# Supplemental Update Report

**CR Number: 2012319113** **Implementation Date:** 16-Jan-19 Related CR: 2012319113

| Change Requested | Add a new SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed SMQ | *Infusion related reactions* | Rejected After Suspension | | |

MSSO Comment: The proposal to add a new SMQ Infusion related reactions is not approved after suspension. The ICH Advisory Panel did approve this SMQ topic to go into the development phase and it underwent testing in three databases (two regulatory authorities and one company). However, there were numerous challenges encountered in testing and the consensus decision of the CIOMS SMQ Implementation Working Group was that the topic could not be developed to go into production as an SMQ. Most notably, in contrast to other SMQs, this query could not be tested using negative control compounds because it was not possible to identify suitable compounds administered via infusion that were not associated with some type of reaction. In addition, there is no internationally agreed definition of an infusion related reaction and the range of potential reactions associated with the large variety of compounds given by infusion is very broad and heterogenous. Testing was conducted on a set of around 500 terms, the majority of which was already included in Anaphylactic reaction (SMQ), Angioedema (SMQ), and Hypersensitivity (SMQ). It proved difficult to identify potential cases of infusion related reactions in post-marketing databases where the temporal relationship of the event to the infusion is typically not available. In clinical trial databases where this information is more easily available, users are encouraged to provide more specificity about the event, e.g., by reporting “Anaphylactic reaction” when it is known that this event is temporally associated with the infusion. In summary, this topic was too broad and non-specific to be developed into an SMQ without the benefit of suitable negative controls for testing. Users could consider using or modifying existing SMQs such as Anaphylactic reaction (SMQ), Angioedema (SMQ), and Hypersensitivity (SMQ) to address this query.

**CR Number: 2018337001** **Implementation Date:** 09-Jan-19 Related CR: 2018337001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Aorto-bronchial fistula* | Approved as Requested | Proposed PT | |
| | | | *Aorto-bronchial fistula* | 10082565 |
| | | | HLT primary | |
| | | | *Bronchial conditions NEC* | 10006429 |
| | | | SOC primary | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |
| | | | HLT secondary | |
| | | | *Haemorrhages NEC* | 10018987 |
| | | | SOC secondary | |
| | | | *Vascular disorders* | 10047065 |

MSSO Comment: The proposal to add a new term Aorto-bronchial fistula is approved as requested. An aorto-bronchial fistula (ABF) is a connection between the aorta and the tracheobronchial tree. The main symptom of ABF is coughing up blood or bloodstained mucus from the lungs, a condition known as hemoptysis, which may result in a life-threatening haemorrhage. ABF may develop as a complication of an aneurysm of the aorta, whether atherosclerotic, syphilitic, dissecting, or in association with inflammation. More often it is a surgical complication from procedures such as valve replacement, aortocoronary bypass, interruption of persistent ductus arteriosus and reconstructive procedures of the aorta. Aorto-bronchial fistula will be added as a PT to primary HLT Bronchial conditions NEC, to secondary HLT Haemorrhages NEC and to secondary HLT Cardiac and vascular procedural complications.

# Supplemental Update Report

**CR Number: 2018365142** **Implementation Date:** 09-Jan-19 Related CR: 2018337001

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Aorto-bronchial fistula* | Approved as Requested | Proposed PT | |
| To HLT | *Cardiac and vascular procedural complications* | | *Aorto-bronchial fistula* | 10082565 |
| | | | To HLT | |
| | | | *Cardiac and vascular procedural complications* | 10007602 |

MSSO Comment:

**CR Number: 2018338001** **Implementation Date:** 09-Jan-19 Related CR: 2018338001

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Nasolaryngoscopy* | Approved as Requested | Proposed PT | |
| HLT primary | *Respiratory tract and thoracic imaging procedures* | | *Nasolaryngoscopy* | 10082566 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Respiratory tract and thoracic imaging procedures* | 10006476 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Nasolaryngoscopy to primary HLT Respiratory tract and thoracic imaging procedures in SOC Investigations is approved as requested. Nasolaryngoscopy (fiberoptic laryngoscopy) uses a small flexible video scope. The instrument is passed through the nose and into the pharynx and laryngeal area while the patient is conscious. This is the most common means for the visual examination of the larynx.

# Supplemental Update Report

**CR Number: 2018338006** **Implementation Date:** 09-Jan-19 Related CR: 2018338006

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Plasminogen activator inhibitor deficiency type 1* | Approved Not as Requested | Proposed PT | |
| HLT primary | *Acquired gene mutations and other alterations* | | *Plasminogen activator inhibitor deficiency type 1* | |
| SOC primary | *General disorders and administration site conditions* | | HLT primary | |
| | | | *Coagulation disorders congenital* | 10009735 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary | |
| | | | *Coagulopathies* | 10053567 |
| | | | SOC secondary | |
| | | | *Blood and lymphatic system disorders* | 10005329 |

MSSO Comment: The proposal to add a new PT Plasminogen activator inhibitor deficiency type 1 to primary HLT Acquired gene mutations and other alterations in SOC General disorders and administration site conditions and secondary HLT Coagulopathies in SOC Blood and lymphatic system disorders is approved but not as requested. Plasminogen inhibitor-1 deficiency is a rare autosomal recessive hematologic disorder characterized by increased bleeding after trauma, injury, or surgery. Affected females have menorrhagia. The bleeding defect is due to increased fibrinolysis of fibrin blood clots due to deficiency of PAI1, which inhibits tissue (PLAT; 173370) and urinary (PLAU; 191840) activators of plasminogen (PLG; 173350). Plasminogen activator inhibitor deficiency type 1 will be added as a PT to primary HLT Coagulation disorders congenital and secondary HLT Coagulopathies.

**CR Number: 2018338009** **Implementation Date:** 09-Jan-19 Related CR: 2018338009

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Adenoid ameloblastoma with dentinoid* | Approved as Requested | Proposed LLT | |
| | | | *Adenoid ameloblastoma with dentinoid* | 10082568 Current |
| | | | To PT | |
| | | | *Ameloblastoma* | 10066796 |

MSSO Comment: The proposal to add a new term Adenoid ameloblastoma with dentinoid is approved as requested. Adenoid ameloblastoma with dentinoid is a rare lesion. Due to the diverse histopathological presentation and also the paucity of reported cases, pathologists may face diagnostic confusion on many occasions. Hence, it can be considered as rare hybrid variants of ameloblastoma. Adenoid ameloblastoma with dentinoid will be added as a sub-concept LLT to PT Ameloblastoma.

# Supplemental Update Report

**CR Number:** **2018340002** **Implementation Date:** 09-Jan-19 Related CR: 2018340002

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Dysdialysis syndrome* | Rejected | | |
| HLT primary | *Dialysis related complications* | | | |
| SOC primary | *Injury, poisoning and procedural complications* | | | |

MSSO Comment: The proposal to add a new PT Dysdialysis syndrome to primary HLT Dialysis related complications in SOC Injury, poisoning and procedural complications and secondary HLT Vascular hypotensive disorders in SOC Vascular disorders is not approved. Dysdialysis syndrome does not appear to be an internationally recognized concept. References describing Dysdialysis syndrome were only identified in Japanese articles.

**CR Number:** **2018340003** **Implementation Date:** 09-Jan-19 Related CR: 2018340003

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Diaphragm resection* | Approved as Requested | Proposed LLT | |
| | | | *Diaphragm resection* | 10082564 Current |
| | | | To PT | |
| | | | *Diaphragmatic operation* | 10061817 |

MSSO Comment: The proposal to add a new term Diaphragm resection is approved as requested. Resection, or excision of the diaphragm is performed for a variety of indications, including neoplastic invasion or metastasis involving the diaphragmatic tissue. Diaphragm resection will be added as a subconcept LLT to PT Diaphragmatic operation.

**CR Number:** **2018340005** **Implementation Date:** 09-Jan-19 Related CR: 2018340005

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Penile rash* | Approved Not as Requested | Proposed LLT | |
| HLT primary | *Penile disorders NEC (excl erection and ejaculation)* | | *Penile rash* | 10082571 |
| | | | To PT | |
| SOC primary | *Reproductive system and breast disorders* | | *Genital rash* | 10018175 |

MSSO Comment: The proposal to add a new PT Penile rash to primary HLT Penile disorders NEC (excl erection and ejaculation) in SOC Reproductive system and breast disorders is approved but not as requested. Penile rash will be added as anatomical sub-concept LLT to the broad PT Genital rash.

# Supplemental Update Report

**CR Number:** **2018340006** **Implementation Date:** 09-Jan-19 Related CR: 2018340006

| Change Requested | | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Promote an LLT | | | | |
| Proposed LLT | *Rash acneiform* | Rejected | | |
| From PT | *Dermatitis acneiform* | | | |

MSSO Comment: The proposal to promote the LLT Rash acneiform from PT Dermatitis acneiform is not approved. Rash acneiform is best placed as quasi-synonym under PT Dermatitis acneiform which is defined as; Cutaneous eruptions resembling acne, characterized by the presence of papulonodules, pustules, comedones, or cysts in the face, trunk, and extremities. Causes include infections and the use of certain medications.

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**CR Number:** **2018340007** **Implementation Date:** 09-Jan-19 Related CR: 2018340007

| Change Requested | | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Add a New LLT | | | | |
| Proposed LLT | *Pimply rash* | Rejected | | |

MSSO Comment: The proposal to add a new LLT Pimply rash is not approved. Pimply rash is a colloquial expression which can be represented by LLT Pimple-like rash which will be added in change request 2018340008 in batch 10110138.

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**CR Number:** **2018340008** **Implementation Date:** 09-Jan-19 Related CR: 2018340008

| Change Requested | | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Add a New LLT | | | | |
| Proposed LLT | *Pimple-like rash* | Approved as Requested | Proposed LLT | |
| | | | *Pimple-like rash* | 10082570 Current |
| | | | To PT | |
| | | | *Dermatitis acneiform* | 10012432 |

MSSO Comment: The proposal to add a new LLT Pimple-like rash is approved as requested. Pimple-like rash, a colloquial expression of exisitng PT Dermatitis acneiform, will be added as LLT under PT Dermatitis acneiform.

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# Supplemental Update Report

**CR Number:** **2018340009** **Implementation Date:** 09-Jan-19 Related CR: 2018340009

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Rash bullous* | Rejected | | |
| From PT | *Dermatitis bullous* | | | |

MSSO Comment: The proposal to promote the LLT Rash bullous from PT Dermatitis bullous is not approved. The most important part of this dermatological descriptive concept is "bullous" and therefore best grouped under PT Dermatitis bullous. Promotion rather may lead to dilution.

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**CR Number:** **2018340010** **Implementation Date:** 09-Jan-19 Related CR: 2018340010

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Eye discomfort* | Approved as Requested | Proposed LLT | |
| To PT | *Ocular discomfort* | | *Eye discomfort* | 10082572 Current |
| | | | To PT | |
| | | | *Ocular discomfort* | 10052143 |

MSSO Comment: The proposal to add a new LLT Eye discomfort to PT Ocular discomfort is approved as requested. Eye discomfort and Ocular discomfort are synonymously used.

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**CR Number:** **2018340011** **Implementation Date:** 09-Jan-19 Related CR: 2018340011

| Change Requested | Change Status of LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| LLT to change | *Hyperactive* | Rejected | | |
| Status | *non-current* | | | |

MSSO Comment: The proposal to change status of LLT Hyperactive to non-current is not approved. The term "hyperactive" is not vague and is defined as "the state or condition of being overly active". Hyperactive and Hyperactivity are LLTs in MedDRA since v2.1 and flagging non-current may have impact of legacy data. The PT Psychomotor hyperactivity the two LLTs are assigned to contains both components "psycho" and "motor" and furthermore, is linked to the two respective SOCs. For reports, where the terms historically and occasionally still may be used for ADHD, appropriate LLTs under PT Attention deficit/hyperactivity disorder, such as LLT Hyperactive child syndrome, could be considered as coding options.

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# Supplemental Update Report

**CR Number: 2018340012** **Implementation Date:** 09-Jan-19 Related CR: 2018340012

| Change Requested | Change Status of LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| LLT to change | *Hyperactivity* | Rejected | | |
| Status | *non-current* | | | |

MSSO Comment: The proposal to change status of LLT Hyperactivity to non-current is not approved. The term "hyperactivity" is not vague and is defined as "the state or condition of being overly active". Hyperactive and Hyperactivity are LLTs in MedDRA since v2.1 and flagging non-current may have impact of legacy data. The PT Psychomotor hyperactivity the two LLTs are assigned to contains both components "psycho" and "motor" and furthermore, is linked to the two respective SOCs. For reports, where the terms historically and occasionally still may be used for ADHD, appropriate LLTs under PT Attention deficit/hyperactivity disorder, such as LLT Hyperactive child syndrome, could be considered as coding options.

**CR Number: 2018340013** **Implementation Date:** 09-Jan-19 Related CR: 2018340013

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Testicular exfoliation* | Rejected | | |

MSSO Comment: The proposal to add a new term Testicular exfoliation is not approved. Testicular exfoliation is ambiguous concept because it can refer to external to dermatologic condition or to a toxicological germ cell pathology.

**CR Number: 2018340014** **Implementation Date:** 09-Jan-19 Related CR: 2018340014

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Genital exfoliation* | Approved as Requested | Proposed PT | |
| | | | *Genital exfoliation* | 10082569 |
| | | | HLT primary | |
| | | | *Reproductive tract signs and symptoms NEC* | 10040674 |
| | | | SOC primary | |
| | | | *Reproductive system and breast disorders* | 10038604 |
| | | | HLT secondary | |
| | | | *Exfoliative conditions* | 10015664 |
| | | | SOC secondary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment: The proposal to add a new PT Genital exfoliation is approved as requested. Genital exfoliation refers to skin or mucosal exfoliation in the genital area, which is a region of frequently exposed to inflammatory processes, such as those associated to allergic dermatitis, contact irritants, or venereal infections. Genital exfoliation will be added as a PT with a primary link to HLT Reproductive tract signs and symptoms NEC, with a secondary link to HLT Exfoliative conditions.

# Supplemental Update Report

**CR Number:** **2018340015** **Implementation Date:** 09-Jan-19 Related CR: 2018340015

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Clamminess* | Rejected | | |
| From PT | *Cold sweat* | | | |
| To PT | *Hyperhidrosis* | | | |

MSSO Comment: The proposal to move the LLT Clamminess from PT Cold sweat to PT Hyperhidrosis is not approved. Clammy refers to a surface covered with a cold, sticky moisture, provoking a cold and damp sensation. The term is better represented in its current location, as a characteristic of the skin associated to normal sweating, rather than under the proposed hyperhidrosis, which is disorder term representing excessive sweating.

**CR Number:** **2018340016** **Implementation Date:** 09-Jan-19 Related CR: 2018340016

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Clammy* | Rejected | | |
| From PT | *Cold sweat* | | | |
| To PT | *Hyperhidrosis* | | | |

MSSO Comment: The proposal to move the LLT Clammy from PT Cold sweat to PT Hyperhidrosis is not approved. Clammy refers to a surface covered with a cold, sticky moisture, provoking a cold and damp sensation. The term is better represented in its current location, as a characteristic of the skin associated to normal sweating, rather than under the proposed hyperhidrosis, which is disorder term representing excessive sweating.

**CR Number:** **2018340017** **Implementation Date:** 09-Jan-19 Related CR: 2018340017

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Red spotty rash* | Rejected | | |
| To PT | *Rash macular* | | | |

MSSO Comment: The proposal to add a new LLT Red spotty rash to PT Rash macular is not approved. The consumer friendly alternatives to the medical term Erythromacular rash mentioned in subscriber's justification can be found in the more coloquial LLTs Blotchy rash, Red blotches, Skin blotches, or Spot-like rash, all of which subordinated together with LLT Erythromacular rash under the PT Rash macular.

# Supplemental Update Report

**CR Number: 2018340018** **Implementation Date:** 09-Jan-19 Related CR: 2018340018

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Generalised erythema* | Approved as Requested | PT to merge | |
| To PT | *Erythema* | | *Generalised erythema* | 10051576 Current |
| | | | To PT | |
| | | | *Erythema* | 10015150 |

MSSO Comment: The proposal to demote the PT Generalised erythema under PT Erythema is approved as requested. This demotion will align Generalised erythema as a sub-concept LLT with LLT Localised erythema under PT Erythema.

**CR Number: 2018340019** **Implementation Date:** 09-Jan-19 Related CR: 2018340019

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Pruritus generalised* | Approved as Requested | PT to merge | |
| To PT | *Pruritus* | | *Pruritus generalised* | 10052576 Current |
| | | | To PT | |
| | | | *Pruritus* | 10037087 |

MSSO Comment: The proposal to demote the PT Pruritus generalised under PT Pruritus is approved as requested. This demotion will align Pruritus generalised as a sub-concept LLT with LLT Localised pruritus under PT Pruritus.

**CR Number: 2018340020** **Implementation Date:** 09-Jan-19 Related CR: 2018340020

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Rash generalised* | Approved as Requested | PT to merge | |
| To PT | *Rash* | | *Rash generalised* | 10037858 Current |
| | | | To PT | |
| | | | *Rash* | 10037844 |

MSSO Comment: The proposal to demote the PT Rash generalised under PT Rash is approved as requested. This demotion will align Rash generalised as a sub-concept LLT with LLT Localised rash under PT Rash.

# Supplemental Update Report

**CR Number: 2018340040** **Implementation Date:** 10-Jan-19 Related CR: 2018340040

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Stoma site mucositis* | Approved Not as Requested | Proposed LLT | |
| HLT primary | *Stoma complications* | | *Stoma site mucositis* | 10082573 Current |
| SOC primary | *Injury, poisoning and procedural complications* | | To PT | |
| | | | *Stoma site inflammation* | 10065669 |

MSSO Comment: The proposal to add a new PT Stoma site mucositis to primary HLT Stoma complications in SOC Injury, poisoning and procedural complications is approved but not as requested. Mucosal tissue injury is a dose-limiting toxicity of many cancer therapies. Because the number of patients treated with combinations of high-dose chemotherapy agents is likely to increase, more patients are at risk for mucositis. Patients who have a stoma may thus experience stomal site mucositis, as an effect of chemotherapy treatment. Stoma site mucositis will be added as an sub-concept LLT, consistent with other Mucositis terms, to PT Stoma site inflammation.

**CR Number: 2018344001** **Implementation Date:** 10-Jan-19 Related CR: 2018344001

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Central nervous system lymphoma* | Approved as Requested | Proposed PT | |
| To HLT | *Nervous system disorders NEC* | | *Central nervous system lymphoma* | 10007953 |
| | | | To HLT | |
| | | | *Nervous system disorders NEC* | 10057185 |

MSSO Comment: The proposal to link the PT Central nervous system lymphoma to the HLT Nervous system disorders NEC is approved as requested. Central nervous system lymphoma is a rare non-Hodgkin lymphoma in which malignant cells from lymph tissue form in the brain and/or spinal cord (primary lymphoma), or spread from other parts of the body to the brain and/or spinal cord (secondary lymphoma). The addition of secondary link HLT Nervous system disorders NEC represents the site of manifestation of this disorder.

