed PT	
To HLT	<i>Orbital infections, inflammations and irritations</i>		<i>Rhinocerebral mucormycosis</i>	10076959
			To HLT	
			<i>Orbital infections, inflammations and irritations</i>	10031049

MSSO Comment: The proposal to link the PT Rhinocerebral mucormycosis to the HLT Orbital infections, inflammations and irritations is approved as requested. Rhinocerebral mucormycosis is a rare opportunistic infection of the sinuses, nasal passages, oral cavity, and brain caused by saprophytic fungi. PT Rhinocerebral mucormycosis warrants addition of a secondary link to SOC Eye disorders because this cranial fungus infection often extends to the orbit and the ocular tissues, reflected by LLT Rhino-orbital-cerebral that is grouped under the PT. Furthermore, PT Rhinocerebral mucormycosis will be linked to secondary HLT Fungal upper respiratory tract infections.

CR Number: 2019149026      Implementation Date: 29-May-19      Related CR: 2019143057

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Rhinocerebral mucormycosis</i>	Approved as Requested	Proposed PT	
To HLT	<i>Fungal upper respiratory tract infections</i>		<i>Rhinocerebral mucormycosis</i>	10076959
			To HLT	
			<i>Fungal upper respiratory tract infections</i>	10079103

MSSO Comment:

# Supplemental Update Report

CR Number: 2019143078 Implementation Date: 28-May-19 Related CR: 2019143078

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Glycogen storage disease type IX (and/or type IXa)</i>	Approved Not as Requested	Proposed PT <i>Glycogen storage disease type IX</i>	10083034
			HLT primary <i>Inborn errors of carbohydrate metabolism (excl glucose)</i>	10021604
			SOC primary <i>Congenital, familial and genetic disorders</i>	10010331
			HLT secondary <i>Inborn errors of carbohydrate metabolism (excl glucose)</i>	10021604
			SOC secondary <i>Metabolism and nutrition disorders</i>	10027433

**MSSO Comment:** The proposal to add a new LLT Glycogen storage disease type IX (and/or type IXa) is approved but not as requested. Glycogen storage disease type IX is a group of at least four disorders characterized by a deficiency of the enzyme phosphorylase kinase, an enzyme is necessary to metabolize glycogen. Because individuals with GSD-IX cannot properly break down glycogen, excess amounts accumulate in the liver, muscles, or both. Glycogen storage disease type IX is sometimes categorized into a liver form (caused by phosphorylase kinase deficiency in the liver, or liver and muscle) and muscle form, which is rare and is caused by phosphorylase kinase deficiency in the muscle only. Glycogen storage disease type IX will be added as a new PT to HLT Inborn errors of carbohydrate metabolism (excl glucose) which is bi-axial to primary SOC Congenital, familial and genetic disorders, and to secondary SOC Metabolism and nutrition disorders. In a related change, sub-types Glycogen storage disease type IXa and Glycogen storage disease type IXb will be added to the new PT Glycogen storage disease type IX.

CR Number: 2019148006 Implementation Date: 28-May-19 Related CR: 2019143078

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Glycogen storage disease type IXa</i>	Approved as Requested	Proposed LLT <i>Glycogen storage disease type IXa</i>	10083035 Current
To PT	<i>Glycogen storage disease type IX</i>		To PT <i>Glycogen storage disease type IX</i>	10083034

**MSSO Comment:**

# Supplemental Update Report

CR Number: 2019148007 Implementation Date: 28-May-19 Related CR: 2019143078

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Glycogen storage disease type IXb</i>	Approved as Requested	Proposed LLT	
To PT	<i>Glycogen storage disease type IX</i>		<i>Glycogen storage disease type IXb</i>	10083036 Current
			To PT	
			<i>Glycogen storage disease type IX</i>	10083034

MSSO  
Comment:

CR Number: 2019143079 Implementation Date: 29-May-19 Related CR: 2019143079

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	<i>Trousseau's syndrome</i>	Approved as Requested	PT to merge	
To PT	<i>Thrombophlebitis migrans</i>		<i>Trousseau's syndrome</i>	10060905 Current
			To PT	
			<i>Thrombophlebitis migrans</i>	10043581

MSSO  
Comment: The proposal to demote the PT Trousseau's syndrome under PT Thrombophlebitis migrans is approved as requested. Thrombophlebitis migrans (superficial migratory thrombophlebitis) has been associated with significant systemic diseases, such as malignancy (Trousseau sign of malignancy or Trousseau's syndrome) which are recurrent or appearing in different locations over time (thrombophlebitis migrans or migratory thrombophlebitis), Behcet's disease, Buerger's disease, inflammatory bowel disease, and deep vein thrombosis, which should be considered in the patient's work-up. Trousseau's syndrome is synonymous to thrombophlebitis migrans which can represent varied systemic disease states in addition to Trousseau's syndrome. In a related change, Thrombophlebitis migrans will be linked to a secondary HLT Paraneoplastic syndromes NEC.