**CR Number: 2018346001** **Implementation Date:** 10-Jan-19 Related CR: 2018346001

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Pancreatic nodule* | Approved as Requested | Proposed LLT | |
| From PT | *Pancreatic neoplasm* | | *Pancreatic nodule* | 10050212 Current |
| To PT | *Pancreatic mass* | | From PT | |
| | | | *Pancreatic neoplasm* | 10061902 |
| | | | To PT | |
| | | | *Pancreatic mass* | 10049082 |

MSSO Comment: The proposal to move the LLT Pancreatic nodule from PT Pancreatic neoplasm to PT Pancreatic mass is approved as requested. In MedDRA, a "nodule" is usually not represented as a neoplastic concept. Nodule concepts are generally represented at the LLT level under the most appropriate “mass,” “disorder” or "nodule" term, e.g. LLT Subcutaneous nodule to PT Skin mass.

# Supplemental Update Report

**CR Number: 2018346002** **Implementation Date:** 10-Jan-19 Related CR: 2018346002

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Allergy to Vitamin B12* | Approved Not as Requested | Proposed LLT | |
| | | | *Allergy to vitamin B12* | 10082574 Current |
| | | | To PT | |
| | | | *Drug hypersensitivity* | 10013700 |

MSSO Comment: The proposal to add a new term Allergy to Vitamin B12 is approved but not as requested. Vitamin B12 injections are generally considered to be very safe. They have no major side effects. However, in very rare cases, some people can experience side effects caused by allergic reactions or sensitivity. Allergy to vitamin B12 will be added as an LLT, with corrected capitalization in accordance to MedDRA convetions, to PT Drug hypersensitivity.

**CR Number: 2018346003** **Implementation Date:** 10-Jan-19 Related CR: 2018346003

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Lung diffusion test abnormal* | Approved as Requested | Proposed LLT | |
| | | | *Lung diffusion test abnormal* | 10082576 |
| | | | To PT | |
| | | | *Carbon monoxide diffusing capacity decreased* | 10065906 Current |

MSSO Comment: The proposal to add a new term Lung diffusion test abnormal is approved as requested. Lung diffusion testing is synonymous with gas diffusion study or diffusing capacity of the lung for carbon monoxide. Lung diffusion test abnormal will be added as a synonym LLT to PT Carbon monoxide diffusing capacity decreased.

**CR Number: 2018346004** **Implementation Date:** 10-Jan-19 Related CR: 2018346004

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Respiratory mucosal hyperemia* | Approved Not as Requested | Proposed PT | |
| | | | *Bronchial mucosa hyperaemia* | 10082575 |
| | | | HLT primary | |
| | | | *Bronchial conditions NEC* | 10006429 |
| | | | SOC primary | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |

MSSO Comment: The proposal to add a new term Respiratory mucosal hyperemia is approved but not as requested. Based upon on subscriber initial justification the more precise concept Bronchial mucosa hyperaemia will be added as PT to HLT Bronchial conditions NEC. In a related change, the American English spelled counterpart Bronchial mucosa hyperemia will be added as an LLT to the new PT Bronchial mucosa hyperaemia.

# Supplemental Update Report

**CR Number: 2018365174** **Implementation Date:** 10-Jan-19 Related CR: 2018346004

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Bronchial mucosa hyperemia* | Approved as Requested | Proposed LLT | |
| To PT | *Bronchial mucosa hyperaemia* | | *Bronchial mucosa hyperemia* | 10082577 Current |
| | | | To PT | |
| | | | *Bronchial mucosa hyperaemia* | 10082575 |

MSSO Comment:

**CR Number: 2018346005** **Implementation Date:** 14-Jan-19 Related CR: 2018346005

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Orbital reconstruction* | Approved as Requested | PT to merge | |
| To PT | *Orbit plastic repair* | | *Orbital reconstruction* | 10082385 Current |
| | | | To PT | |
| | | | *Orbit plastic repair* | 10031034 |

MSSO Comment: The proposal to demote the PT Orbital reconstruction under PT Orbit plastic repair is approved as requested. Orbit plastic repair (also called Ophthalmic Plastic or Oculoplastic Surgery) is plastic and reconstructive surgery of the periocular area, which includes the eyelids, eyebrows, eye socket/orbit and tear duct/lacrimal system. Orbital reconstruction (mainly post-traumatic) is a complex intervention that involves both the soft tissue and bony injury.

# Supplemental Update Report

**CR Number: 2018348001** **Implementation Date:** 10-Jan-19 Related CR: 2018348001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Musculoskeletal toxicity* | Approved as Requested | Proposed PT | |
| | | | *Musculoskeletal toxicity* | 10082578 |
| | | | HLT primary | |
| | | | *Musculoskeletal and connective tissue conditions NEC* | 10080711 |
| | | | SOC primary | |
| | | | *Musculoskeletal and connective tissue disorders* | 10028395 |
| | | | HLT secondary | |
| | | | *Poisoning and toxicity* | 10035777 |
| | | | SOC secondary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |

MSSO Comment: The proposal to add a new term Musculoskeletal toxicity is approved as requested. Musculoskeletal toxicity encompasses a diverse spectrum of adverse effects affecting the structure and/or function of the muscles, bones, and joints caused by exposure to a toxic chemical, or drug. It is often chronic and progressive, leading to deformities and disability. Musculoskeletal toxicity will be placed as PT to primary HLT Musculoskeletal and connective tissue conditions NEC and secondary HLT Poisoning and toxicity.

**CR Number: 2018348002** **Implementation Date:** 11-Jan-19 Related CR: 2018348002

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Diffuse idiopathic pulmonary neuroendocrine cell hyperplasia* | Approved as Requested | Proposed PT | |
| HLT primary | *Parenchymal lung disorders NEC* | | *Diffuse idiopathic pulmonary neuroendocrine cell hyperplasia* | 10082591 |
| SOC primary | *Respiratory, thoracic and mediastinal disorders* | | HLT primary | |
| | | | *Parenchymal lung disorders NEC* | 10033979 |
| | | | SOC primary | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |

MSSO Comment: The proposal to add a new PT Diffuse idiopathic pulmonary neuroendocrine cell hyperplasia to primary HLT Parenchymal lung disorders NEC in SOC Respiratory, thoracic and mediastinal disorders is approved as requested. Diffuse idiopathic pulmonary neuroendocrine cell hyperplasia is a rare lesion consisting on a diffuse proliferation of neuroendocrine cells, but without invasion of the basement membrane. It can exist as a diffuse increase in the number of single neuroendocrine cells, or as small lesions less than 5.0 mm in diameter. Lesions over 5.0 mm in size or that breach the basement membrane are carcinoid tumors.

# Supplemental Update Report

**CR Number: 2018348003** **Implementation Date:** 11-Jan-19 Related CR: 2018348003

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Epiploic appendage removal* | Approved Not as Requested | Proposed PT | |
| HLT primary | *Abdominal therapeutic procedures NEC* | | *Epiploic appendage removal* | 10082592 |
| SOC primary | *Surgical and medical procedures* | | HLT primary | |
| | | | *Large intestine therapeutic procedures* | 10023803 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment: The proposal to add a new PT Epiploic appendage removal to primary HLT Abdominal therapeutic procedures NEC in SOC Surgical and medical procedures is approved but not as requested. The epiploic appendices are small pouches of the peritoneum filled with fat and situated along the colon. PT Epiploic appendage removal will be added to the more specific HLT Large intestine therapeutic procedures.

**CR Number: 2018348004** **Implementation Date:** 11-Jan-19 Related CR: 2018348004

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Intrathecal injection* | Approved as Requested | Proposed PT | |
| HLT primary | *Spine and spinal cord therapeutic procedures* | | *Intrathecal injection* | 10082593 |
| SOC primary | *Surgical and medical procedures* | | HLT primary | |
| | | | *Spine and spinal cord therapeutic procedures* | 10041590 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment: The proposal to add a new PT Intrathecal injection to primary HLT Spine and spinal cord therapeutic procedures in SOC Surgical and medical procedures is approved as requested. An intrathecal administration of a drug is one that is injected into the subarachnoid space.

# Supplemental Update Report

**CR Number: 2018351001** **Implementation Date:** 11-Jan-19 Related CR: 2018351001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Foville syndrome* | Approved as Requested | Proposed PT | |
| | | | *Foville syndrome* | 10082594 |
| | | | HLT primary | |
| | | | *Nervous system disorders NEC* | 10057185 |
| | | | SOC primary | |
| | | | *Nervous system disorders* | 10029205 |
| | | | HLT secondary | |
| | | | *Cerebrovascular and spinal necrosis and vascular insufficiency* | 10008192 |
| | | | SOC secondary | |
| | | | *Vascular disorders* | 10047065 |

MSSO Comment: The proposal to add a new term Foville syndrome is approved as requested. The term, which describes a brainstem stroke syndrome associated with hemiparesis/hemiplegia, peripheral facial weakness and dysconjugate gaze will be added as PT to primary HLT Nervous system disorders NEC and secondary HLT Cerebrovascular and spinal necrosis and vascular insufficiency and secondary HLT Ocular nerve and muscle disorders.

**CR Number: 2018365178** **Implementation Date:** 11-Jan-19 Related CR: 2018351001

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Foville syndrome* | Approved as Requested | Proposed PT | |
| To HLT | *Ocular nerve and muscle disorders* | | *Foville syndrome* | 10082594 |
| | | | To HLT | |
| | | | *Ocular nerve and muscle disorders* | 10030059 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2018351002** **Implementation Date:** 11-Jan-19 Related CR: 2018351002

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Vitreopapillary traction* | Approved Not as Requested | Proposed LLT | |
| | | | *Vitreopapillary traction syndrome* | 10082597 Current |
| | | | To PT | |
| | | | *Optic disc traction syndrome* | 10082596 |

MSSO Comment: The proposal to add a new term Vitreopapillary traction is approved but not as requested. Optic disc traction (vitreopapillary traction), a newly recognized disorder, is characterized by traction of the optic disc by fibrocellular proliferating membrane or posterior vitreous detachment. This abnormality has been described in proliferative diabetic retinopathy and may be accompanied by intrapapillary and subretinal peripapillary hemorrhages, especially in young patients. Vitreopapillary traction will be modified to Vitreopapillary traction syndrome and added as synonym LLT to a new PT Optic disc traction syndrome. PT Optic disc traction syndrome will be added in change request 2018351003.

**CR Number: 2018351003** **Implementation Date:** 11-Jan-19 Related CR: 2018351003

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Optic disc traction* | Approved Not as Requested | Proposed PT | |
| | | | *Optic disc traction syndrome* | 10082596 |
| | | | HLT primary | |
| | | | *Optic disc abnormalities NEC* | 10030913 |
| | | | SOC primary | |
| | | | *Eye disorders* | 10015919 |
| | | | HLT secondary | |
| | | | *Ocular vascular disorders NEC* | 10030067 |
| | | | SOC secondary | |
| | | | *Vascular disorders* | 10047065 |

MSSO Comment: The proposal to add a new term Optic disc traction is approved but not as requested. Optic disc traction (vitreopapillary traction), a newly recognized disorder, is characterized by traction of the optic disc by fibrocellular proliferating membrane or posterior vitreous detachment. This abnormality has been described in proliferative diabetic retinopathy and may be accompanied by intrapapillary and subretinal peripapillary hemorrhages, especially in young patients. The requested term will be modified and added as PT Optic disc traction syndrome to primary HLT Optic disc abnormalities NEC and secondary HLT Ocular vascular disorders NEC. In related changes, LLT Vitreoretinal traction syndrome will be promoted from PT Vitreous adhesions to a level PT and linked to primary HLT Retinal structural change, deposit and degeneration. Furthermore, LLT Vitreomacular traction syndrome will be moved from PT Vitreous adhesions to the newly promoted PT Vitreoretinal traction syndrome for better alignment.

# Supplemental Update Report

**CR Number: 2018365179** **Implementation Date:** 11-Jan-19 Related CR: 2018351003

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Vitreoretinal traction syndrome* | Approved as Requested | Proposed LLT | |
| From PT | *Vitreous adhesions* | | *Vitreoretinal traction syndrome* | 10071181 |
| HLT primary | *Retinal structural change, deposit and degeneration* | | From PT | |
| | | | *Vitreous adhesions* | 10057435 |
| | | | HLT primary | |
| | | | *Retinal structural change, deposit and degeneration* | 10038896 |
| | | | SOC primary | |
| | | | *Eye disorders* | 10015919 |

MSSO Comment:

**CR Number: 2018365180** **Implementation Date:** 11-Jan-19 Related CR: 2018351003

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Vitreomacular traction syndrome* | Approved as Requested | Proposed LLT | |
| From PT | *Vitreous adhesions* | | *Vitreomacular traction syndrome* | 10051065 Current |
| To PT | *Vitreoretinal traction syndrome* | | From PT | |
| | | | *Vitreous adhesions* | 10057435 |
| | | | To PT | |
| | | | *Vitreoretinal traction syndrome* | 10071181 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2018351004** **Implementation Date:** 11-Jan-19 Related CR: 2018351004

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Arteriovenous graft site necrosis* | Approved Not as Requested | Proposed PT | |
| | | | *Arteriovenous graft site necrosis* | 10082595 |
| | | | HLT primary | |
| | | | *Cardiac and vascular procedural complications* | 10007602 |
| | | | SOC primary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |
| | | | HLT secondary | |
| | | | *Non-site specific necrosis and vascular insufficiency NEC* | 10029558 |
| | | | SOC secondary | |
| | | | *Vascular disorders* | 10047065 |

MSSO Comment: The proposal to add a new LLT Arteriovenous graft site necrosis is approved but not as requested. Skin necrosis complicating a haemodialysis angioaccess that is associated with bleeding is a serious (even lethal) complication, which needs treatment with an application of a local skin flap. Arteriovenous graft site necrosis will be added as a PT to primary HLT Cardiac and vascular procedural complications and secondary HLT Non-site specific necrosis and vascular insufficiency NEC.

**CR Number: 2018351005** **Implementation Date:** 11-Jan-19 Related CR: 2018351005

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Strongyloides IgG antibody positive* | Approved as Requested | Proposed LLT | |
| | | | *Strongyloides IgG antibody positive* | 10082600 Current |
| | | | To PT | |
| | | | *Strongyloides test positive* | 10082598 |

MSSO Comment: The proposal to add a new term Strongyloides IgG antibody positive is approved as requested. Infection with Strongyloides, a human pathogenic parasitic roundworm, is confirmed by either stool specimen examination or the presence of Strongyloides IgG antibody in serum. Strongyloides IgG antibody positive will be added as an LLT to a new PT Strongyloides test positive. In a related change, new PT Strongyloides test positive will be added to HLT Parasite identification and serology. Furthermore LLT Strongyloides stool test positive will also be added to new PT Strongyloides test positive as a sub-concept.

# Supplemental Update Report

**CR Number: 2018365181** **Implementation Date:** 11-Jan-19 Related CR: 2018351005

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Strongyloides test positive* | Approved as Requested | Proposed PT<br>*Strongyloides test positive* | 10082598 |
| HLT primary | *Parasite identification and serology* | | HLT primary<br>*Parasite identification and serology* | 10033903 |
| SOC primary | *Investigations* | | SOC primary<br>*Investigations* | 10022891 |

MSSO Comment:

**CR Number: 2018365182** **Implementation Date:** 11-Jan-19 Related CR: 2018351005

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Strongyloides stool test positive* | Approved as Requested | Proposed LLT<br>*Strongyloides stool test positive* | 10082601 Current |
| To PT | *Strongyloides test positive* | | To PT<br>*Strongyloides test positive* | 10082598 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2018351006** **Implementation Date:** 11-Jan-19 Related CR: 2018351006

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Corneal toxicity* | Approved Not as Requested | Proposed PT<br>*Corneal toxicity* | 10082599 |
| | | | HLT primary<br>*Corneal injuries* | 10011024 |
| | | | SOC primary<br>*Eye disorders* | 10015919 |
| | | | HLT secondary<br>*Poisoning and toxicity* | 10035777 |
| | | | SOC secondary<br>*Injury, poisoning and procedural complications* | 10022117 |

MSSO Comment: The proposal to add a new LLT Corneal toxicity is approved but not as requested. Corneal toxicity is a commonly cited concept associated with topical ocular medications, the use of contact lens solutions, etc. Corneal toxicity will be added as a PT to primary HLT Corneal injuries and secondary HLT Poisoning and toxicity.

**CR Number: 2018351007** **Implementation Date:** 21-Mar-19 Related CR: 2018351007

| Change Requested | Add a new SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed SMQ | *Serotonin syndrome (SMQ)* | Rejected After Suspension | | |

MSSO Comment: The proposal to add a new SMQ Serotonin syndrome (SMQ) is not approved after suspension. An international team of regulatory and industry representatives evaluated this request and does not recommend the development of this SMQ based on the following considerations. The CIOMS SMQ Implementation Working Group has previously made two attempts to develop and test an SMQ for serotonin syndrome, including using an algorithmic approach. However, these efforts failed to produce a workable SMQ and development was discontinued. The challenges are that the manifestations of serotonin syndrome include a variety of non-specific signs and symptoms and that there is no universally agreed definition for the condition. Given these considerations, another attempt at developing this SMQ is unlikely to be successful and cannot be supported at this time.

# Supplemental Update Report

**CR Number: 2018351008** **Implementation Date:** 11-Jan-19 Related CR: 2018351008

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Tongue sensation loss of* | Approved as Requested | Proposed LLT | |
| From PT | *Hypoaesthesia oral* | | *Tongue sensation loss of* | 10043978 Current |
| To PT | *Anaesthesia oral* | | From PT | |
| | | | *Hypoaesthesia oral* | 10057371 |
| | | | To PT | |
| | | | *Anaesthesia oral* | 10082548 |

MSSO Comment: The proposal to move the LLT Tongue sensation loss of from PT Hypoaesthesia oral to PT Anaesthesia oral is approved as requested for better alignment.

**CR Number: 2018352001** **Implementation Date:** 11-Jan-19 Related CR: 2018352001

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Glucocorticoid deficiency* | Approved Not as Requested | Proposed PT | |
| Old Primary SOC | *Endocrine disorders* | | *Familial glucocorticoid deficiency* | 10082603 |
| New Primary SOC | *Congenital, familial and genetic disorders* | | HLT primary | |
| | | | *Adrenal disorders congenital* | 10001349 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary | |
| | | | *Adrenal cortical hypofunctions* | 10001343 |
| | | | SOC secondary | |
| | | | *Endocrine disorders* | 10014698 |

MSSO Comment: The proposal to reassign the primary SOC of PT Glucocorticoid deficiency from current SOC Endocrine disorders to SOC Congenital, familial and genetic disorders is approved but not as requested. Familial glucocorticoid deficiency, otherwise known as hereditary unresponsiveness to ACTH, is a rare autosomal recessive disease characterized by glucocorticoid deficiency in the absence of mineralocorticoid deficiency. Glucocorticoid deficiency may be caused by other causes than congenital adrenocortical deficiencies such as Addison's disease and therefore the placement and links for PT Glucocorticoid deficiency are appropriate. However, a new PT Familial glucocorticoid deficiency will be added with primary HLT Adrenal disorders congenital, secondary HLT Adrenal cortical hypofunctions and secondary HLT Metabolic disorders NEC to represent the hereditary type of this deficiency.

# Supplemental Update Report

**CR Number: 2018365184** **Implementation Date:** 11-Jan-19 Related CR: 2018352001

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Familial glucocorticoid deficiency* | Approved as Requested | Proposed PT | |
| To HLT | *Metabolic disorders NEC* | | *Familial glucocorticoid deficiency* | 10082603 |
| | | | To HLT | |
| | | | *Metabolic disorders NEC* | 10027428 |

MSSO Comment:

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**CR Number: 2018353001** **Implementation Date:** 11-Jan-19 Related CR: 2018353001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Primary obstructed megaureter* | Approved as Requested | Proposed LLT | |
| | | | *Primary obstructed megaureter* | 10082602 Current |
| | | | To PT | |
| | | | *Congenital megaureter* | 10010540 |

MSSO Comment: The proposal to add a new term Primary obstructed megaureter is approved as requested. Primary obstructed megaureter usually represents a congenital etiology and will be added as an LLT sub-concept under PT Congenital megaureter.

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**CR Number: 2018353002** **Implementation Date:** 11-Jan-19 Related CR: 2018353002

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Acquired megaureter* | Rejected | | |

MSSO Comment: The proposal to add a new term Acquired megaureter is not approved. Megaureter is used for congential types of ureteric dilatations. Non-congential ureteric dilatations can be represented by LLT Ureteric dilatation or LLT Hydroureter.

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# Supplemental Update Report

**CR Number: 2018353003** **Implementation Date:** 11-Jan-19 Related CR: 2018353003

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Uterine atony* | Approved as Requested | Proposed PT | |
| | | | *Uterine atony* | 10046763 |
| Old Primary SOC | *Reproductive system and breast disorders* | | Old Primary SOC | |
| | | | *Reproductive system and breast disorders* | 10038604 |
| New Primary SOC | *Pregnancy, puerperium and perinatal conditions* | | New Primary SOC | |
| | | | *Pregnancy, puerperium and perinatal conditions* | 10036585 |

MSSO Comment: The proposal to reassign the primary SOC of PT Uterine atony from current SOC Reproductive system and breast disorders to SOC Pregnancy, puerperium and perinatal conditions is approved as requested. Uterine atony is fundamentally an obstetric condition, like most of the terms under HLT Uterine tone disorders, and therefore will be linked to HLT Maternal complications of labour NEC and its primary link changed to SOC Pregnancy, puerperium and perinatal conditions.

**CR Number: 2018353004** **Implementation Date:** 11-Jan-19 Related CR: 2018353004

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Uterine atony* | Approved as Requested | Proposed PT | |
| | | | *Uterine atony* | 10046763 |
| To HLT | *Maternal complications of labour NEC* | | To HLT | |
| | | | *Maternal complications of labour NEC* | 10026907 |

MSSO Comment: The proposal to link the PT Uterine atony to the HLT Maternal complications of labour NEC is approved as requested. Uterine atony is fundamentally an obstetric condition, like most of the terms under HLT Uterine tone disorders, and therefore will be linked to HLT Maternal complications of labour NEC. Furthermore, the primary SOC for PT Uterine atony will be changed from SOC Reproductive system and breast disorders to SOC Pregnancy, puerperium and perinatal conditions as carried out in change request 2018353003.

**CR Number: 2018353005** **Implementation Date:** 14-Jan-19 Related CR: 2018353005

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Invasive Squamous Cell Carcinoma of the Skin* | Approved Not as Requested | Proposed LLT | | |
| | | | *Invasive squamous cell carcinoma of the skin* | 10082619 | Current |
| | | | To PT | | |
| | | | *Squamous cell carcinoma of skin* | 10041834 | |

MSSO Comment: The proposal to add a new LLT Invasive Squamous Cell Carcinoma of the Skin is approved but not as requested. Cutaneous squamous cell carcinoma is an invasive disease, referring to cancer cells that have grown beyond the epidermis and not any longer "in situ" and can refer to T1 - T4 in the TNM classification and stage Ia - IV. Invasive squamous cell carcinoma of the skin with corrected capitalization will be added as sub-concept LLT to PT Squamous cell carcinoma of skin.

# Supplemental Update Report

**CR Number: 2018354001** **Implementation Date:** 15-Jan-19 Related CR: 2018354001

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Perineal infection* | Approved as Requested | Proposed PT | |
| To HLT | *Reproductive tract disorders NEC (excl neoplasms)* | | *Perineal infection* | 10066876 |
| | | | To HLT | |
| | | | *Reproductive tract disorders NEC (excl neoplasms)* | 10027696 |

MSSO Comment: The proposal to link the PT Perineal infection to the HLT Reproductive tract disorders NEC (excl neoplasms) is approved as requested. The perineum is the space between the anus and scrotum in the male and between the anus and the vulva in the female. Perineal tears and episiotomy often occur in childbirth with first-time deliveries. The perineum is also an erogenous zone for both males and females. Perineal terms usually have a link to the SOC Reproductive system and breast disorders in MedDRA.

**CR Number: 2018354002** **Implementation Date:** 15-Jan-19 Related CR: 2018354002

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Perineal injury* | Approved as Requested | Proposed PT | |
| To HLT | *Reproductive tract disorders NEC (excl neoplasms)* | | *Perineal injury* | 10073329 |
| | | | To HLT | |
| | | | *Reproductive tract disorders NEC (excl neoplasms)* | 10027696 |

MSSO Comment: The proposal to link the PT Perineal injury to the HLT Reproductive tract disorders NEC (excl neoplasms) is approved as requested. The perineum is the space between the anus and scrotum in the male and between the anus and the vulva in the female. Perineal tears and episiotomy often occur in childbirth with first-time deliveries. The perineum is also an erogenous zone for both males and females. Perineal terms usually have a link to the SOC Reproductive system and breast disorders in MedDRA.

**CR Number: 2018354003** **Implementation Date:** 15-Jan-19 Related CR: 2018354003

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Metastases to perineum* | Approved as Requested | Proposed PT | |
| To HLT | *Reproductive tract neoplasms NEC* | | *Metastases to perineum* | 10051673 |
| | | | To HLT | |
| | | | *Reproductive tract neoplasms NEC* | 10027697 |

MSSO Comment: The proposal to link the PT Metastases to perineum to the HLT Reproductive tract neoplasms NEC is approved as requested. The perineum is the space between the anus and scrotum in the male and between the anus and the vulva in the female. Perineal tears and episiotomy often occur in childbirth with first-time deliveries. The perineum is also an erogenous zone for both males and females. Perineal terms usually have a link to the SOC Reproductive system and breast disorders in MedDRA.

# Supplemental Update Report

**CR Number:** **2018354004** **Implementation Date:** 15-Jan-19 Related CR: 2018354004

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Perineal repair breakdown* | Approved as Requested | Proposed PT | |
| To HLT | *Reproductive tract disorders NEC (excl neoplasms)* | | *Perineal repair breakdown* | 10034528 |
| | | | To HLT | |
| | | | *Reproductive tract disorders NEC (excl neoplasms)* | 10027696 |

MSSO Comment: The proposal to link the PT Perineal repair breakdown to the HLT Reproductive tract disorders NEC (excl neoplasms) is approved as requested. The perineum is the space between the anus and scrotum in the male and between the anus and the vulva in the female. Perineal tears and episiotomy often occur in childbirth with first-time deliveries. The perineum is also an erogenous zone for both males and females. Perineal terms usually have a link to the SOC Reproductive system and breast disorders in MedDRA.

**CR Number:** **2018354005** **Implementation Date:** 15-Jan-19 Related CR: 2018354005

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Perineal abscess* | Approved Not as Requested | Proposed PT | |
| To HLT | *Reproductive tract disorders NEC (excl neoplasms)* | | *Perineal abscess* | 10052457 |
| | | | To HLT | |
| | | | *Reproductive tract infections and inflammations NEC* | 10038613 |

MSSO Comment: The proposal to link the PT Perineal abscess to the HLT Reproductive tract disorders NEC (excl neoplasms) is approved but not as requested. The perineum is the space between the anus and scrotum in the male and between the anus and the vulva in the female. Perineal tears and episiotomy often occur in childbirth with first-time deliveries. The perineum is also an erogenous zone for both males and females. Perineal terms usually have a link to the SOC Reproductive system and breast disorders in MedDRA. All CRs in this internal batch are related to the follow up note in CR 2017362408. PT Perineal abscess will be linked to the more specific HLT Reproductive tract infections and inflammations NEC.

**CR Number:** **2018354006** **Implementation Date:** 11-Jan-19 Related CR: 2018354006

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Enterobacter tracheobronchitis* | Approved as Requested | Proposed PT | |
| From HLT | *Bacterial upper respiratory tract infections* | | *Enterobacter tracheobronchitis* | 10054220 |
| To HLT | *Bacterial lower respiratory tract infections* | | From HLT | |
| | | | *Bacterial upper respiratory tract infections* | 10004054 |
| | | | To HLT | |
| | | | *Bacterial lower respiratory tract infections* | 10004048 |

MSSO Comment: The proposal to move the PT Enterobacter tracheobronchitis from HLT Bacterial upper respiratory tract infections to HLT Bacterial lower respiratory tract infections is approved as requested for better alignment with related concepts.

# Supplemental Update Report

**CR Number: 2018354007** **Implementation Date:** 11-Jan-19 Related CR: 2018354007

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Connective Tissue Dysplasia* | Approved Not as Requested | Proposed PT | |
| HLT primary | *Connective tissue disorders congenital* | | *Connective tissue dysplasia* | 10082604 |
| SOC primary | *Congenital, familial and genetic disorders* | | HLT primary | |
| | | | *Connective tissue disorders congenital* | 10010763 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary | |
| | | | *Connective tissue disorders congenital* | 10010763 |
| | | | SOC secondary | |
| | | | *Musculoskeletal and connective tissue disorders* | 10028395 |

MSSO Comment: The proposal to add a new PT Connective Tissue Dysplasia to primary HLT Connective tissue disorders congenital in SOC Congenital, familial and genetic disorders is approved but not as requested. The name "connective tissue dysplasia" covers a wide range of disorders, which are caused by a abnormality of connective tissue development such as bone, ligaments, tendons and skin. Most connective tissue dysplasias follow common patterns of inheritance. The proposed term will be added with corrected capitalization in accordance to MedDRA standards as PT Connective tissue dysplasia to bi-axial HLT Connective tissue disorders congenital (primary SOC Congenital, familial and genetic disorders and secondary SOC Musculoskeletal and connective tissue disorders).

**CR Number: 2018354009** **Implementation Date:** 15-Jan-19 Related CR: 2018354009

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vascular access site inflammation* | Approved as Requested | Proposed PT | |
| From HLT | *Inflammations* | | *Vascular access site inflammation* | 10077650 |
| To HLT | *Vascular complications associated with device* | | From HLT | |
| | | | *Inflammations* | 10021950 |
| | | | To HLT | |
| | | | *Vascular complications associated with device* | 10069789 |

MSSO Comment: The proposal to move the PT Vascular access site inflammation from HLT Inflammations to HLT Vascular complications associated with device is approved as requested for a better alignment and higher grouping specificity.

# Supplemental Update Report

**CR Number: 2018354010** **Implementation Date:** 15-Jan-19 Related CR: 2018354010

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vascular access site vesicles* | Approved as Requested | Proposed PT | |
| To HLT | *Vascular complications associated with device* | | *Vascular access site vesicles* | 10079926 |
| | | | To HLT | |
| | | | *Vascular complications associated with device* | 10069789 |

MSSO Comment: The proposal to link the PT Vascular access site vesicles to the HLT Vascular complications associated with device is approved as requested. This is an additional valuable link for representation of this term and is consistent with other vascular access site terms.

**CR Number: 2018354011** **Implementation Date:** 15-Jan-19 Related CR: 2018354011

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vascular access site infection* | Approved as Requested | Proposed PT | |
| From HLT | *Complications associated with device NEC* | | *Vascular access site infection* | 10077651 |
| To HLT | *Vascular complications associated with device* | | From HLT | |
| | | | *Complications associated with device NEC* | 10069785 |
| | | | To HLT | |
| | | | *Vascular complications associated with device* | 10069789 |

MSSO Comment: The proposal to move the PT Vascular access site infection from HLT Complications associated with device NEC to HLT Vascular complications associated with device is approved as requested for a better alignment. In related changes, the following PTs will be moved from HLT Complications associated with device NEC to HLT Vascular complications associated with device: Vascular access complication; Vascular access site bruising; Vascular access site complication; Vascular access site haematoma; Vascular access site haemorrhage; Vascular access site occlusion; Vascular access site pseudoaneurysm; and Vascular access site rupture.

# Supplemental Update Report

**CR Number: 2018365194** **Implementation Date:** 15-Jan-19 Related CR: 2018354011

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vascular access site bruising* | Approved as Requested | Proposed PT | |
| From HLT | *Complications associated with device NEC* | | *Vascular access site bruising* | 10077767 |
| To HLT | *Vascular complications associated with device* | | From HLT | |
| | | | *Complications associated with device NEC* | 10069785 |
| | | | To HLT | |
| | | | *Vascular complications associated with device* | 10069789 |

MSSO Comment:

**CR Number: 2018365195** **Implementation Date:** 15-Jan-19 Related CR: 2018354011

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vascular access site complication* | Approved as Requested | Proposed PT | |
| From HLT | *Complications associated with device NEC* | | *Vascular access site complication* | 10077644 |
| To HLT | *Vascular complications associated with device* | | From HLT | |
| | | | *Complications associated with device NEC* | 10069785 |
| | | | To HLT | |
| | | | *Vascular complications associated with device* | 10069789 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2018365196** **Implementation Date:** 15-Jan-19 Related CR: 2018354011

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vascular access site haematoma* | Approved as Requested | Proposed PT | |
| From HLT | *Complications associated with device NEC* | | *Vascular access site haematoma* | 10077647 |
| To HLT | *Vascular complications associated with device* | | From HLT | |
| | | | *Complications associated with device NEC* | 10069785 |
| | | | To HLT | |
| | | | *Vascular complications associated with device* | 10069789 |

MSSO Comment:

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**CR Number: 2018365197** **Implementation Date:** 15-Jan-19 Related CR: 2018354011

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vascular access site haemorrhage* | Approved as Requested | Proposed PT | |
| From HLT | *Complications associated with device NEC* | | *Vascular access site haemorrhage* | 10077643 |
| To HLT | *Vascular complications associated with device* | | From HLT | |
| | | | *Complications associated with device NEC* | 10069785 |
| | | | To HLT | |
| | | | *Vascular complications associated with device* | 10069789 |

MSSO Comment:

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# Supplemental Update Report

**CR Number: 2018365198** **Implementation Date:** 15-Jan-19 Related CR: 2018354011

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vascular access site occlusion* | Approved as Requested | Proposed PT | |
| From HLT | *Complications associated with device NEC* | | *Vascular access site occlusion* | 10077648 |
| To HLT | *Vascular complications associated with device* | | From HLT | |
| | | | *Complications associated with device NEC* | 10069785 |
| | | | To HLT | |
| | | | *Vascular complications associated with device* | 10069789 |

MSSO Comment:

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**CR Number: 2018365199** **Implementation Date:** 15-Jan-19 Related CR: 2018354011

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vascular access site pseudoaneurysm* | Approved as Requested | Proposed PT | |
| From HLT | *Complications associated with device NEC* | | *Vascular access site pseudoaneurysm* | 10077649 |
| To HLT | *Vascular complications associated with device* | | From HLT | |
| | | | *Complications associated with device NEC* | 10069785 |
| | | | To HLT | |
| | | | *Vascular complications associated with device* | 10069789 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2018365200** **Implementation Date:** 15-Jan-19 Related CR: 2018354011

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vascular access site rupture* | Approved as Requested | Proposed PT | |
| From HLT | *Complications associated with device NEC* | | *Vascular access site rupture* | 10077652 |
| To HLT | *Vascular complications associated with device* | | From HLT | |
| | | | *Complications associated with device NEC* | 10069785 |
| | | | To HLT | |
| | | | *Vascular complications associated with device* | 10069789 |

MSSO Comment:

**CR Number: 2018365201** **Implementation Date:** 15-Jan-19 Related CR: 2018354011

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vascular access complication* | Approved as Requested | Proposed PT | |
| From HLT | *Complications associated with device NEC* | | *Vascular access complication* | 10062169 |
| To HLT | *Vascular complications associated with device* | | From HLT | |
| | | | *Complications associated with device NEC* | 10069785 |
| | | | To HLT | |
| | | | *Vascular complications associated with device* | 10069789 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2018354012** **Implementation Date:** 15-Jan-19 Related CR: 2018354012

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vascular access site oedema* | Approved as Requested | Proposed PT | |
| From HLT | *Oedema NEC* | | *Vascular access site oedema* | 10077645 |
| To HLT | *Vascular complications associated with device* | | From HLT | |
| | | | *Oedema NEC* | 10030113 |
| | | | To HLT | |
| | | | *Vascular complications associated with device* | 10069789 |

MSSO Comment: The proposal to move the PT Vascular access site oedema from HLT Oedema NEC to HLT Vascular complications associated with device is approved as requested for a better alignment and higher grouping specificity.

**CR Number: 2018354025** **Implementation Date:** 15-Jan-19 Related CR: 2018354025

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Positron emission tomogram breast* | Approved Not as Requested | Proposed PT | |
| HLT primary | *Imaging procedures NEC* | | *Positron emission tomogram breast* | 10082623 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Reproductive organ and breast imaging procedures* | 10038602 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Positron emission tomogram breast to primary HLT Imaging procedures NEC in SOC Investigations is approved but not as requested. Positron emission tomography (PET) of the breast is an important imaging study used in the evaluation of potential breast neoplasms. Positron emission tomogram breast will be placed as a PT under HLT Reproductive organ and breast imaging procedures to facilitate proper anatomic placement within MedDRA.

# Supplemental Update Report

**CR Number: 2018354026** **Implementation Date:** 15-Jan-19 Related CR: 2018354026

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Positron emission tomogram breast abnormal* | Approved Not as Requested | Proposed PT | |
| HLT primary | *Imaging procedures NEC* | | *Positron emission tomogram breast abnormal* | 10082622 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Reproductive organ and breast imaging procedures* | 10038602 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Positron emission tomogram breast abnormal to primary HLT Imaging procedures NEC in SOC Investigations is approved but not as requested. Positron emission tomography (PET) of the breast is an important diagnostic study in the evaluation of potential breast neoplasms. Positron emission tomogram breast abnormal will be placed as a PT under HLT Reproductive organ and breast imaging procedures to facilitate proper anatomic placement within MedDRA.