CR Number: 2019150622 Implementation Date: 29-May-19 Related CR: 2019143079

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Thrombophlebitis migrans</i>	Approved as Requested	Proposed PT	
To HLT	<i>Paraneoplastic syndromes NEC</i>		<i>Thrombophlebitis migrans</i>	10043581
			To HLT	
			<i>Paraneoplastic syndromes NEC</i>	10067229

MSSO  
Comment:

# Supplemental Update Report

CR Number: 2019143080 Implementation Date: 29-May-19 Related CR: 2019143080

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Immune-mediated nephritis	Approved as Requested	Proposed PT	
HLT primary	Nephritis NEC		Immune-mediated nephritis	10083070
SOC primary	Renal and urinary disorders		HLT primary	
			Nephritis NEC	10029137
			SOC primary	
			Renal and urinary disorders	10038359
			HLT secondary	
			Immune and associated conditions NEC	10027682
			SOC secondary	
			Immune system disorders	10021428

MSSO Comment: The proposal to add a new PT Immune-mediated nephritis to primary HLT Nephritis NEC in SOC Renal and urinary disorders is approved as requested. Nephritis is a general term given to inflammation of the spaces between the renal tubules of the kidneys which can lead to inflammation, swelling and a decrease in kidney function. There are a number of causes of nephritis and one of which is an "immune system" related inflammation or reaction in response to specific drugs and/or medications. New PT Immune-mediated nephritis will also be linked to secondary HLT Immune and associated conditions NEC.

CR Number: 2019143081 Implementation Date: 29-May-19 Related CR: 2019143081

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Nephritis immune-mediated	Rejected		

MSSO Comment: The proposal to add a new term Nephritis immune-mediated is not approved. The concept can be represented by LLT Immune-mediated nephritis which was added in previous change request 2019143080.

# Supplemental Update Report

CR Number: 2019143082      Implementation Date: 29-May-19      Related CR: 2019143082

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Immune-mediated thyroiditis	Approved as Requested	Proposed PT	
HLT primary	Acute and chronic thyroiditis		Immune-mediated thyroiditis	10083071
SOC primary	Endocrine disorders		HLT primary	
			Acute and chronic thyroiditis	10043779
			SOC primary	
			Endocrine disorders	10014698
			HLT secondary	
			Immune and associated conditions NEC	10027682
			SOC secondary	
			Immune system disorders	10021428

**MSSO Comment:** The proposal to add a new PT Immune-mediated thyroiditis to primary HLT Acute and chronic thyroiditis in SOC Endocrine disorders is approved as requested. Immune mediated is defined as an inflammatory process caused by an unspecified immune reaction leading to dysregulation of the normal immune response. Immune mediated diseases are often based on an autoimmune mechanism but not limited to. New PT Immune-mediated thyroiditis will also be linked to secondary HLT Immune and associated conditions NEC.

CR Number: 2019143083      Implementation Date: 29-May-19      Related CR: 2019143083

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Thyroiditis immune-mediated	Rejected		

**MSSO Comment:** The proposal to add a new term Thyroiditis immune-mediated is not approved. Please use the newly added PT Immune-mediated thyroiditis in change request 2019143082 for your coding needs to avoid overpopulation of MedDRA with lexical variant concepts.

# Supplemental Update Report

CR Number: 2019143084 Implementation Date: 29-May-19 Related CR: 2019143084

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Immune-mediated uveitis</i>	Approved as Requested	Proposed PT <i>Immune-mediated uveitis</i>	10083069
HLT primary	<i>Iris and uveal tract infections, irritations and inflammations</i>		HLT primary <i>Iris and uveal tract infections, irritations and inflammations</i>	10022953
SOC primary	<i>Eye disorders</i>		SOC primary <i>Eye disorders</i>	10015919
			HLT secondary <i>Immune and associated conditions NEC</i>	10027682
			SOC secondary <i>Immune system disorders</i>	10021428

MSSO Comment: The proposal to add a new PT Immune-mediated uveitis to primary HLT Iris and uveal tract infections, irritations and inflammations in SOC Eye disorders is approved as requested. Immune mediated is defined as an inflammatory process caused by an unspecified immune reaction leading to dysregulation of the normal immune response. Immune mediated diseases are often based on an autoimmune mechanism but not limited to. New PT Immune-mediated uveitis will also be linked to secondary HLT Immune and associated conditions NEC.

CR Number: 2019143085 Implementation Date: 29-May-19 Related CR: 2019143085

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Uveitis immune-mediated</i>	Rejected		

MSSO Comment: The proposal to add a new term Uveitis immune-mediated is not approved. Please use the newly added PT Immune-mediated uveitis in change request 2019143084 for your coding needs to avoid overpopulation of MedDRA with lexical variant concepts.

# Supplemental Update Report

CR Number: 2019143086 Implementation Date: 29-May-19 Related CR: 2019143086

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Immune-mediated pancreatitis</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Acute and chronic pancreatitis</i>		<i>Immune-mediated pancreatitis</i>	10083072
SOC primary	<i>Gastrointestinal disorders</i>		HLT primary	
			<i>Acute and chronic pancreatitis</i>	10033646
			SOC primary	
			<i>Gastrointestinal disorders</i>	10017947
			HLT secondary	
			<i>Immune and associated conditions NEC</i>	10027682
			SOC secondary	
			<i>Immune system disorders</i>	10021428

**MSSO Comment:** The proposal to add a new PT Immune-mediated pancreatitis to primary HLT Acute and chronic pancreatitis in SOC Gastrointestinal disorders is approved as requested. "Immune mediated" is defined as an inflammatory process caused by an unspecified immune reaction leading to dysregulation of the normal immune response. Immune mediated diseases often are based on an autoimmune mechanism but not limited to. New PT Immune-mediated pancreatitis will also be linked to secondary HLT Immune and associated conditions NEC.

CR Number: 2019143087 Implementation Date: 29-May-19 Related CR: 2019143087

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Pancreatitis immune-mediated</i>	Rejected		

**MSSO Comment:** The proposal to add a new term Pancreatitis immune-mediated is not approved. Please use the newly added PT Immune-mediated pancreatitis in change request 2019143086 for your coding needs to avoid overpopulation of MedDRA with lexical variant concepts.

# Supplemental Update Report

CR Number: 2019143088 Implementation Date: 29-May-19 Related CR: 2019143088

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT	Approved as Requested	Proposed PT	
HLT primary	<i>Immune-mediated myositis</i>		<i>Immune-mediated myositis</i>	10083073
SOC primary	<i>Muscle infections and inflammations</i>		HLT primary	
	<i>Musculoskeletal and connective tissue disorders</i>		<i>Muscle infections and inflammations</i>	10021992
			SOC primary	
			<i>Musculoskeletal and connective tissue disorders</i>	10028395
			HLT secondary	
			<i>Immune and associated conditions NEC</i>	10027682
			SOC secondary	
			<i>Immune system disorders</i>	10021428

MSSO Comment: The proposal to add a new PT Immune-mediated myositis to primary HLT Muscle infections and inflammations in SOC Musculoskeletal and connective tissue disorders is approved as requested. "Immune mediated" is defined as an inflammatory process caused by an unspecified immune reaction leading to dysregulation of the normal immune response. Immune mediated diseases are often based on an autoimmune mechanism but not limited to. New PT Immune-mediated myositis will also be linked to secondary HLT Immune and associated conditions NEC. In a related change, PT Immune-mediated necrotising myopathy will be demoted and added as a sub-concept LLT to new PT Immune-mediated myositis.

CR Number: 2019150462 Implementation Date: 29-May-19 Related CR: 2019143088

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
PT to merge	Demote a PT	Approved as Requested	PT to merge	
To PT	<i>Immune-mediated necrotising myopathy</i>		<i>Immune-mediated necrotising myopathy</i>	10072155 Current
	<i>Immune-mediated myositis</i>		To PT	
			<i>Immune-mediated myositis</i>	10083073

MSSO Comment:

# Supplemental Update Report

CR Number: 2019143089 Implementation Date: 29-May-19 Related CR: 2019143089

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Myositis immune-mediated</i>	Rejected		

MSSO Comment: The proposal to add a new term Myositis immune-mediated is not approved. Please use the newly added PT Immune-mediated myositis in change request 2019143088 for your coding needs to avoid overpopulation of MedDRA with lexical variant concepts.