**CR Number: 2018354027** **Implementation Date:** 15-Jan-19 Related CR: 2018354027

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Radioisotope scan breast* | Approved Not as Requested | Proposed LLT | |
| HLT primary | *Imaging procedures NEC* | | *Radioisotope scan breast* | 10082628 Current |
| SOC primary | *Investigations* | | To PT | |
| | | | *Breast scan* | 10071224 |

MSSO Comment: The proposal to add a new PT Radioisotope scan breast to primary HLT Imaging procedures NEC in SOC Investigations is approved but not as requested. Radioisotope scan breast is an important diagnostic study in the evaluation of potential breast neoplasms. Radioisotope scan breast will be added as a sub-concept LLT under PT Breast scan.

**CR Number: 2018354028** **Implementation Date:** 15-Jan-19 Related CR: 2018354028

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Radioisotope scan breast abnormal* | Approved Not as Requested | Proposed LLT | |
| HLT primary | *Imaging procedures NEC* | | *Radioisotope scan breast abnormal* | 10082626 Current |
| SOC primary | *Investigations* | | To PT | |
| | | | *Breast scan abnormal* | 10082620 |

MSSO Comment: The proposal to add a new PT Radioisotope scan breast abnormal to primary HLT Imaging procedures NEC in SOC Investigations is approved but not as requested. Radioisotope scan breast is an important diagnostic study in the evaluation of potential breast neoplasms. Radioisotope scan breast abnormal will be placed as a sub-concept LLT under the new PT Breast scan abnormal. In a related change, Breast scan abnormal will be added as a PT to primary HLT Reproductive organ and breast imaging procedures.

# Supplemental Update Report

**CR Number: 2018365192** **Implementation Date:** 15-Jan-19 Related CR: 2018354028

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Breast scan abnormal* | Approved as Requested | Proposed PT | |
| HLT primary | *Reproductive organ and breast imaging procedures* | | *Breast scan abnormal* | 10082620 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Reproductive organ and breast imaging procedures* | 10038602 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment:

**CR Number: 2018354029** **Implementation Date:** 15-Jan-19 Related CR: 2018354029

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Radioisotope uptake increased* | Approved as Requested | Proposed PT | |
| HLT primary | *Imaging procedures NEC* | | *Radioisotope uptake increased* | 10082624 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Imaging procedures NEC* | 10021404 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Radioisotope uptake increased to primary HLT Imaging procedures NEC in SOC Investigations is approved as requested. Radioisotope uptake increased it is a general term which represents the increased absorption of radioisotope in a tissue during a scan exploration.

# Supplemental Update Report

**CR Number: 2018354030** **Implementation Date:** 15-Jan-19 Related CR: 2018354030

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *False positive radioisotope investigation result* | Approved as Requested | Proposed PT | |
| HLT primary | *Imaging procedures NEC* | | *False positive radioisotope investigation result* | 10082621 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Imaging procedures NEC* | 10021404 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT False positive radioisotope investigation result to primary HLT Imaging procedures NEC in SOC Investigations is approved as requested. The proposed concept is added to represent the artifactual absorption of radioisotope in a non-diseased tissue, such as a lactating breast.

**CR Number: 2018354031** **Implementation Date:** 15-Jan-19 Related CR: 2018354031

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Lactation normal* | Approved Not as Requested | Proposed PT | |
| HLT primary | *Reproductive organ and breast histopathology procedures* | | *Lactation normal* | 10082625 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Normal pregnancy, labour and delivery* | 10029772 |
| | | | SOC primary | |
| | | | *Pregnancy, puerperium and perinatal conditions* | 10036585 |

MSSO Comment: The proposal to add a new PT Lactation normal to primary HLT Reproductive organ and breast histopathology procedures in SOC Investigations is approved but not as requested. Lactation describes the secretion of milk from the mammary glands and the period of time that a mother lactates to feed her baby. PT Lactation normal will be linked to the more appropriate HLT Normal pregnancy, labour and delivery.

**CR Number: 2018354032** **Implementation Date:** 15-Jan-19 Related CR: 2018354032

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Breastfeeding unilateral* | Approved Not as Requested | Proposed LLT | |
| HLT primary | *Reproductive organ and breast histopathology procedures* | | *Breast feeding unilateral* | 10082629 Current |
| SOC primary | *Investigations* | | To PT | |
| | | | *Breast feeding* | 10006247 |

MSSO Comment: The proposal to add a new PT Breastfeeding unilateral to primary HLT Reproductive organ and breast histopathology procedures in SOC Investigations is approved but not as requested. The practice of unilateral breastfeeding is uncommon, but described in the medical literature. The proposed term will be rephrased to Breast feeding unilateral to meet MedDRA naming conventions and will be added as an LLT under the existing PT Breast feeding.

# Supplemental Update Report

**CR Number: 2018354033** **Implementation Date:** 15-Jan-19 Related CR: 2018354033

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Breastfeeding bilateral* | Approved Not as Requested | Proposed LLT | |
| HLT primary | *Reproductive organ and breast histopathology procedures* | | *Breast feeding bilateral* | 10082627 Current |
| SOC primary | *Investigations* | | To PT | |
| | | | *Breast feeding* | 10006247 |

MSSO Comment: The proposal to add a new PT Breastfeeding bilateral to primary HLT Reproductive organ and breast histopathology procedures in SOC Investigations is approved but not as requested. The proposed term will be rephrased to Breast feeding bilateral to meet MedDRA naming conventions and will be added as an LLT under the existing PT Breast feeding.

**CR Number: 2018355001** **Implementation Date:** 11-Jan-19 Related CR: 2018355001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Cervical canal atresia* | Approved Not as Requested | Proposed PT | |
| | | | *Uterine cervix canal atresia* | 10082605 |
| | | | HLT primary | |
| | | | *Female reproductive tract disorders congenital* | 10016416 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary | |
| | | | *Cervix disorders NEC* | 10008352 |
| | | | SOC secondary | |
| | | | *Reproductive system and breast disorders* | 10038604 |

MSSO Comment: The proposal to add a new term Cervical canal atresia is approved but not as requested. Congenital cervical atresia is a relatively rare Müllerian duct anomaly of the female reproductive tract that manifests as an absent or deformed uterine cervix. It is associated with acute or chronic abdominal or pelvic pain and reproductive problems. The requested term will be rephrased for clarification and added as PT Uterine cervix canal atresia to primary HLT Female reproductive tract disorders congenital and secondary HLT Cervix disorders NEC.

**CR Number: 2018355003** **Implementation Date:** 11-Jan-19 Related CR: 2018355003

| Change Requested | Change Status of LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| LLT to change | *Fever chills* | Rejected | | |
| Status | *non-current* | | | |

MSSO Comment: The proposal to change status of LLT Fever chills to non-current is not approved. LLTs "Chills & Fever" and “Chills and fever" were made non-current because they are multi-concept, whereas the term Fever chills is not. LLT Fever chills describes the shivering of muscles induced by the heat of pyrexia and is therefore a valid single concept as currently represented in MedDRA.

# Supplemental Update Report

**CR Number: 2018355004** **Implementation Date:** 11-Jan-19 Related CR: 2018355004

| Change Requested | Rename PT/LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Term to modify | *tingling feet/hands* | Rejected | | |
| Replacement term | *Two separate LLTs for Tingling feet and tingling hands* | | | |

MSSO Comment: The proposal to rename PT/LLT tingling feet/hands to Two separate LLTs for Tingling feet and tingling hands is not approved. Existing LLT Tingling feet/hands is a sub-concept under the PT Paraesthesia and should be used to characterize circumstances when both hands and both feet are affected. To characterize circumstances affecting one hand or one food in isolation, existing LLT Paresthesia hand or LLT Paresthesia foot may be selected.

**CR Number: 2018355005** **Implementation Date:** 15-Jan-19 Related CR: 2018355005

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Lung infection* | Approved After Suspension | PT to merge | |
| To PT | *Pneumonia* | | *Lung infection* | 10061229 Current |
| | | | To PT | |
| | | | *Pneumonia* | 10035664 |

MSSO Comment: The proposal to demote the PT Lung infection under PT Pneumonia is approved as requested after suspension. After re-evaluation and for consistent approach the MSSO agreed that Lung infection concepts can be considered synonymously used with Pneumonia concepts. For the same reason, PT Parasitic lung infection will be demoted under PT Parasitic pneumonia and PT Lung infection pseudomonal will be demoted under PT Pneumonia pseudomonal.

**CR Number: 2018365202** **Implementation Date:** 15-Jan-19 Related CR: 2018355005

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Parasitic lung infection* | Approved as Requested | PT to merge | |
| To PT | *Parasitic pneumonia* | | *Parasitic lung infection* | 10078884 Current |
| | | | To PT | |
| | | | *Parasitic pneumonia* | 10078883 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2018365203** **Implementation Date:** 15-Jan-19 Related CR: 2018355005

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Lung infection pseudomonal* | Approved as Requested | PT to merge | |
| To PT | *Pneumonia pseudomonal* | | *Lung infection pseudomonal* | 10057582 Current |
| | | | To PT | |
| | | | *Pneumonia pseudomonal* | 10035731 |

MSSO Comment:

**CR Number: 2018355006** **Implementation Date:** 10-Jan-19 Related CR: 2018355006

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Myocardial hypoperfusion* | Approved as Requested | Proposed PT | |
| HLT primary | *Cardiac disorders NEC* | | *Myocardial hypoperfusion* | 10082580 |
| SOC primary | *Cardiac disorders* | | HLT primary | |
| | | | *Cardiac disorders NEC* | 10007543 |
| | | | SOC primary | |
| | | | *Cardiac disorders* | 10007541 |
| | | | HLT secondary | |
| | | | *Site specific vascular disorders NEC* | 10057188 |
| | | | SOC secondary | |
| | | | *Vascular disorders* | 10047065 |

MSSO Comment: The proposal to add a new PT Myocardial hypoperfusion to primary HLT Cardiac disorders NEC in SOC Cardiac disorders is approved as requested. Myocardial hypoperfusion due to an inadequate coronary arterial supply may lead to myocardial ischaemia and infarction. Myocardial hypoperfusion will additionally be linked to secondary HLT Site specific vascular disorders NEC.

**CR Number: 2018355007** **Implementation Date:** 10-Jan-19 Related CR: 2018355007

| Change Requested | Rename PT/LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Term to modify | *Obstructive sialadentitis* | Approved as Requested | Term to modify | |
| Replacement term | *Obstructive sialadenitis* | | *Obstructive sialadentitis* | |
| | | | Replacement term | |
| | | | *Obstructive sialadenitis* | 10082481 Current |

MSSO Comment: The proposal to rename PT/LLT Obstructive sialadentitis to Obstructive sialadenitis is approved as requested. The term will be renamed in order to correct wrong spelling.

# Supplemental Update Report

**CR Number: 2018355008** **Implementation Date:** 10-Jan-19 Related CR: 2018355008

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Obstructive pyelonephritis* | Approved as Requested | Proposed LLT<br>*Obstructive pyelonephritis*<br>To PT<br>*Pyelonephritis* | 10082589 Current<br>10037596 |

MSSO Comment: The proposal to add a new LLT Obstructive pyelonephritis is approved as requested. Obstructive pyelonephritis, often a result of urolithiasis, represents an emergent disease in the urological field with relatively high mortality. Patients with older age or poor conditions should be hospitalized, and intervention by a urology specialist is likely to be required. Obstructive pyelonephritis will be added as a sub-concept LLT to PT Pyelonephritis.

**CR Number: 2018355009** **Implementation Date:** 10-Jan-19 Related CR: 2018355009

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Obstructive cholangitis* | Approved as Requested | Proposed LLT<br>*Obstructive cholangitis*<br>To PT<br>*Cholangitis* | 10082584 Current<br>10008604 |

MSSO Comment: The proposal to add a new LLT Obstructive cholangitis is approved as requested. Obstructive cholangitis (usually acute, and frequently caused by bacterial infection) is a clinical syndrome characterized by right upper abdominal pain, jaundice, chills with fever (Charcot's triad), central nervous system signs such as lethargy, disorientation, or coma, which can evolve to septic shock. Obstructive cholangitis will be added as a sub-concept LLT to PT Cholangitis.

**CR Number: 2018355010** **Implementation Date:** 10-Jan-19 Related CR: 2018355010

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Obstructive pneumonitis* | Approved as Requested | Proposed LLT<br>*Obstructive pneumonitis*<br>To PT<br>*Pneumonitis* | 10082588 Current<br>10035742 |

MSSO Comment: The proposal to add a new LLT Obstructive pneumonitis is approved as requested. Obstructive pneumonitis is pneumonitis distal to an obstructed airway, often due to a tumor, and the result of infection. Obstructive pneumonitis will be added as a sub-concept LLT to PT Pneumonitis.

# Supplemental Update Report

**CR Number: 2018355011** **Implementation Date:** 10-Jan-19 Related CR: 2018355011

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vitritis infective* | Approved as Requested | Proposed PT<br>*Vitritis infective* | 10082583 |
| | | | HLT primary<br>*Eye and eyelid infections* | 10015909 |
| | | | SOC primary<br>*Infections and infestations* | 10021881 |
| | | | HLT secondary<br>*Retinal, choroid and vitreous infections and inflammations* | 10038909 |
| | | | SOC secondary<br>*Eye disorders* | 10015919 |

MSSO Comment: The proposal to add a new PT Vitritis infective is approved as requested. Infectious uveitis is an inflammatory condition of the vitreous caused by viral, bacterial, fungal, helminthic, and parasitic organisms, and is one of the most common and visually devastating causes of uveitis. PT Vitritis infective will be added to primary HLT Eye and eyelid infections and secondary HLT Retinal, choroid and vitreous infections and inflammations. In related changes, LLT Intermediate uveitis and LLT Peripheral uveitis (a synonym of pars planitis) will be moved from PT Autoimmune uveitis to PT Uveitis for better conceptual alignment, because the etiology of intermediate uveitis is not limited only to autoimmune or immunological factors.

**CR Number: 2018365175** **Implementation Date:** 10-Jan-19 Related CR: 2018355011

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Intermediate uveitis* | Approved as Requested | Proposed LLT<br>*Intermediate uveitis* | 10022557 Current |
| From PT | *Autoimmune uveitis* | | From PT<br>*Autoimmune uveitis* | 10075690 |
| To PT | *Uveitis* | | To PT<br>*Uveitis* | 10046851 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2018365176** **Implementation Date:** 10-Jan-19 Related CR: 2018355011

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Peripheral uveitis* | Approved as Requested | Proposed LLT | | |
| From PT | *Autoimmune uveitis* | | *Peripheral uveitis* | 10034631 | Current |
| To PT | *Uveitis* | | From PT | | |
| | | | *Autoimmune uveitis* | 10075690 | |
| | | | To PT | | |
| | | | *Uveitis* | 10046851 | |

MSSO Comment:

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**CR Number: 2018355012** **Implementation Date:** 10-Jan-19 Related CR: 2018355012

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Myocardial perfusion stress test* | Approved as Requested | Proposed LLT | | |
| To PT | *Scan myocardial perfusion* | | *Myocardial perfusion stress test* | 10082586 | Current |
| | | | To PT | | |
| | | | *Scan myocardial perfusion* | 10054082 | |

MSSO Comment: The proposal to add a new LLT Myocardial perfusion stress test to PT Scan myocardial perfusion is approved as requested. Stress myocardial perfusion imaging is a nuclear cardiology procedure that is widely used to assess patients with known or suspected coronary artery disease. This technique measures myocardial perfusion during stress, and often at rest, after the injection of a small amount of a radiopharmaceutical that is extracted by myocardial cells in proportion to myocardial blood flow.

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**CR Number: 2018355013** **Implementation Date:** 10-Jan-19 Related CR: 2018355013

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed Term | *Myocardial late gadolinium enhancement MRI* | Approved as Requested | Proposed LLT | | |
| | | | *Myocardial late gadolinium enhancement MRI* | 10082585 | Current |
| | | | To PT | | |
| | | | *Nuclear magnetic resonance imaging heart* | 10076374 | Current |

MSSO Comment: The proposal to add a new term Myocardial late gadolinium enhancement MRI is approved as requested. Late gadolinium enhancement is a useful tool for scar detection, based on differences in the volume of distribution of gadolinium, which concentrates at a higher proportion in the extracellular space. The presence of fibrosis in the myocardium amenable to be detected with late gadolinium enhancement MRI is found not only in ischemic cardiomyopathy, in which it offers information regarding viability and prognosis, but also in a wide variety of non-ischemic cardiomyopathies. Myocardial late gadolinium enhancement MRI will be added as a sub-concept LLT to PT Nuclear magnetic resonance imaging heart.

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# Supplemental Update Report

**CR Number: 2018355014** **Implementation Date:** 10-Jan-19 Related CR: 2018355014

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Bone remodeling disorder* | Approved as Requested | Proposed LLT | |
| | | | *Bone remodeling disorder* | 10082587 Current |
| | | | To PT | |
| | | | *Bone metabolism disorder* | 10058972 |

MSSO Comment: The proposal to add a new term Bone remodeling disorder is approved as requested. Bone remodeling (or bone metabolism) is a lifelong process where mature bone tissue is removed from the skeleton (a process called bone resorption) and new bone tissue is formed (a process called ossification or new bone formation). These processes also control the reshaping or replacement of bone following injuries like fractures but also micro-damage, which occurs during normal activity. Bone remodeling disorder and its British spelled counterpart Bone remodelling disorder will both be added as sub-concept LLTs to PT Bone metabolism disorder.

**CR Number: 2018365177** **Implementation Date:** 10-Jan-19 Related CR: 2018355014

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Bone remodelling disorder* | Approved as Requested | Proposed LLT | |
| To PT | *Bone metabolism disorder* | | *Bone remodelling disorder* | 10082590 Current |
| | | | To PT | |
| | | | *Bone metabolism disorder* | 10058972 |

MSSO Comment:

**CR Number: 2018355015** **Implementation Date:** 10-Jan-19 Related CR: 2018355015

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pulmonary imaging procedure* | Approved as Requested | Proposed PT | |
| HLT primary | *Respiratory tract and thoracic imaging procedures* | | *Pulmonary imaging procedure* | 10082579 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Respiratory tract and thoracic imaging procedures* | 10006476 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Pulmonary imaging procedure to primary HLT Respiratory tract and thoracic imaging procedures in SOC Investigations is approved as requested. Pulmonary imaging encompasses a variety of techniques, including x-ray, CT, MRI, radioisotope scans, and multiple methods of internal scoping of lower respiratory tract anatomy.

# Supplemental Update Report

**CR Number: 2018355016** **Implementation Date:** 10-Jan-19 Related CR: 2018355016

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pulmonary imaging procedure normal* | Approved as Requested | Proposed PT | |
| HLT primary | *Respiratory tract and thoracic imaging procedures* | | *Pulmonary imaging procedure normal* | 10082581 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Respiratory tract and thoracic imaging procedures* | 10006476 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Pulmonary imaging procedure normal to primary HLT Respiratory tract and thoracic imaging procedures in SOC Investigations is approved as requested. Pulmonary imaging encompasses a variety of techniques, including x-ray, CT, MRI, radioisotope scans, and multiple methods of internal scoping of lower respiratory tract anatomy.