CR Number: 2019143090 Implementation Date: 29-May-19 Related CR: 2019143090

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Immune-mediated encephalitis</i>	Approved as Requested	Proposed PT	
			<i>Immune-mediated encephalitis</i>	10083074
			HLT primary	
			<i>Encephalitis NEC</i>	10014599
			SOC primary	
			<i>Nervous system disorders</i>	10029205
			HLT secondary	
			<i>Immune and associated conditions NEC</i>	10027682
			SOC secondary	
			<i>Immune system disorders</i>	10021428

MSSO Comment: The proposal to add a new term Immune-mediated encephalitis is approved as requested. "Immune mediated" is defined as an inflammatory process caused by an unspecified immune reaction leading to dysregulation of the normal immune response. Immune mediated diseases are often based on an autoimmune mechanism but not limited to. New concepts for MedDRA will be added in the natural word order as PTs. Immune-mediated encephalitis will be added as PT to primary HLT Encephalitis NEC and to secondary HLT Immune and associated conditions NEC.

CR Number: 2019143091 Implementation Date: 29-May-19 Related CR: 2019143091

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Encephalitis immune-mediated</i>	Rejected		
HLT primary	<i>Encephalitis NEC</i>			
SOC primary	<i>Nervous system disorders</i>			

MSSO Comment: The proposal to add a new PT Encephalitis immune-mediated to primary HLT Encephalitis NEC in SOC Nervous system disorders and secondary HLT Paraneoplastic syndromes NEC in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is not approved. New concepts will only be added in the natural word order to avoid overpopulation of MedDRA. Please see Change request 2019143090 for addition of PT Immune-mediated encephalitis.

# Supplemental Update Report

CR Number: 2019143092 Implementation Date: 29-May-19 Related CR: 2019143092

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	<i>Immune-mediated hypothyroidism</i>	Approved as Requested	Proposed PT	
HLT primary	<i>Thyroid hypofunction disorders</i>		<i>Immune-mediated hypothyroidism</i>	10083075
SOC primary	<i>Endocrine disorders</i>		HLT primary	
			<i>Thyroid hypofunction disorders</i>	10043741
			SOC primary	
			<i>Endocrine disorders</i>	10014698
			HLT secondary	
			<i>Immune and associated conditions NEC</i>	10027682
			SOC secondary	
			<i>Immune system disorders</i>	10021428

MSSO Comment: The proposal to add a new PT Immune-mediated hypothyroidism to primary HLT Thyroid hypofunction disorders in SOC Endocrine disorders is approved as requested. "Immune mediated" is defined as an inflammatory process caused by an unspecified immune reaction leading to dysregulation of the normal immune response. Immune mediated diseases are often based on an autoimmune mechanism but not limited to. New PT Immune-mediated hypothyroidism will also be linked to secondary HLT Immune and associated conditions NEC.

CR Number: 2019143093 Implementation Date: 29-May-19 Related CR: 2019143093

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	<i>Hypothyroidism immune-mediated</i>	Rejected		

MSSO Comment: The proposal to add a new term Hypothyroidism immune-mediated is not approved. New concepts will only be added in the natural word order to avoid overpopulation of MedDRA. Please see change request 2019143092 for addition of PT Immune-mediated hypothyroidism.

CR Number: 2019143094 Implementation Date: 29-May-19 Related CR: 2019143094

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	<i>Myocarditis immune-mediated</i>	Rejected		
To PT	<i>Immune-mediated myocarditis</i>			

MSSO Comment: The proposal to add a new LLT Myocarditis immune-mediated to PT Immune-mediated myocarditis is not approved. New concepts will only be added in the natural word order to avoid overpopulation of MedDRA. Please use PT Immune-mediated myocarditis, recently added in Change request 2018360001, for your coding needs.

# Supplemental Update Report

**CR Number:** 2019144001      **Implementation Date:** 29-May-19      **Related CR:** 2019144001

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term	Approved as Requested	Proposed LLT <i>Levoscoliosis</i>	10083076 Current
			To PT <i>Scoliosis</i>	10039722

**MSSO Comment:** The proposal to add a new term Levoscoliosis is approved as requested. Scoliosis is an appreciable lateral deviation in the normally straight vertical line of the spine. Levoscoliosis, lateral deviation to the left, will be added as sub-concept LLT to PT Scoliosis.

**CR Number:** 2019144002      **Implementation Date:** 29-May-19      **Related CR:** 2019144002

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT	Approved as Requested	Proposed PT <i>Intrathecal infusion pump user</i>	10083063
HLT primary	<i>Disability issues</i>		HLT primary <i>Disability issues</i>	10057171
SOC primary	<i>Social circumstances</i>		SOC primary <i>Social circumstances</i>	10041244

**MSSO Comment:** The proposal to add a new PT Intrathecal infusion pump user to primary HLT Disability issues in SOC Social circumstances is approved as requested. In intrathecal drug delivery, pain medications and/or medications used for spasticity are introduced directly to the spinal fluid (intrathecal space) through a drug delivery system comprised of a pump and catheter. With this method, less medication is necessary than if medication were taken orally, and fewer side effects are seen.

**CR Number:** 2019144003      **Implementation Date:** 29-May-19      **Related CR:** 2019144003

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT	Approved as Requested	Proposed LLT <i>Tetraparesis</i>	10083066 Current
To PT	<i>Quadriparesis</i>		To PT <i>Quadriparesis</i>	10049680

**MSSO Comment:** The proposal to add a new LLT Tetraparesis to PT Quadriparesis is approved as requested. Tetraparesis is a synonym of quadriparesis.

# Supplemental Update Report

**CR Number:** 2019144004      **Implementation Date:** 29-May-19      **Related CR:** 2019144004

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Anal papillectomy</i>	Approved Not as Requested	Proposed LLT <i>Anal papillectomy</i>	10083065 Current
HLT primary	<i>Anorectal therapeutic procedures</i>		To PT <i>Anal skin tag excision</i>	10002171
SOC primary	<i>Surgical and medical procedures</i>			

**MSSO Comment:** The proposal to add a new PT Anal papillectomy to primary HLT Anorectal therapeutic procedures in SOC Surgical and medical procedures is approved but not as requested. Considering that an anal papilla, hypertrophied anal papilla, and anal skin tag are often used interchangeably, Anal papillectomy will be added as an LLT to PT Anal skin tag excision.

**CR Number:** 2019144005      **Implementation Date:** 29-May-19      **Related CR:** 2019144005

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed LLT	Add a New LLT <i>Hypertrophied anal papillae resection</i>	Approved as Requested	Proposed LLT <i>Hypertrophied anal papillae resection</i>	10083064 Current
			To PT <i>Anal skin tag excision</i>	10002171

**MSSO Comment:** The proposal to add a new LLT Hypertrophied anal papillae resection is approved as requested. Hypertrophied anal papillae resection will be added as an LLT to PT Anal skin tag excision as it is a synonym of Anal papillectomy added in change request 2019144004.

**CR Number:** 2019144006      **Implementation Date:** 29-May-19      **Related CR:** 2019144006

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed PT	Add a New PT <i>Drug-procedure interaction</i>	Rejected		
HLT primary	<i>Interactions</i>			
SOC primary	<i>General disorders and administration site conditions</i>			

**MSSO Comment:** The proposal to add a new PT Drug-procedure interaction to primary HLT Interactions in SOC General disorders and administration site conditions is not approved. Drug-procedure interaction does not appear to be a recognized concept in the medical literature.

# Supplemental Update Report

CR Number: 2019144007 Implementation Date: 29-May-19 Related CR: 2019144007

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Swelling of retina</i>	Approved as Requested	Proposed LLT <i>Swelling of retina</i>	10083080 Current
			To PT <i>Retinal oedema</i>	10038886

MSSO Comment: The proposal to add a new term Swelling of retina is approved as requested. Swelling of retina will be added as a colloquial synonym LLT to PT Retinal oedema.

CR Number: 2019144008 Implementation Date: 29-May-19 Related CR: 2019144008

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Macular swelling</i>	Approved as Requested	Proposed LLT <i>Macular swelling</i>	10083081 Current
			To PT <i>Macular oedema</i>	10025415

MSSO Comment: The proposal to add a new term Macular swelling is approved as requested. Macular swelling will be added as a colloquial synonym LLT to PT Macular oedema.