**CR Number: 2018355017** **Implementation Date:** 10-Jan-19 Related CR: 2018355017

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pulmonary imaging procedure abnormal* | Approved as Requested | Proposed PT | |
| HLT primary | *Respiratory tract and thoracic imaging procedures* | | *Pulmonary imaging procedure abnormal* | 10082582 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Respiratory tract and thoracic imaging procedures* | 10006476 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Pulmonary imaging procedure abnormal to primary HLT Respiratory tract and thoracic imaging procedures in SOC Investigations is approved as requested. Pulmonary imaging encompasses a variety of techniques, including x-ray, CT, MRI, radioisotope scans, and multiple methods of internal scoping of lower respiratory tract anatomy.

# Supplemental Update Report

**CR Number: 2018360001** **Implementation Date:** 11-Jan-19 Related CR: 2018360001

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Immune-mediated myocarditis* | Approved as Requested | Proposed PT | |
| | | | *Immune-mediated myocarditis* | 10082606 |
| | | | HLT primary | |
| | | | *Noninfectious myocarditis* | 10029548 |
| | | | SOC primary | |
| | | | *Cardiac disorders* | 10007541 |
| | | | 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 myocarditis is approved as requested. Myocarditis is clinically and pathologically defined as inflammation of the myocardium in the absence of the predominant acute or chronic ischemia characteristic of coronary artery disease. It is a clinical syndrome of nonischemic myocardial inflammation resulting from a heterogeneous group of infectious, immune, and nonimmune diseases. Immune-mediated myocarditis will be added as PT to primary HLT Noninfectious myocarditis and secondary HLT Immune and associated conditions NEC.

**CR Number: 2018361001** **Implementation Date:** 11-Jan-19 Related CR: 2018361001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Rectal dysplasia* | Approved as Requested | Proposed LLT | |
| | | | *Rectal dysplasia* | 10082607 Current |
| | | | To PT | |
| | | | *Anogenital dysplasia* | 10051999 |

MSSO Comment: The proposal to add a new LLT Rectal dysplasia is approved as requested. Anal dysplasia is a pre-cancerous condition which occurs when the lining of the anal canal undergoes abnormal changes. It can be classified as low-grade squamous intraepithelial lesions (LSIL) and high-grade squamous intraepithelial lesions (HSIL). Most cases are not associated with symptoms, but people may notice lumps in and around the anus. Rectal dysplasia will be added as sub-concept LLT to PT Anogenital dysplasia.

# Supplemental Update Report

**CR Number: 2018362001** **Implementation Date:** 11-Jan-19 Related CR: 2018362001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Nasal cannula* | Approved Not as Requested | Proposed LLT | |
| | | | *Nasal cannula oxygen therapy* | 10082608 Current |
| | | | To PT | |
| | | | *Oxygen therapy* | 10078798 |

MSSO Comment: The proposal to add a new term Nasal cannula is approved but not as requested. A nasal cannula is a thin tube with two small nozzles that protrude into the patient's nostrils. It can only comfortably provide oxygen at low flow rates, 2–6 litres per minute, delivering a concentration of 24–40%. The requested term will be modified for clarification of a procedural concept and added as LLT Nasal cannula oxygen therapy to PT Oxygen therapy.

**CR Number: 2018365001** **Implementation Date:** 11-Jan-19 Related CR: 2018365001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Abdominal wall edema* | Approved as Requested | Proposed LLT | |
| | | | *Abdominal wall edema* | 10082610 Current |
| | | | To PT | |
| | | | *Abdominal wall oedema* | 10082609 |

MSSO Comment: The proposal to add a new term Abdominal wall edema is approved as requested. Edema of the abdominal wall may be associated with a variety of conditions, such as congestive heart failure, hepatic disease, renal failure, portal vein thrombosis, pancreatitis, malignancy, endocrine disorders, etc. Abdominal wall edema will be added as the American English spelling counterpart LLT to PT Abdominal wall oedema. In a related change, Abdominal wall oedema will be added as a new PT to primary HLT Abdominal wall conditions NEC and second HLT Oedema NEC, and to secondary HLT Total fluid volume increased.

# Supplemental Update Report

**CR Number: 2018365185** **Implementation Date:** 11-Jan-19 Related CR: 2018365001

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Abdominal wall oedema* | Approved as Requested | Proposed PT | |
| HLT primary | *Abdominal wall conditions NEC* | | *Abdominal wall oedema* | 10082609 |
| SOC primary | *Gastrointestinal disorders* | | HLT primary | |
| | | | *Abdominal wall conditions NEC* | 10052777 |
| | | | SOC primary | |
| | | | *Gastrointestinal disorders* | 10017947 |
| | | | HLT secondary | |
| | | | *Oedema NEC* | 10030113 |
| | | | SOC secondary | |
| | | | *General disorders and administration site conditions* | 10018065 |

MSSO Comment:

**CR Number: 2018365186** **Implementation Date:** 11-Jan-19 Related CR: 2018365001

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Abdominal wall oedema* | Approved as Requested | Proposed PT | |
| To HLT | *Total fluid volume increased* | | *Abdominal wall oedema* | 10082609 |
| | | | To HLT | |
| | | | *Total fluid volume increased* | 10044085 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2018365002** **Implementation Date:** 11-Jan-19 Related CR: 2018365002

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Sialectomy* | Approved as Requested | Proposed LLT<br>*Sialectomy*<br>To PT<br>*Salivary gland resection* | 10082611 Current<br>10039422 |

MSSO Comment: The proposal to add a new LLT Sialectomy is approved as requested. Sialectomy, the removal of one or more salivary glands, is one technique to remove salivary gland stones. Sialectomy will be placed as synonym LLT to PT Salivary gland resection.

**CR Number: 2018365003** **Implementation Date:** 11-Jan-19 Related CR: 2018365003

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT<br>To PT | *Swimmer's Ear*<br>*Otitis media* | Approved Not as Requested | Proposed LLT<br>*Swimmer's ear*<br>To PT<br>*Otitis externa* | 10082612 Current<br>10033072 |

MSSO Comment: The proposal to add a new LLT Swimmer's Ear to PT Otitis media is approved but not as requested. Swimmer's ear is an infection of the ear canal, the passage that carries sounds from the outside of the body to the eardrum. It can be caused by many different types of bacteria or fungi. Swimmer's ear (or otitis externa) is common in kids who spend a lot of time in the water. The requested term will be modified according to MedDRA capitalisation conventions and added as LLT Swimmer's ear to PT Otitis externa aligned with LLT Acute swimmers' ear.

**CR Number: 2018365004** **Implementation Date:** 11-Jan-19 Related CR: 2018365004

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Below ankle amputation* | Approved as Requested | Proposed LLT<br>*Below ankle amputation*<br>To PT<br>*Foot amputation* | 10082613 Current<br>10016960 |

MSSO Comment: The proposal to add a new term Below ankle amputation is approved as requested. Below ankle amputation provides a quasi-synonym for PT Foot amputation in cases of no further information regarding the procedure e.g. Lyme, Lisfranc, Chopart. Below ankle amputation will be added as an LLT to PT Foot amputation.

# Supplemental Update Report

**CR Number: 2018365005** **Implementation Date:** 11-Jan-19 Related CR: 2018365005

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Asynclitic presentation* | Approved Not as Requested | Proposed PT | |
| | | | *Asynclitic presentation* | 10082614 |
| | | | HLT primary | |
| | | | *Foetal position and presentation abnormalities* | 10000190 |
| | | | SOC primary | |
| | | | *Pregnancy, puerperium and perinatal conditions* | 10036585 |

MSSO Comment: The proposal to add a new LLT Asynclitic presentation is approved but not as requested. Asynclitic birth is an oblique presentation of the fetal head in labor. The head of the baby is presenting first (a cephalic presentation). The head tilts sideways so that a parietal bone enters the pelvic brim. Asynclitic presentation will be added as a PT to HLT Foetal position and presentation abnormalities.

**CR Number: 2018365006** **Implementation Date:** 11-Jan-19 Related CR: 2018365006

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Cephaledema* | Rejected | | |

MSSO Comment: The proposal to add a new term Cephaledema is not approved. Cephaledema is an obsolete term for oedema of the head and is represented in MedDRA by LLT Cerebral oedema.

**CR Number: 2018365007** **Implementation Date:** 11-Jan-19 Related CR: 2018365007

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Bowel obstruction repair* | Rejected | | |

MSSO Comment: The proposal to add a new term Bowel obstruction repair is not approved. The proposed concept can be represented by existing terms LLT Large intestinal obstruction reduction and/or LLT Small intestinal obstruction reduction.

# Supplemental Update Report

**CR Number: 2018365008** **Implementation Date:** 11-Jan-19 Related CR: 2018365008

| Change Requested | Rename PT/LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Term to modify | *Knee total replacement* | Approved Not as Requested | Proposed LLT | |
| Replacement term | *Knee replacement* | | *Knee replacement* | 10082617 Current |
| | | | To PT | |
| | | | *Knee arthroplasty* | 10023469 |

MSSO Comment: The proposal to rename PT/LLT Knee total replacement to Knee replacement is approved but not as requested. Rather than renaming an existing term, which may alter other subscribers data, the more general term LLT Knee replacement will be added under PT Knee arthroplasty to represent those cases where the extent of the knee operation (partial or total) is not precise.

**CR Number: 2018365009** **Implementation Date:** 11-Jan-19 Related CR: 2018365009

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Pericardial cyst resection* | Approved as Requested | Proposed PT | |
| | | | *Pericardial cyst resection* | 10082616 |
| | | | HLT primary | |
| | | | *Cardiac therapeutic procedures NEC* | 10027660 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment: The proposal to add a new term Pericardial cyst resection is approved as requested. The management of pericardial cysts includes observation, percutaneous drainage, and resection. The indications for resection of pericardial cysts include large size, symptoms, patient concern, uncertainty of malignant potential, and prevention of the life threatening emergencies. Pericardial cyst resection will be added as a PT to HLT Cardiac therapeutic procedures NEC.

**CR Number: 2018365010** **Implementation Date:** 11-Jan-19 Related CR: 2018365010

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Amblyopia correction* | Approved as Requested | Proposed LLT | |
| | | | *Amblyopia correction* | 10082618 Current |
| | | | To PT | |
| | | | *Amblyopia therapy* | 10074284 |

MSSO Comment: The proposal to add a new term Amblyopia correction is approved as requested. Amblyopia correction can be considered a synonym of existing PT Amblyopia therapy. As such, Amblyopia correction will be added as an LLT to PT Amblyopia therapy.

# Supplemental Update Report

**CR Number: 2018365011** **Implementation Date:** 11-Jan-19 Related CR: 2018365011

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Coronary sinus dilation* | Approved Not as Requested | Proposed PT | |
| | | | *Coronary sinus dilatation* | 10082615 |
| | | | HLT primary | |
| | | | *Coronary artery disorders NEC* | 10011083 |
| | | | SOC primary | |
| | | | *Cardiac disorders* | 10007541 |
| | | | HLT secondary | |
| | | | *Pulmonary hypertensions* | 10037401 |
| | | | SOC secondary | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |

MSSO Comment: The proposal to add a new term Coronary sinus dilation is approved but not as requested. Although rarely seen in healthy patients, the coronary sinus is often visualized on echocardiography in patients with right-sided heart disease. Though the prevalence of this finding and its relation to right-sided heart structure and pressure remains undefined, coronary sinus dilation has been observed in 81% of a selected group of patients with pulmonary hypertension in the absence of structural disease of the tricuspid valve. Based on the MedDRA convention of usage of dilation vs dilatation as stated in the MedDRA Introductory Guide 21.1 Section 5.1 GENERAL WORD USAGE, the requested term will be modified and added as PT Coronary sinus dilatation to primary HLT Coronary artery disorders NEC and secondary HLT Pulmonary hypertensions.

**CR Number: 2018365012** **Implementation Date:** 15-Jan-19 Related CR: 2018365012

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Hypersensitivity pneumonitis* | Rejected | | |
| To PT | *Immune-mediated pneumonitis* | | | |

MSSO Comment: The proposal to demote the PT Hypersensitivity pneumonitis under PT Immune-mediated pneumonitis is not approved. Hypersensitivity pneumonitis is referring to a very specific diagnosis. It is a syndrome of cough, dyspnea, and fatigue caused by sensitization and subsequent hypersensitivity to environmental (frequently occupational) antigens. In contrast, Immune-mediated pneumonitis is mainly a drug-related pneumonitis. The two concepts are not synonyms.

# Supplemental Update Report

**CR Number: 2018365013** **Implementation Date:** 15-Jan-19 Related CR: 2018365013

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Immune-mediated endocrinopathy* | Approved as Requested | Proposed LLT | |
| From PT | *Autoimmune endocrine disorder* | | *Immune-mediated endocrinopathy* | 10078964 |
| HLT primary | *Endocrine disorders NEC* | | From PT | |
| | | | *Autoimmune endocrine disorder* | 10078953 |
| | | | HLT primary | |
| | | | *Endocrine disorders NEC* | 10014700 |
| | | | SOC primary | |
| | | | *Endocrine disorders* | 10014698 |
| | | | HLT secondary | |
| | | | *Immune and associated conditions NEC* | 10027682 |
| | | | SOC secondary | |
| | | | *Immune system disorders* | 10021428 |

MSSO Comment: The proposal to promote the LLT Immune-mediated endocrinopathy from PT Autoimmune endocrine disorder to primary HLT Endocrine disorders NEC in SOC Endocrine disorders and secondary HLT Immune and associated conditions NEC in SOC Immune system disorders is approved as requested. "Immune mediated" is defined as an inflammatory process caused by an unspecified immune reaction leading to a dysregulation of the normal immune response. Immune mediated diseases often are based on an autoimmune mechanism but not limited to. Similar to the broad PT Immune-mediated adverse reaction, all organ specific immune-mediated adverse reaction need to be consistently represented on PT level and not subordinated to autoimmune disease PTs as they are not limited to an autoimmune mechanism.

# Supplemental Update Report

**CR Number: 2018365014** **Implementation Date:** 15-Jan-19 Related CR: 2018365014

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Immune-mediated neuropathy* | Approved as Requested | Proposed LLT | |
| From PT | *Autoimmune neuropathy* | | *Immune-mediated neuropathy* | 10078963 |
| HLT primary | *Peripheral neuropathies NEC* | | From PT | |
| | | | *Autoimmune neuropathy* | 10070439 |
| | | | HLT primary | |
| | | | *Peripheral neuropathies NEC* | 10034607 |
| | | | SOC primary | |
| | | | *Nervous system disorders* | 10029205 |
| | | | HLT secondary | |
| | | | *Immune and associated conditions NEC* | 10027682 |
| | | | SOC secondary | |
| | | | *Immune system disorders* | 10021428 |

MSSO Comment: The proposal to promote the LLT Immune-mediated neuropathy from PT Autoimmune neuropathy to primary HLT Peripheral neuropathies NEC in SOC Nervous system disorders and secondary HLT Immune and associated conditions NEC in SOC Immune system disorders is approved as requested. "Immune mediated" is defined as an inflammatory process caused by an unspecified immune reaction leading to a dysregulation of the normal immune response. Immune mediated diseases often are based on an autoimmune mechanism but not limited to. Similar to the broad PT Immune-mediated adverse reaction, all organ specific immune-mediated adverse reaction need to be consistently represented on PT level and not subordinated to autoimmune disease PTs as they are not limited to an autoimmune mechanism.

**CR Number: 2018365015** **Implementation Date:** 15-Jan-19 Related CR: 2018365015

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Immune thrombocytopenic purpura* | Approved as Requested | Proposed PT | |
| From HLT | *Blood autoimmune disorders* | | *Immune thrombocytopenic purpura* | 10074667 |
| To HLT | *Immune and associated conditions NEC* | | From HLT | |
| | | | *Blood autoimmune disorders* | 10003817 |
| | | | To HLT | |
| | | | *Immune and associated conditions NEC* | 10027682 |

MSSO Comment: The proposal to move the PT Immune thrombocytopenic purpura from HLT Blood autoimmune disorders to HLT Immune and associated conditions NEC is approved as requested. Immune thrombocytopenic purpura is an acquired thrombocytopenia due to immune mediated shortened circulating platelet survival in the absence of other disturbances of haemostasis or coagulation. In most childhood ITP platelet autoantibodies are absent.

# Supplemental Update Report

**CR Number: 2018365016** **Implementation Date:** 15-Jan-19 Related CR: 2018365016

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed PT | *Immune-mediated necrotising myopathy* | Approved as Requested | Proposed PT | | |
| From HLT | *Muscular autoimmune disorders* | | *Immune-mediated necrotising myopathy* | 10072155 | Current |
| To HLT | *Immune and associated conditions NEC* | | From HLT | | |
| | | | *Muscular autoimmune disorders* | 10003821 | |
| | | | To HLT | | |
| | | | *Immune and associated conditions NEC* | 10027682 | |

MSSO Comment: The proposal to move the PT Immune-mediated necrotising myopathy from HLT Muscular autoimmune disorders to HLT Immune and associated conditions NEC is approved as requested. Immune-mediated necrotizing myopathy (IMNM) is a newly identified subgroup of idiopathic inflammatory myopathies. It is defined as a rare and severe disease, with symmetrical and proximal muscle weakness and a characteristic histology. An autoimmune aspect of IMNM is suggested by its association with autoantibodies directed against signal recognition particle (SRP) and 3-hydroxy-3-methylglutaryl-coenzyme A reductase (HMGCR) in the majority of patients. As the autoimmune aspect only is suggested but the pathophysiological mechanisms of this disease are still poorly understood, it seems to be appropriate to group this immune-mediated concept consistent with other such concepts in the SOC Immune system disorders.

**CR Number: 2018365021** **Implementation Date:** 15-Jan-19 Related CR: 2018365021

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Non-paroxysmal atrioventricular junctional tachycardia* | Approved as Requested | Proposed LLT | | |
| To PT | *Junctional ectopic tachycardia* | | *Non-paroxysmal atrioventricular junctional tachycardia* | 10082631 | Current |
| | | | To PT | | |
| | | | *Junctional ectopic tachycardia* | 10074640 | |

MSSO Comment: The proposal to add a new LLT Non-paroxysmal atrioventricular junctional tachycardia to PT Junctional ectopic tachycardia is approved as requested. Junctional ectopic tachycardia is characterized by rapid heart rate for a person's age that is driven by a focus with abnormal automaticity within or immediately adjacent to the atrioventricular junction of the cardiac conduction system. Non-paroxysmal atrioventricular junctional tachycardia is a type of junctional ectopic tachycardia that is a well-known manifestation of digitalis toxicity and can be associated with cardiac surgery, myocardial infarction, and rheumatic fever.

**CR Number: 2018365022** **Implementation Date:** 15-Jan-19 Related CR: 2018365022

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| PT to merge | *Hypercorticoidism* | Approved as Requested | PT to merge | | |
| To PT | *Hyperadrenocorticism* | | *Hypercorticoidism* | 10020610 | Current |
| | | | To PT | | |
| | | | *Hyperadrenocorticism* | 10020564 | |

MSSO Comment: The proposal to demote the PT Hypercorticoidism under PT Hyperadrenocorticism is approved as requested. Hypercorticoidism and Hyperadrenocorticism are used synonymously.

# Supplemental Update Report

**CR Number: 2018365023** **Implementation Date:** 15-Jan-19 Related CR: 2018365023

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Hyperadrenalism* | Rejected | | |
| To PT | *Hyperadrenocorticism* | | | |

MSSO Comment: The proposal to demote the PT Hyperadrenalism under PT Hyperadrenocorticism is not approved. Hyperadrenalism is a condition in which the adrenal glands are secreting excessive amounts of the hormones that they produce. The existing term represents the hormonal function of the entire adrenal gland.

**CR Number: 2018365140** **Implementation Date:** 15-Jan-19 Related CR: 2018365140

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Off label dosing route* | Rejected | | |
| To PT | *Off label use* | | | |

MSSO Comment: The proposal to add a new LLT Off label dosing route to PT Off label use is not approved. An off label dosing route is a route of administration that is not in accordance with the approved product information. The requested concept can be represented by split coding with LLT Incorrect route of product administration and LLT Off label use.

# Supplemental Update Report

**CR Number: 2018365141** **Implementation Date:** 15-Jan-19 Related CR: 2018365141

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *New onset diabetes after transplantation* | Approved as Requested | Proposed PT | |
| | | | *New onset diabetes after transplantation* | 10082630 |
| | | | HLT primary | |
| | | | *Diabetes mellitus (incl subtypes)* | 10012602 |
| | | | SOC primary | |
| | | | *Metabolism and nutrition disorders* | 10027433 |
| | | | HLT secondary | |
| | | | *Endocrine procedural complications* | 10014716 |
| | | | SOC secondary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |

MSSO Comment: The proposal to add a new PT New onset diabetes after transplantation is approved as requested. New onset diabetes after transplantation a is well known complication after organ transplantation especially after solid organ transplantation, bone marrow and hematopoietic stem cells. It is not known why some patients develop early-onset (within 1-year after transplantation), late-onset (1-year after transplantation), or transient diabetes mellitus i.e. New onset diabetes after transplantation diagnosed within the first year post-transplantation, with recovery to normal glucose tolerance status. New onset diabetes after transplantation will be added as a PT to primary HLT Diabetes mellitus (incl subtypes) under an HLGT which is bi-axial to (primary SOC Metabolism and nutrition disorders and secondary SOC Endocrine disorders) and to secondary HLT Endocrine procedural complications.

# Supplemental Update Report

**CR Number: 2018365143** **Implementation Date:** 18-Jan-19 Related CR: 2018365143

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Paroxysmal autonomic instability with dystonia* | Approved as Requested | Proposed PT | |
| | | | *Paroxysmal autonomic instability with dystonia* | 10082638 |
| | | | HLT primary | |
| | | | *Cerebral injuries NEC* | 10052638 |
| | | | SOC primary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |
| | | | HLT secondary | |
| | | | *Autonomic nervous system disorders* | 10003839 |
| | | | SOC secondary | |
| | | | *Nervous system disorders* | 10029205 |

MSSO Comment: The proposal to add a new term Paroxysmal autonomic instability with dystonia is approved as requested. Autonomic dysregulation (dysautonomia) is a risk factor for increased morbidity in patients with brain injury. Paroxysmal autonomic instability with dystonia (PAID) syndrome, a subset of dysautonomia, is a discrete clinical entity that can mimic certain other life-threatening conditions with similar presentations. The essential features of this characteristic syndrome include paroxysms of marked agitation, diaphoresis, hyperthermia, hypertension, tachycardia and tachypnoea accompanied by hypertonia and extensor posturing. Paroxysmal autonomic instability with dystonia will be added as a new PT to primary HLT Cerebral injuries NEC; to secondary HLT Autonomic nervous system disorders and to secondary HLT Vascular hypertensive disorders NEC.

**CR Number: 2018365210** **Implementation Date:** 18-Jan-19 Related CR: 2018365143

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Paroxysmal autonomic instability with dystonia* | Approved as Requested | Proposed PT | |
| To HLT | *Vascular hypertensive disorders NEC* | | *Paroxysmal autonomic instability with dystonia* | 10082638 |
| | | | To HLT | |
| | | | *Vascular hypertensive disorders NEC* | 10020774 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2018365144** **Implementation Date:** 18-Jan-19 Related CR: 2018365144

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Trachyonychia* | Approved Not as Requested | Proposed LLT | |
| HLT primary | *Nail and nail bed conditions (excl infections and infestations)* | | *Trachyonychia* | 10082641 Current |
| | | | To PT | |
| SOC primary | *Skin and subcutaneous tissue disorders* | | *Nail ridging* | 10062283 |

MSSO Comment: The proposal to add a new PT Trachyonychia to primary HLT Nail and nail bed conditions (excl infections and infestations) in SOC Skin and subcutaneous tissue disorders is approved but not as requested. Trachyonychia, sometimes called sandpapered nails, is a condition characterized by rough accentuated longitudinal striations or ridges on the nails of the fingers and toes. The nails become opalescent, thin, dull, fragile, and finely longitudinally ridged, and, as a result, distally notched. It can be idiopathic, or a manifestation of lichen planus, psoriasis, alopecia areata, immunoglobulin A deficiency, atopic dermatitis, and ichthyosis vulgaris. Trachyonychia will be placed as an LLT to PT Nail ridging.

**CR Number: 2018365145** **Implementation Date:** 18-Jan-19 Related CR: 2018365145

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Endothelial keratoplasty* | Approved as Requested | Proposed LLT | |
| | | | *Endothelial keratoplasty* | 10082640 Current |
| | | | To PT | |
| | | | *Keratoplasty* | 10066900 |

MSSO Comment: The proposal to add a new term Endothelial keratoplasty is approved as requested. Endothelial keratoplasty, also referred to as posterior lamellar keratoplasty, is a form of corneal transplantation in which the diseased inner layer of the cornea, the endothelium, is replaced with healthy donor tissue. The endothelium removes fluid from and limits fluid into the stroma, thereby maintaining the ordered arrangement of collagen and preserving the cornea's transparency. Diseases that affect the endothelial layer, often resulting in corneal edema and visual impairmnant, include Fuchs endothelial dystrophy, aphakic and pseudophakic bullous keratopathy (corneal edema following cataract extraction), and failure or rejection of a previous corneal transplant. Endothelial keratoplasty will be added as an LLT to PT Keratoplasty.

**CR Number: 2018365146** **Implementation Date:** 18-Jan-19 Related CR: 2018365146

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Labiaplasty* | Approved as Requested | Proposed LLT | |
| | | | *Labiaplasty* | 10082642 Current |
| | | | To PT | |
| | | | *Genital labial operation* | 10062030 |

MSSO Comment: The proposal to add a new term Labiaplasty is approved as requested. Labiaplasty, or labia reconstruction, is a surgical procedure that aims to improve the general appearance of the female genitals, specifically, the labia minora and the labia majora. Indications for this procedure include a variety of congenital, medical, and traumatic conditions. Labiaplasty will be added as an LLT to PT Genital labial operation.

# Supplemental Update Report

**CR Number: 2018365147** **Implementation Date:** 18-Jan-19 Related CR: 2018365147

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Facet joint injection* | Approved as Requested | Proposed LLT<br>*Facet joint injection*<br>To PT<br>*Facet joint block* | 10082644 Current<br>10052018 |

MSSO Comment: The proposal to add a new LLT Facet joint injection is approved as requested. A facet joint injection is one of the most frequently performed spinal interventional procedures, as both a treatment for and diagnosis of radicular pain syndrome and facet syndrome. It can be performed under fluoroscopic, or CT image guidance. Cervical, thoracic or most commonly lumbar facet joints are injected with an anaesthetic with or without an anti-inflammatory agent. Often the procedure is performed at multiple levels or bilaterally. Indications include: facet syndrome, both diagnostic (i.e. relief of pain after injection of local anesthetic) and therapeutic; chronic low back or neck pain; and post-laminectomy syndrome. Facet joint injection will be added as a sub-concept LLT to PT Facet joint block.

**CR Number: 2018365148** **Implementation Date:** 18-Jan-19 Related CR: 2018365148

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vulvar basal cell carcinoma* | Approved as Requested | Proposed PT<br>*Vulvar basal cell carcinoma* | 10082639 |
| HLT primary | *Vulval neoplasms malignant* | | HLT primary<br>*Vulval neoplasms malignant* | 10047750 |
| SOC primary | *Neoplasms benign, malignant and unspecified (incl cysts and polyps)* | | SOC primary<br>*Neoplasms benign, malignant and unspecified (incl cysts and polyps)* | 10029104 |
| | | | HLT secondary<br>*Vulvovaginal cysts and neoplasms* | 10047785 |
| | | | SOC secondary<br>*Reproductive system and breast disorders* | 10038604 |

MSSO Comment: The proposal to add a new PT Vulvar basal cell carcinoma to primary HLT Vulval neoplasms malignant in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) and secondary HLT Vulvovaginal cysts and neoplasms in SOC Reproductive system and breast disorders is approved as requested. Vulvar basal cell carcinoma is rare, accounting for less than 5% of all vulvar neoplasms, and less than 1% of all basal cell carcinomas. Vulvar basal cell carcinomas are usually diagnosed late because they are often asymptomatic and tend to grow at slow rates. They may be invasive and destructive if neglected or improperly treated, but they have a very low propensity for metastatic spread, and frequently recur after simple excision.

# Supplemental Update Report

**CR Number: 2018365149** **Implementation Date:** 18-Jan-19 Related CR: 2018365149

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Dorsal hump* | Approved Not as Requested | Proposed LLT | |
| | | | *Nasal dorsal hump* | 10082643 Current |
| | | | To PT | |
| | | | *Nose deformity* | 10061875 |

MSSO Comment: The proposal to add a new term Dorsal hump is approved but not as requested. A dorsal hump is a bump on the ridge of the nose. This bump can have a range of prominence and can be the result of multiple causes, including trauma. The proposed term will be rephrased for anatomical clarification and added as sub-concept LLT Nasal dorsal hump to PT Nose deformity.

**CR Number: 2018365150** **Implementation Date:** 18-Jan-19 Related CR: 2018365150

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Apolipoprotein E e4 gene carrier* | Approved as Requested | Proposed PT | |
| HLT primary | *Abnormal gene carriers* | | *Apolipoprotein E e4 gene carrier* | 10082637 |
| SOC primary | *Congenital, familial and genetic disorders* | | HLT primary | |
| | | | *Abnormal gene carriers* | 10052636 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |

MSSO Comment: The proposal to add a new PT Apolipoprotein E e4 gene carrier to primary HLT Abnormal gene carriers in SOC Congenital, familial and genetic disorders is approved as requested. Apolipoprotein E (ApoE) is a major cholesterol carrier that supports lipid transport and injury repair in the brain. APOE polymorphic alleles are the main genetic determinants of Alzheimer disease (AD) risk: individuals carrying the e4 allele are at increased risk of AD compared with those carrying the more common e3 allele, whereas the e2 allele decreases risk. Presence of the APOE e4 allele is also associated with increased risk for cerebral amyloid angiopathy and age-related cognitive decline during normal ageing.

# Supplemental Update Report

**CR Number: 2018365151** **Implementation Date:** 18-Jan-19 Related CR: 2018365151

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Gait velocity decreased* | Approved Not as Requested | Proposed PT | |
| | | | *Decreased gait velocity* | 10082636 |
| | | | HLT primary | |
| | | | *Gait disturbances* | 10017578 |
| | | | SOC primary | |
| | | | *General disorders and administration site conditions* | 10018065 |
| | | | HLT secondary | |
| | | | *Neurological signs and symptoms NEC* | 10029306 |
| | | | SOC secondary | |
| | | | *Nervous system disorders* | 10029205 |

MSSO Comment: The proposal to add a new term Gait velocity decreased is approved but not as requested. Although decreased gait velocity can be associated with physical aspects of ageing, studies have suggested that gait is slower up to 7 years prior to clinical onset of dementia. Decline in gate speed is also more accelerated, suggesting strong links between cognitive and motor function in older adults. The proposed term will be rephrased in the natural word order to Decreased gait velocity, and will be added as a new PT to primary HLT Gait disturbances, and to secondary HLT Neurological signs and symptoms NEC.

**CR Number: 2018365152** **Implementation Date:** 18-Jan-19 Related CR: 2018365152

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Daily dosing times taken more frequently* | Approved Not as Requested | Proposed LLT | | |
| To PT | *Inappropriate schedule of drug administration* | | *Scheduled daily dosing taken more frequently* | 10082649 | Current |
| | | | To PT | | |
| | | | *Inappropriate schedule of product administration* | 10081572 | |

MSSO Comment: The proposal to add a new LLT Daily dosing times taken more frequently to PT Inappropriate schedule of drug administration is approved but not as requested. The proposed term will be rephrased for clarification and added as LLT Scheduled daily dosing taken more frequently to PT Inappropriate schedule of product administration.

# Supplemental Update Report

**CR Number: 2018365153** **Implementation Date:** 18-Jan-19 Related CR: 2018365153

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Daily dosing times taken less frequently* | Approved Not as Requested | Proposed LLT | | |
| To PT | *Inappropriate schedule of drug administration* | | *Scheduled daily dosing taken less frequently* | 10082648 | Current |
| | | | To PT | | |
| | | | *Inappropriate schedule of product administration* | 10081572 | |

MSSO Comment: The proposal to add a new LLT Daily dosing times taken less frequently to PT Inappropriate schedule of drug administration is approved but not as requested. The requested term will be modified for clarification and added as LLT Scheduled daily dosing taken less frequently to PT Inappropriate schedule of product administration.

**CR Number: 2018365154** **Implementation Date:** 18-Jan-19 Related CR: 2018365154

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Weekly dosing times taken more frequently* | Approved Not as Requested | Proposed LLT | | |
| To PT | *Inappropriate schedule of drug administration* | | *Scheduled weekly dosing taken more frequently* | 10082645 | Current |
| | | | To PT | | |
| | | | *Inappropriate schedule of product administration* | 10081572 | |

MSSO Comment: The proposal to add a new LLT Weekly dosing times taken more frequently to PT Inappropriate schedule of drug administration is approved but not as requested. The requested term will be modified for clarification and added as LLT Scheduled weekly dosing taken more frequently to PT Inappropriate schedule of product administration.

**CR Number: 2018365155** **Implementation Date:** 18-Jan-19 Related CR: 2018365155

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Weekly dosing times taken less frequently* | Approved Not as Requested | Proposed LLT | | |
| To PT | *Inappropriate schedule of drug administration* | | *Scheduled weekly dosing taken less frequently* | 10082646 | Current |
| | | | To PT | | |
| | | | *Inappropriate schedule of product administration* | 10081572 | |

MSSO Comment: The proposal to add a new LLT Weekly dosing times taken less frequently to PT Inappropriate schedule of drug administration is approved but not as requested. The requested term will be modified for clarification and added as LLT Scheduled weekly dosing taken less frequently to PT Inappropriate schedule of product administration.

# Supplemental Update Report

**CR Number: 2018365156** **Implementation Date:** 18-Jan-19 Related CR: 2018365156

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Monthly dosing times taken more frequently* | Approved Not as Requested | Proposed LLT | |
| To PT | *Inappropriate schedule of drug administration* | | *Scheduled monthly dosing taken more frequently* | 10082647 Current |
| | | | To PT | |
| | | | *Inappropriate schedule of product administration* | 10081572 |

MSSO Comment: The proposal to add a new LLT Monthly dosing times taken more frequently to PT Inappropriate schedule of drug administration is approved but not as requested. The requested term will be modified for clarification and added as LLT Scheduled monthly dosing taken more frequently to PT Inappropriate schedule of product administration.

**CR Number: 2018365157** **Implementation Date:** 18-Jan-19 Related CR: 2018365157

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Monthly dosing times taken less frequently* | Approved Not as Requested | Proposed LLT | |
| To PT | *Inappropriate schedule of drug administration* | | *Scheduled monthly dosing taken less frequently* | 10082650 Current |
| | | | To PT | |
| | | | *Inappropriate schedule of product administration* | 10081572 |

MSSO Comment: The proposal to add a new LLT Monthly dosing times taken less frequently to PT Inappropriate schedule of drug administration is approved but not as requested. The requested term will be modified for clarification and added as LLT Scheduled monthly dosing taken less frequently to PT Inappropriate schedule of product administration.

**CR Number: 2018365158** **Implementation Date:** 18-Jan-19 Related CR: 2018365158

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Possibility of prescription to pregnant woman* | Rejected | | |

MSSO Comment: The proposal to add a new term Possibility of prescription to pregnant woman is not approved. Possibility of prescription to pregnant woman is a vague term and ambiguous in meaning as it may refer to a suspected prescribing error, or intentional use issue, or suspected contraindication.

# Supplemental Update Report

**CR Number: 2018365183** **Implementation Date:** 17-Jan-19 Related CR: 2018365183

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Neurodegeneration with brain iron accumulation disorder* | Approved as Requested | Proposed PT | |
| | | | *Neurodegeneration with brain iron accumulation disorder* | 10082633 |
| | | | HLT primary | |
| | | | *Central nervous system disorders congenital NEC* | 10009713 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary | |
| | | | *Dyskinesias and movement disorders NEC* | 10013929 |
| | | | SOC secondary | |
| | | | *Nervous system disorders* | 10029205 |

MSSO Comment: The proposal to add a new PT Neurodegeneration with brain iron accumulation disorder is approved as requested. Neurodegeneration with brain iron accumulation is a group of inherited neurologic disorders in which iron accumulates in the basal ganglia resulting in progressive dystonia, spasticity, parkinsonism, neuropsychiatric abnormalities, and optic atrophy or retinal degeneration. Ten types and their associated genes are recognized. The age of onset ranges from infancy to late adulthood; the rate of progression varies. Neurodegeneration with brain iron accumulation disorder will be added as a new PT to primary HLT Central nervous system disorders congenital NEC, to secondary HLT Dyskinesias and movement disorders NEC, and to secondary HLT Structural change, deposit and degeneration of eye NEC.

**CR Number: 2018365214** **Implementation Date:** 17-Jan-19 Related CR: 2018365183

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Neurodegeneration with brain iron accumulation disorder* | Approved as Requested | Proposed PT | |
| | | | *Neurodegeneration with brain iron accumulation disorder* | 10082633 |
| To HLT | *Structural change, deposit and degeneration of eye NEC* | | To HLT | |
| | | | *Structural change, deposit and degeneration of eye NEC* | 10042260 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2018365187** **Implementation Date:** 17-Jan-19 Related CR: 2018365187

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Scrotal skin dryness* | Approved as Requested | Proposed LLT | |
| | | | *Scrotal skin dryness* | 10082634 Current |
| | | | To PT | |
| | | | *Dry skin* | 10013786 |

MSSO Comment: The proposal to add a new LLT Scrotal skin dryness is approved as requested. Dry, red skin on the scrotum is a fairly common problem caused by a wide variety of chronic dermatoses, such as several forms of eczema, psoriasis, lichen planus, etc. In the other hand, since the scrotal area provides optimum conditions for bacterial and fungal growth, many problems about dry, red skin on the scrotum are due to bacterial or fungal infections. Scrotal skin dryness will be added as an LLT to PT Dry skin.