CR Number: 2019144009 Implementation Date: 29-May-19 Related CR: 2019144009

<u>Change Requested</u>		<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term	Add a New Term <i>Right atrial volume abnormal</i>	Approved as Requested	Proposed PT <i>Right atrial volume abnormal</i>	10083077
			HLT primary <i>Cardiac function diagnostic procedures</i>	10007566
			SOC primary <i>Investigations</i>	10022891

MSSO Comment: The proposal to add a new term Right atrial volume abnormal is approved as requested. An abnormal right atrial volume is identified when the measured value is outside of the established normal reference range. Right atrial volume disorders typically include tricuspid regurgitation/ stenosis, right ventricular failure, valvular heart disease, atrial fibrillation, pulmonary embolism, pulmonary hypertension, and atrial septal defect. Right atrial volume abnormal will be added as a PT to HLT Cardiac function diagnostic procedures.

# Supplemental Update Report

CR Number: 2019144010      Implementation Date: 29-May-19      Related CR: 2019144010

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term <i>Right atrial volume increased</i>	Approved as Requested	Proposed PT <i>Right atrial volume increased</i>	10083079
		HLT primary <i>Cardiac function diagnostic procedures</i>	10007566
		SOC primary <i>Investigations</i>	10022891

**MSSO Comment:** The proposal to add a new term Right atrial volume increased is approved as requested. An increased right atrial volume is identified when the measured value exceeds the established normal reference range. Right atrial volume disorders typically include tricuspid regurgitation/ stenosis, right ventricular failure, valvular heart disease, atrial fibrillation, pulmonary embolism, pulmonary hypertension, and atrial septal defect. Right atrial volume increased will be added as a PT to HLT Cardiac function diagnostic procedures.

CR Number: 2019144011      Implementation Date: 29-May-19      Related CR: 2019144011

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term <i>Right atrial volume decreased</i>	Approved as Requested	Proposed PT <i>Right atrial volume decreased</i>	10083078
		HLT primary <i>Cardiac function diagnostic procedures</i>	10007566
		SOC primary <i>Investigations</i>	10022891

**MSSO Comment:** The proposal to add a new term Right atrial volume decreased is approved as requested. A decreased right atrial volume is identified when the measured value is less than the established normal reference range. Right atrial volume disorders typically include tricuspid regurgitation/ stenosis, right ventricular failure, valvular heart disease, atrial fibrillation, pulmonary embolism, pulmonary hypertension, and atrial septal defect. Right atrial volume decreased will be added as a PT to HLT Cardiac function diagnostic procedures.

CR Number: 2019144012      Implementation Date: 29-May-19      Related CR: 2019144012

<u>Change Requested</u>	<u>Final Disposition</u>	<u>Final Placement</u>	<u>MedDRA Code #</u>
Proposed Term <i>Chest myalgia</i>	Rejected		

**MSSO Comment:** The proposal to add a new term Chest myalgia is not approved. 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 Myalgia and LLT Chest pain (non-cardiac), or LLT Musculoskeletal chest pain. Please review the MedDRA Term Selection: Points to Consider document, Section 3.5.

# Supplemental Update Report

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CR Number: 2019144013

Implementation Date: 29-May-19

Related CR: 2019144013

Change Requested

Add a New Term

Final Disposition

Final Placement

MedDRA  
Code #

Proposed Term *Feeling unsteady*

Rejected

MSSO Comment: The proposal to add a new term Feeling unsteady is not approved. MedDRA cannot accommodate individual terms that represent all possible corresponding nouns, adjectives, adverbs, etc. that pertain to a particular concept. Please consider existing LLT Unstable feeling or LLT Unsteadiness for your coding needs. If less specificity is required, LLT Feeling abnormal may be coded.

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CR Number: 2019147001

Implementation Date: 29-May-19

Related CR: 2019147001

Change Requested

Add a New Term

Final Disposition

Final Placement

MedDRA  
Code #

Proposed Term *Lipoprotein-associated phospholipase A2*

Approved as Requested

Proposed PT

*Lipoprotein-associated phospholipase A2*

10083082

HLT primary

*Tissue enzyme analyses NEC*

10043891

SOC primary

*Investigations*

10022891

MSSO Comment: The proposal to add a new term Lipoprotein-associated phospholipase A2 is approved as requested. Lipoprotein-associated phospholipase (Lp-PL)A2 is an acute-phase reaction enzyme and a useful plasma biomarker associated with cardiovascular disease. Lipoprotein-associated phospholipase A2 will be added as PT to HLT Tissue enzyme analyses NEC.

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