**CR Number: 2018365190** **Implementation Date:** 17-Jan-19 Related CR: 2018365190

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Diabulimia* | Approved Not as Requested | Proposed PT | |
| | | | *Diabulimia* | 10082635 |
| | | | HLT primary | |
| | | | *Eating disorders NEC* | 10014068 |
| | | | SOC primary | |
| | | | *Psychiatric disorders* | 10037175 |
| | | | HLT secondary | |
| | | | *Anorexia nervosa and bulimia* | 10002650 |
| | | | SOC secondary | |
| | | | *Metabolism and nutrition disorders* | 10027433 |

MSSO Comment: The proposal to add a new LLT Diabulimia is approved but not as requested. Diabulimia is a media-coined term that refers to an eating disorder in a person with diabetes, typically type I diabetes, wherein the person purposefully restricts insulin in order to lose weight. Since the proposed term is essentially a form of bulimic behavior in the context of a type 1 diabetes (but not a diabetes complication per se), and in consideration also of the non-medical, but rather media-coined character of the term, Diabulimia will be added as a PT to primary HLT Eating disorders NEC and secondary HLT Anorexia nervosa and bulimia.

# Supplemental Update Report

**CR Number: 2018365191** **Implementation Date:** 17-Jan-19 Related CR: 2018365191

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Reversible splenial lesion syndrome* | Approved as Requested | Proposed PT | |
| | | | *Reversible splenial lesion syndrome* | 10082632 |
| | | | HLT primary | |
| | | | *Nervous system disorders NEC* | 10057185 |
| | | | SOC primary | |
| | | | *Nervous system disorders* | 10029205 |

MSSO Comment: The proposal to add a new PT Reversible splenial lesion syndrome is approved as requested. Reversible splenial lesion syndrome (RESLES) is a disorder characterized by the presence of a focal lesion often involving the central area of the splenium of the corpus callosum (SCC), followed by complete reversibility on follow-up magnetic resonance imaging (MRI) after a variable period of time. Possible causes of SCC abnormalities include infarction, trauma, tumor, alcohol abuse, seizure, heat stroke, multiple sclerosis, epilepsy, drug intoxication, and panhypopituitarism. Reversible splenial lesion syndrome will be added as a PT and linked to HLT Nervous system disorders NEC.

**CR Number: 2018365204** **Implementation Date:** 22-Jan-19 Related CR: 2018365204

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Off label dosing amount* | Approved as Requested | Proposed LLT | |
| To PT | *Off label use* | | *Off label dosing amount* | 10082651 Current |
| | | | To PT | |
| | | | *Off label use* | 10053762 |

MSSO Comment: The proposal to add a new LLT Off label dosing amount to PT Off label use is approved as requested. Off label dosing amount is a frequent off label use circumstance which complements existing LLT Off label dosing frequency.

**CR Number: 2018365207** **Implementation Date:** 22-Jan-19 Related CR: 2018365207

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Gastric decompression* | Approved as Requested | Proposed LLT | |
| | | | *Gastric decompression* | 10082654 Current |
| | | | To PT | |
| | | | *Gastrointestinal decompression* | 10082064 |

MSSO Comment: The proposal to add a new term Gastric decompression is approved as requested. Decompression of the stomach is usually performed using nasogastric or intestinal intubation to treat gastric atony, ileus, or obstruction. Gastric decompression is also implemented to empty the gastric contents to prevent aspiration during anesthesia or in a physically compromised patient. Gastric decompression will be added as a sub-concept LLT to existing PT Gastrointestinal decompression.

# Supplemental Update Report

**CR Number: 2018365208** **Implementation Date:** 22-Jan-19 Related CR: 2018365208

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Non-rhabdomyosarcoma soft-tissue sarcoma* | Approved as Requested | Proposed LLT | | |
| To PT | *Soft tissue sarcoma* | | *Non-rhabdomyosarcoma soft-tissue sarcoma* | 10082652 | Current |
| | | | To PT | | |
| | | | *Soft tissue sarcoma* | 10075333 | |

MSSO Comment: The proposal to add a new LLT Non-rhabdomyosarcoma soft-tissue sarcoma to PT Soft tissue sarcoma is approved as requested. Soft-tissue sarcomas that are not rhabdomyosarcomas are classified as non-rhabdomyosarcoma soft tissue sarcomas (NRSTS). Examples of the many types of NRSTS cancers include fibrosarcoma, leiomyosarcoma, liposarcoma, neurofibrosarcoma, peripheral nerve sheath tumors and synovial sarcoma.

**CR Number: 2018365209** **Implementation Date:** 22-Jan-19 Related CR: 2018365209

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Pigmented purpuric dermatosis* | Approved as Requested | Proposed LLT | | |
| | | | *Pigmented purpuric dermatosis* | 10082653 | Current |
| | | | To PT | | |
| | | | *Chronic pigmented purpura* | 10072726 | |

MSSO Comment: The proposal to add a new LLT Pigmented purpuric dermatosis is approved as requested. Pigmented purpuric dermatosis (PPD) is a chronic condition characterized by reddish-brown skin lesions caused by leaky capillaries. Although they can arise on any part of the body, they are most commonly located on the lower legs. In some cases, the skin lesions cause severe itching. The skin lesions may spread over time, or clear up on their own. The cause of pigmented purpuric dermatosis is unknown. There are multiple synonyms: purpura pigmentosa chronica, pigmented purpura, pigmented purpuric dermatitis, chronic purpuric dermatitis. Pigmented purpuric dermatosis will be added as synonym LLT to PT Chronic pigmented purpura.

**CR Number: 2018365215** **Implementation Date:** 22-Jan-19 Related CR: 2018365215

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Urethral meatus paresthesia post voiding* | Rejected | | |

MSSO Comment: The proposal to add a new LLT Urethral meatus paresthesia post voiding is not approved. Brief paresthesias (abnormal sensations such as burning, prickling or tingling) perceived at the urethral orifice (meatus urethrae) after micturition is a descriptive symptom often related to urethritis or cystitis and may be best represented by PT Dysuria or any suitable LLTs under PT Dysuria.

# Supplemental Update Report

**CR Number: 2018365216** **Implementation Date:** 22-Jan-19 Related CR: 2018365216

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Bronchial superinfection* | Approved as Requested | Proposed LLT | |
| To PT | *Bronchitis* | | *Bronchial superinfection* | 10082655 Current |
| | | | To PT | |
| | | | *Bronchitis* | 10006451 |

MSSO Comment: The proposal to add a new LLT Bronchial superinfection to PT Bronchitis is approved as requested. Superinfection is a new infection occurring in a patient having a preexisting infection. Bronchitis is mostly caused by viruses. However, bacteria may establish themselves on the damaged bronchial mucous membranes causing a bronchial superinfection.

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**CR Number: 2018365217** **Implementation Date:** 22-Jan-19 Related CR: 2018365217

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Nasopharyngeal biopsy* | Approved Not as Requested | Proposed LLT | |
| | | | *Biopsy nasopharynx* | 10082656 Current |
| | | | To PT | |
| | | | *Biopsy pharynx* | 10004851 |

MSSO Comment: The proposal to add a new term Nasopharyngeal biopsy is approved but not as requested. Under the suspicion of a nasopharyngeal carcinoma, the only way to settle a final diagnose is by taking out cells from the abnormal area and looking at them under a microscope by taking a small piece of tissue during endoscopic exploration. Nasopharyngeal biopsy is a combined term overarching two adjacent anatomical structures. The requested term will be rephrased for consistency with other biopsy terms and added as a sub-element LLT Biopsy nasopharynx to PT Biopsy pharynx. In associate changes, the qualified LLTs Biopsy nasopharynx normal and Biopsy nasopharynx abnormal will be added respectively under existing PTs Biopsy pharynx normal and Biopsy pharynx abnormal.

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**CR Number: 2018365220** **Implementation Date:** 22-Jan-19 Related CR: 2018365217

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Biopsy nasopharynx normal* | Approved as Requested | Proposed LLT | |
| To PT | *Biopsy pharynx normal* | | *Biopsy nasopharynx normal* | 10082657 Current |
| | | | To PT | |
| | | | *Biopsy pharynx normal* | 10004853 |

MSSO Comment:

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# Supplemental Update Report

**CR Number: 2018365221** **Implementation Date:** 22-Jan-19 Related CR: 2018365217

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Biopsy nasopharynx abnormal* | Approved as Requested | Proposed LLT | |
| To PT | *Biopsy pharynx abnormal* | | *Biopsy nasopharynx abnormal* | 10082658 Current |
| | | | To PT | |
| | | | *Biopsy pharynx abnormal* | 10004852 |

MSSO Comment:

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**CR Number: 2018365218** **Implementation Date:** 29-Jan-19 Related CR: 2018365218

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Viral Cold* | Rejected | | |

MSSO Comment: The proposal to add a new LLT Viral Cold is not approved. The common cold, also known simply as a cold, is a viral infectious disease of the upper respiratory tract that primarily affects the nose. The requested term can be represented by existing LLT Common cold.

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**CR Number: 2018365219** **Implementation Date:** 29-Jan-19 Related CR: 2018365219

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Cystolitholapaxy* | Approved as Requested | Proposed LLT | |
| To PT | *Bladder calculus removal* | | *Cystolitholapaxy* | 10082659 Current |
| | | | To PT | |
| | | | *Bladder calculus removal* | 10005002 |

MSSO Comment: The proposal to add a new LLT Cystolitholapaxy to PT Bladder calculus removal is approved as requested. Cystolitholapaxy is a procedure to remove bladder calculi which involves crushing or disintegration of bladder stone(s) using telescopic instruments or laser and removal of the stone fragments using suction apparatus.

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# Supplemental Update Report

**CR Number: 2018365222** **Implementation Date:** 29-Jan-19 Related CR: 2018365222

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Suspected drug exposure via breast milk* | Approved as Requested | Proposed LLT | |
| | | | *Suspected drug exposure via breast milk* | 10082660 Current |
| | | | To PT | |
| | | | *Exposure via breast milk* | 10080751 |

MSSO Comment: The proposal to add a new term Suspected drug exposure via breast milk is approved as requested. Reports of suspected drug exposure via breast milk is an important information for authorities regarding risk asessment of treating or withholding a medication for mothers during breast feeding. Suspected drug exposure via breast milk will be added as sub-concept LLT to PT Exposure via breast milk. This is in line with similar placement of LLT Suspected exposure via ingestion under PT Exposure via ingestion.

**CR Number: 2018365223** **Implementation Date:** 29-Jan-19 Related CR: 2018365223

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Fall from high-places* | Approved Not as Requested | Proposed LLT | |
| | | | *Fall from high place* | 10082661 Current |
| | | | To PT | |
| | | | *Fall* | 10016173 |

MSSO Comment: The proposal to add a new term Fall from high-places is approved but not as requested. Fall from high-places will be rephrased for clarification to Fall from high place and added as LLT to PT Fall. Injuries caused by falls from high places are most severe and many people die from such a fall.

**CR Number: 2018365224** **Implementation Date:** 29-Jan-19 Related CR: 2018365224

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Jump off* | Rejected | | |

MSSO Comment: The proposal to add a new term Jump off is not approved. Jump off is a vague and ambiguous term. If this refers to the act of jumping off something (e.g. bridge) in order to commit suicide; the intent and outcome can be represented e.g. with LLT Attempted suicide or LLT Completed suicide or LLT Intentional self-injury.

# Supplemental Update Report

**CR Number: 2018365225** **Implementation Date:** 29-Jan-19 Related CR: 2018365225

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Cryophobia* | Approved Not as Requested | Proposed PT | |
| | | | *Cryophobia* | 10082662 |
| | | | HLT primary | |
| | | | *Fear symptoms and phobic disorders (incl social phobia)* | 10068299 |
| | | | SOC primary | |
| | | | *Psychiatric disorders* | 10037175 |

MSSO Comment: The proposal to add a new LLT Cryophobia is approved but not as requested. Cryophobia, an abnormal and persistent fear of cold, including cold weather and cold objects, will be added as PT to HLT Fear symptoms and phobic disorders (incl social phobia).

**CR Number: 2018365226** **Implementation Date:** 29-Jan-19 Related CR: 2018365226

| Change Requested | Rename PT/LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Term to modify | *Transnasal humified rapid-insufflation ventilator exchange* | Approved as Requested | Term to modify | |
| | | | *Transnasal humified rapid-insufflation ventilator exchange* | |
| Replacement term | *Transnasal humidified rapid-insufflation ventilatory exchange* | | Replacement term | |
| | | | *Transnasal humidified rapid-insufflation ventilatory exchange* | 10082536 Current |

MSSO Comment: The proposal to rename PT/LLT Transnasal humified rapid-insufflation ventilator exchange to Transnasal humidified rapid-insufflation ventilatory exchange is approved as requested. LLT Transnasal humified rapid-insufflation ventilator exchange was added in Version 22.0 (CR 2018334007) as a sub-concept of PT Mechanical ventilation. The term will be renamed to Transnasal humidified rapid-insufflation ventilatory exchange, which is the correct spelling of the concept as represented in the medical literature.

# Supplemental Update Report

**CR Number: 2018365227** **Implementation Date:** 29-Jan-19 Related CR: 2018365227

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Discoid meniscus* | Approved Not as Requested | Proposed PT | |
| HLT primary | *Musculoskeletal and connective tissue disorders of limbs congenital* | | *Discoid meniscus* | 10082663 |
| | | | HLT primary | |
| SOC primary | *Congenital, familial and genetic disorders* | | *Cartilage disorders* | 10007709 |
| | | | SOC primary | |
| | | | *Musculoskeletal and connective tissue disorders* | 10028395 |

MSSO Comment: The proposal to add a new PT Discoid meniscus to primary HLT Musculoskeletal and connective tissue disorders of limbs congenital in SOC Congenital, familial and genetic disorders is approved but not as requested. A discoid meniscus is a rare human anatomic variant that usually affects the lateral meniscus of the knee. Discoid meniscus is thicker than normal, often oval or disc-shaped, and it is more prone to injury than a normally shaped meniscus. Despite Discoid meniscus antenatal origin, it is a condition whose symptoms present in adulthood, and therefore Discoid meniscus will be placed as a PT to HLT Cartilage disorders for the most appropriate placement.

**CR Number: 2018365228** **Implementation Date:** 29-Jan-19 Related CR: 2018365228

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Off label dosing route* | Rejected | | |
| To PT | *Off label use* | | | |

MSSO Comment: The proposal to add a new LLT Off label dosing route to PT Off label use is not approved. The requested scenario of Off label use can be represented by split coding with LLT Drug use via unapproved administration route and LLT Off label use.

**CR Number: 2018365229** **Implementation Date:** 29-Jan-19 Related CR: 2018365229

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Swelling face* | Approved as Requested | Proposed PT | |
| To HLT | *General signs and symptoms NEC* | | *Swelling face* | 10042682 |
| | | | To HLT | |
| | | | *General signs and symptoms NEC* | 10018072 |

MSSO Comment: The proposal to link the PT Swelling face to the HLT General signs and symptoms NEC is approved as requested. Since not all facial swellings are caused by angioedema, the primary SOC for PT Swelling face will be re-assigned to SOC General disorders and administration site conditions. To capture this change in batch 20110242, Swelling face will be first linked to HLT General signs and symptoms NEC then have the primary SOC re-assigned to SOC General disorders and administration site conditions.

# Supplemental Update Report

**CR Number: 2018365230** **Implementation Date:** 29-Jan-19 Related CR: 2018365230

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Swelling face* | Approved as Requested | Proposed PT | |
| Old Primary SOC | *Skin and subcutaneous tissue disorders* | | *Swelling face* | 10042682 |
| New Primary SOC | *General disorders and administration site conditions* | | Old Primary SOC | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |
| | | | New Primary SOC | |
| | | | *General disorders and administration site conditions* | 10018065 |

MSSO Comment: The proposal to reassign the primary SOC of PT Swelling face from current SOC Skin and subcutaneous tissue disorders to SOC General disorders and administration site conditions is approved as requested. Since not all facial swellings are caused by angioedema, the primary SOC for PT Swelling face will be re-assigned to SOC General disorders and administration site conditions. To capture this change in batch 20110242, Swelling face will be first linked to HLT General signs and symptoms NEC then have the primary SOC re-assigned from SOC Skin and subcutaneous tissue disorders to SOC General disorders and administration site conditions.

**CR Number: 2018365233** **Implementation Date:** 29-Jan-19 Related CR: 2018365233

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Invasive mycosis* | Rejected | | |
| From PT | *Systemic mycosis* | | | |

MSSO Comment: The proposal to promote the LLT Invasive mycosis from PT Systemic mycosis is not approved. In the clinical context of fungal infections, invasive mycosis is generally uncommon, except in certain groups of patients with significant immune deficiency, who often manifest systemic mycosis. LLT Invasive mycosis is thus appropriately placed as an sub-concept of PT Systemic mycosis.

# Supplemental Update Report

**CR Number: 2018365234** **Implementation Date:** 29-Jan-19 Related CR: 2018365234

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *DOUBLE-INLET LEFT VENTRICLE* | Approved Not as Requested | Proposed PT | |
| | | | *Double inlet left ventricle* | 10082665 |
| | | | HLT primary | |
| | | | *Multiple cardiac abnormalities congenital* | 10028177 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary | |
| | | | *Congenital cardiac structural defects NEC* | 10010397 |
| | | | SOC secondary | |
| | | | *Cardiac disorders* | 10007541 |

MSSO Comment: The proposal to add a new PT DOUBLE-INLET LEFT VENTRICLE is approved but not as requested. Double inlet left ventricle is a complex congenital cardiac defect where both atria connect to the same ventricle and/or one ventricle is absent or very hypoplastic. In most cases the infant develops symptoms in the early weeks of life, either with cyanosis, or with breathlessness and failure to gain weight normally. Many affected patients have associated defects in the heart or main arteries, including such problems as pulmonary stenosis, pulmonary atresia, other valve abnormalities, coarctation of the aorta, etc. Double inlet left ventricle will be added, in accordance with MedDRA capitalization conventions, as a new PT to primary HLT Multiple cardiac abnormalities congenital, to secondary HLT Congenital cardiac structural defects NEC, and to secondary HLT Vascular malformations and acquired anomalies.

**CR Number: 2018365277** **Implementation Date:** 29-Jan-19 Related CR: 2018365234

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Double inlet left ventricle* | Approved as Requested | Proposed PT | |
| To HLT | *Vascular malformations and acquired anomalies* | | *Double inlet left ventricle* | 10082665 |
| | | | To HLT | |
| | | | *Vascular malformations and acquired anomalies* | 10047091 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2018365235** **Implementation Date:** 29-Jan-19 Related CR: 2018365235

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *SELF CONSCIOUS* | Approved Not as Requested | Proposed PT | |
| | | | *Self-consciousness* | 10082664 |
| | | | HLT primary | |
| | | | *Behaviour and socialisation disturbances* | 10004209 |
| | | | SOC primary | |
| | | | *Psychiatric disorders* | 10037175 |

MSSO Comment: The proposal to add a new LLT SELF CONSCIOUS is approved but not as requested. Self-consciousness is described as a excessive sense of self-awareness, or a preoccupation with oneself. The proposed term SELF CONSCIOUS will be added as Self-consciousness, the usual expression for this concept, in accordance with MedDRA capitalization conventions, as a PT to HLT Behaviour and socialisation disturbances.

**CR Number: 2018365236** **Implementation Date:** 29-Jan-19 Related CR: 2018365236

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *GASTROINTESTINAL PATHOGEN PANEL* | Approved Not as Requested | Proposed PT | |
| | | | *Gastrointestinal pathogen panel* | 10082666 |
| | | | HLT primary | |
| | | | *Microbiology and serology tests NEC* | 10027530 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new LLT GASTROINTESTINAL PATHOGEN PANEL is approved but not as requested. The gastrointestinal pathogen panel is a multiplexed nucleic acid test intended for the simultaneous qualitative detection and identification of multiple viral, parasitic, and bacterial nucleic acids in human stool specimens from individuals with signs and symptoms of infectious colitis or gastroenteritis. Gastrointestinal pathogen panel will added in accordance with MedDRA capitalization conventions, as a new PT to HLT Microbiology and serology tests NEC.

**CR Number: 2018365237** **Implementation Date:** 29-Jan-19 Related CR: 2018365237

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Cibophobia* | Approved as Requested | PT to merge | |
| To PT | *Sitophobia* | | *Cibophobia* | 10082413 Current |
| | | | To PT | |
| | | | *Sitophobia* | 10080170 |

MSSO Comment: The proposal to demote the PT Cibophobia under PT Sitophobia is approved as requested. Dorland's Medical Dictionary defines sitophobia as the irrational fear of eating, or of food. Dorland's does not include a definition for cibophobia. Other references include the following: Sitophobia is considered to be a specific phobia, the fear of food or eating. The origin of the word sito is Greek (meaning food) and phobia is Greek (meaning fear). Cibophobia is the fear of food or eating. The origin of the word cibo is Latin (meaning food), and phobia is Greek (meaning fear). Cibophobia is also stated to be synonymous with sitophobia and sitiophobia. Because sitophobia and cibophobia are used synonymously, PT Cibophobia will be demoted under PT Sitophobia, which appears to be the more commonly used term.

# Supplemental Update Report

**CR Number: 2018365238** **Implementation Date:** 31-Jan-19 Related CR: 2018365238

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Double inlet left ventricle* | Rejected | | |

MSSO Comment: The proposal to add a new LLT Double inlet left ventricle is not approved. This is a technical rejection because for every new PT added, an identical LLT will also be added automatically; please see change request 2018365234 for the addition of PT Double inlet left ventricle.

**CR Number: 2018365239** **Implementation Date:** 31-Jan-19 Related CR: 2018365239

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Mees' lines* | Approved Not as Requested | Proposed LLT | |
| From PT | *Metal poisoning* | | *Mees' lines* | 10027109 Current |
| To PT | *Nail discolouration* | | From PT | |
| | | | *Metal poisoning* | 10027439 |
| | | | To PT | |
| | | | *Leukonychia* | 10050658 |

MSSO Comment: The proposal to move the LLT Mees' lines from PT Metal poisoning to PT Nail discolouration is approved but not as requested. Mees' lines (leukonychia striata) are transverse white bands on the nail plate laid down during periods of stress. Common associations are poisioning (arsenic, thallium, fluorosis), severe infection, renal disease, cardiac failure, and malignant disease. Instead of promoting LLT Mees' lines will be moved from PT Metal poisoning to a newly promoted PT Leukonychia. In a related change, LLT Leukonychia will be promoted from PT Nail discolouration to a PT and linked primay HLT Nail and nail bed conditions (excl infections and infestations) and secondary HLT Poisoning and toxicity.

# Supplemental Update Report

**CR Number: 2018365298** **Implementation Date:** 31-Jan-19 Related CR: 2018365239

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Leukonychia* | Approved as Requested | Proposed LLT | |
| From PT | *Nail discolouration* | | *Leukonychia* | 10050658 |
| HLT primary | *Nail and nail bed conditions (excl infections and infestations)* | | From PT | |
| | | | *Nail discolouration* | 10028692 |
| | | | HLT primary | |
| | | | *Nail and nail bed conditions (excl infections and infestations)* | 10028685 |
| | | | SOC primary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |
| | | | HLT secondary | |
| | | | *Poisoning and toxicity* | 10035777 |
| | | | SOC secondary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |

MSSO Comment:

**CR Number: 2018365240** **Implementation Date:** 31-Jan-19 Related CR: 2018365240

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Leukonychia striata* | Approved Not as Requested | Proposed LLT | |
| To PT | *Nail discolouration* | | *Leukonychia striata* | 10082667 Current |
| | | | To PT | |
| | | | *Leukonychia* | 10050658 |

MSSO Comment: The proposal to add a new LLT Leukonychia striata to PT Nail discolouration is approved but not as requested. Mees' lines (synonym: leukonychia striata) are transverse white bands on the nail plate laid down during periods of stress. Common associations are poisoning (arsenic, thallium, fluorosis), severe infection, renal disease, cardiac failure, and malignant disease. Leukonychia striata will be added as a synonym LLT to newly promoted PT Leukonychia in change request 2018365239.

# Supplemental Update Report

**CR Number: 2018365241** **Implementation Date:** 01-Feb-19 Related CR: 2018365241

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Testicular redness* | Rejected | | |

MSSO Comment: The proposal to add a new term Testicular redness is not approved. The proposed concept can be represented by existing LLT Scrotal erythema.

**CR Number: 2018365242** **Implementation Date:** 01-Feb-19 Related CR: 2018365242

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Testicular erythema* | Rejected | | |

MSSO Comment: The proposal to add a new term Testicular erythema is not approved. The proposed concept can be represented by existing LLT Scrotal erythema.

**CR Number: 2018365243** **Implementation Date:** 01-Feb-19 Related CR: 2018365243

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Mucosal blister* | Approved as Requested | Proposed LLT | |
| To PT | *Mucosa vesicle* | | *Mucosal blister* | 10082686 Current |
| | | | To PT | |
| | | | *Mucosa vesicle* | 10028103 |

MSSO Comment: The proposal to add a new LLT Mucosal blister to PT Mucosa vesicle is approved as requested as blister, bulla, and vesicle as generally synonymous terms. In a related change, PT Mucosa vesicle will be linked secondarily to HLT Bullous conditions.

# Supplemental Update Report

**CR Number: 2018365303** **Implementation Date:** 01-Feb-19 Related CR: 2018365243

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Mucosa vesicle* | Approved as Requested | Proposed PT | |
| To HLT | *Bullous conditions* | | *Mucosa vesicle* | 10028103 |
| | | | To HLT | |
| | | | *Bullous conditions* | 10006555 |

MSSO Comment:

**CR Number: 2018365244** **Implementation Date:** 01-Feb-19 Related CR: 2018365244

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Anal blister* | Approved Not as Requested | Proposed PT | |
| HLT primary | *Anal and rectal disorders NEC* | | *Anal blister* | 10082677 |
| SOC primary | *Gastrointestinal disorders* | | HLT primary | |
| | | | *Anal and rectal signs and symptoms* | 10002118 |
| | | | SOC primary | |
| | | | *Gastrointestinal disorders* | 10017947 |
| | | | HLT secondary | |
| | | | *Bullous conditions* | 10006555 |
| | | | SOC secondary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment: The proposal to add a new PT Anal blister to primary HLT Anal and rectal disorders NEC in SOC Gastrointestinal disorders is approved but not as requested. Blisters, may be associated with various dermatological conditions and Herpes simplex type 1 and 2 infections in the anal and perianal region. Anal blister will be added as a PT to primary HLT Anal and rectal signs and symptoms and to secondary HLT Bullous conditions.

**CR Number: 2018365245** **Implementation Date:** 01-Feb-19 Related CR: 2018365245

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Skin puffy* | Approved Not as Requested | Proposed LLT | |
| To PT | *Skin swelling* | | *Puffy skin* | 10082691 Current |
| | | | To PT | |
| | | | *Skin swelling* | 10053262 |

MSSO Comment: The proposal to add a new LLT Skin puffy to PT Skin swelling is approved but not as requested. Skin puffy will be added in the natural word order as synonym LLT Puffy skin to PT Skin swelling.

# Supplemental Update Report

**CR Number: 2018365246** **Implementation Date:** 01-Feb-19 Related CR: 2018365246

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Tooth discomfort* | Approved as Requested | Proposed LLT | |
| To PT | *Dental discomfort* | | *Tooth discomfort* | 10082687 Current |
| | | | To PT | |
| | | | *Dental discomfort* | 10054217 |

MSSO Comment: The proposal to add a new LLT Tooth discomfort to PT Dental discomfort is approved as requested. Tooth discomfort is a frequently reported term which is synonymous with PT Dental discomfort.

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**CR Number: 2018365247** **Implementation Date:** 01-Feb-19 Related CR: 2018365247

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Product contamination mould* | Approved as Requested | Proposed LLT | |
| To PT | *Product contamination microbial* | | *Product contamination mould* | 10082682 Current |
| | | | To PT | |
| | | | *Product contamination microbial* | 10069175 |

MSSO Comment: The proposal to add a new LLT Product contamination mould to PT Product contamination microbial is approved as requested. Considering that "mould" contamination appears to be more commonly reported than "fungal" contamination, LLT Product contamination mould will be added to complement LLT Product contamination fungal to PT Product contamination microbial. In a related change, the American English spelling counterpart LLT Product contamination mold will also be added to PT Product contamination microbial.

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**CR Number: 2018365304** **Implementation Date:** 01-Feb-19 Related CR: 2018365247

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Product contamination mold* | Approved as Requested | Proposed LLT | |
| To PT | *Product contamination microbial* | | *Product contamination mold* | 10082695 Current |
| | | | To PT | |
| | | | *Product contamination microbial* | 10069175 |

MSSO Comment:

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# Supplemental Update Report

**CR Number: 2018365248** **Implementation Date:** 01-Feb-19 Related CR: 2018365248

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Scalp discomfort* | Rejected | | |
| To PT | *Skin discomfort* | | | |

MSSO Comment: The proposal to add a new LLT Scalp discomfort to PT Skin discomfort is not approved. It is not feasible to add to such broad concepts such as, LLT Skin discomfort, for every anatomical specificity.

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**CR Number: 2018365249** **Implementation Date:** 01-Feb-19 Related CR: 2018365249

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Paranasal sinus irritation* | Approved Not as Requested | Proposed LLT | |
| HLT primary | *Upper respiratory tract signs and symptoms* | | *Paranasal sinus irritation* | 10082688 Current |
| SOC primary | *Respiratory, thoracic and mediastinal disorders* | | To PT | |
| | | | *Paranasal sinus discomfort* | 10052438 |

MSSO Comment: The proposal to add a new PT Paranasal sinus irritation to primary HLT Upper respiratory tract signs and symptoms in SOC Respiratory, thoracic and mediastinal disorders is approved but not as requested. Paranasal sinus irritation will be added as sub-concept LLT to PT Paranasal sinus discomfort - this placement is in line with the alignement of LLT Nasal irritation under PT Nasal discomfort by avoiding overgranulation for closely related concepts.

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**CR Number: 2018365250** **Implementation Date:** 01-Feb-19 Related CR: 2018365250

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Reaction to flavouring* | Approved as Requested | Proposed LLT | |
| | | | *Reaction to flavouring* | 10082681 Current |
| | | | To PT | |
| | | | *Reaction to food additive* | 10037977 |

MSSO Comment: The proposal to add a new term Reaction to flavouring is approved as requested. Like other food and drug additives, flavorings and taste enhancers (such as Monosodium glutamate , spices, and sweeteners), can cause many types of adverse reactions such as allergy, sensitivity or intolerance. Reaction to flavouring will be added as an LLT to PT Reaction to food additive. In a related change, the American English counterpart LLT Reaction to flavoring will be also added to PT Reaction to food additive.

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# Supplemental Update Report

**CR Number: 2018365305** **Implementation Date:** 01-Feb-19 Related CR: 2018365250

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Reaction to flavoring* | Approved as Requested | Proposed LLT | |
| To PT | *Reaction to food additive* | | *Reaction to flavoring* | 10082697 Current |
| | | | To PT | |
| | | | *Reaction to food additive* | 10037977 |

MSSO Comment:

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**CR Number: 2018365251** **Implementation Date:** 01-Feb-19 Related CR: 2018365251

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Spongiotic dermatitis* | Approved as Requested | Proposed LLT | |
| To PT | *Eczema* | | *Spongiotic dermatitis* | 10082692 Current |
| | | | To PT | |
| | | | *Eczema* | 10014184 |

MSSO Comment: The proposal to add a new LLT Spongiotic dermatitis to PT Eczema is approved as requested. Eczema is a common skin condition with multiple clinical patterns, characterised histologically by a spongiotic tissue reaction pattern. The terms eczema and dermatitis are often used interchangeably to denote a polymorphic inflammatory reaction pattern involving the epidermis and dermis. However, 'dermatitis' means inflammation of the skin and is not synonymous with eczematous processes. The consensus among most dermatopathologists is that the expression 'eczema' should be replaced with the term 'spongiotic dermatitis' to reflect the histopathologic changes that underlie the so-called 'eczemas'. Eczema has been a MedDRA term since version 2.1, initially as an LLT to PT Eczema NOS, and as a PT since version 5.0. Replacing PT Eczema with PT Spongiotic dermatitis may have a potentially significant impact on legacy data.

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**CR Number: 2018365252** **Implementation Date:** 01-Feb-19 Related CR: 2018365252

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Chronic spongiotic dermatitis* | Approved as Requested | Proposed LLT | |
| To PT | *Eczema* | | *Chronic spongiotic dermatitis* | 10082683 Current |
| | | | To PT | |
| | | | *Eczema* | 10014184 |

MSSO Comment: The proposal to add a new LLT Chronic spongiotic dermatitis to PT Eczema is approved as requested. Spongiotic dermatitis is defined by the presence of epithelial intercellular oedema. It is caused by a variety of clinical conditions such as allergic reactions, infections, etc. Spongiotic dermatitis is further subclassified into acute, subacute, and chronic, depending on the histological features and the time the biopsy was performed.

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# Supplemental Update Report

**CR Number: 2018365253** **Implementation Date:** 01-Feb-19 Related CR: 2018365253

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Scaly eczema* | Rejected | | |

MSSO Comment: The proposal to add a new term Scaly eczema is not approved. Scaly eczema is a dermatological descriptive term and can be represented by the combination of LLT Eczema and LLT Skin scaly or LLT Rash scaly or LLT Dermatitis exfoliative.

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**CR Number: 2018365254** **Implementation Date:** 01-Feb-19 Related CR: 2018365254

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Exfoliative eczema* | Rejected | | |

MSSO Comment: The proposal to add a new term Exfoliative eczema is not approved. Exfoliative eczema can be represented by LLT Exfoliative dermatitis

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**CR Number: 2018365255** **Implementation Date:** 01-Feb-19 Related CR: 2018365255

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Faeces abnormal smell of* | Approved as Requested | Proposed LLT | |
| To PT | *Abnormal faeces* | | *Faeces abnormal smell of* | 10082678 Current |
| | | | To PT | |
| | | | *Abnormal faeces* | 10000133 |

MSSO Comment: The proposal to add a new LLT Faeces abnormal smell of to PT Abnormal faeces is approved as requested to represent the British English spelled counterpart concept of LLT Feces abnormal smell of.

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# Supplemental Update Report

**CR Number: 2018365256** **Implementation Date:** 01-Feb-19 Related CR: 2018365256

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Faecal impaction NOS* | Rejected | | |
| To PT | *Faecaloma* | | | |

MSSO Comment: The proposal to add a new LLT Faecal impaction NOS to PT Faecaloma is not approved. The requested term can be represented by LLT Faecal impaction - without "NOS". Please note that per the direction of the MedDRA Management Committee, as of MedDRA Version 6.1, no additional “NOS” terms will be accepted into the terminology.

**CR Number: 2018365257** **Implementation Date:** 01-Feb-19 Related CR: 2018365257

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Periorbital pain* | Rejected | | |
| To HLT | *Dermal and epidermal conditions NEC* | | | |

MSSO Comment: The proposal to link the PT Periorbital pain to the HLT Dermal and epidermal conditions NEC is not approved. While eyelid is an extension of the skin (thus supporting the link of Eyelid pain to HLT Dermal and epidermal conditions NEC) the periorbital space includes other anatomical structures different than skin, such as nerves, tendons and muscles, all of which are more frequently the origin of painful sensations than the skin in this area. Therefore, the link of Periorbital pain to HLT Dermal and epidermal conditions NEC is not considered suitable.

**CR Number: 2018365258** **Implementation Date:** 01-Feb-19 Related CR: 2018365258

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Testicular rash* | Approved Not as Requested | Proposed LLT | |
| | | | *Scrotal rash* | 10082689 |
| | | | To PT | |
| | | | *Genital rash* | 10018175 |

MSSO Comment: The proposal to add a new term Testicular rash is approved but not as requested. Unless the requested term intentionally represents a rash of the appearance of the testes, anatomically beneath the surface of the scrotum, the MSSO assumes that the concept pertains to a scrotal rash. Rash on the scrotum may be associated with a variety of conditions such as infection, hyperhidrosis, contact dermatitis, and other causes of skin rash. Scrotal rash will be added as a sub-concept LLT to PT Genital rash.

# Supplemental Update Report

**CR Number: 2018365259** **Implementation Date:** 01-Feb-19 Related CR: 2018365259

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vulvovaginal hyperaesthesia* | Approved Not as Requested | Proposed LLT | |
| HLT primary | *Vulvovaginal signs and symptoms* | | *Vulvovaginal hyperaesthesia* | 10082684 Current |
| SOC primary | *Reproductive system and breast disorders* | | To PT | |
| | | | *Genital hyperaesthesia* | 10073421 |

MSSO Comment: The proposal to add a new PT Vulvovaginal hyperaesthesia to primary HLT Vulvovaginal signs and symptoms in SOC Reproductive system and breast disorders and secondary HLT Paraesthesias and dysaesthesias in SOC Nervous system disorders is approved but not as requested. Vulvovaginal hyperaesthesia consists of increased sensitivity in the vulvovaginal region, particularly referring to a painful sensation resulting from a normally painless touch stimulus will be added as a sub-concept LLT to PT Genital hyperaesthesia. In a related change, the American English spelled counterpart Vulvovaginal hyperesthesia will be added as an LLT to PT Genital hyperaesthesia. Furthermore, PT Vulvovaginal hypoaesthesia will be demoted under the broader PT Genital hypoaesthesia to avoid over granularity at the PT level.

**CR Number: 2018365306** **Implementation Date:** 01-Feb-19 Related CR: 2018365259

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Vulvovaginal hyperesthesia* | Approved as Requested | Proposed LLT | |
| To PT | *Genital hyperaesthesia* | | *Vulvovaginal hyperesthesia* | 10082693 Current |
| | | | To PT | |
| | | | *Genital hyperaesthesia* | 10073421 |

MSSO Comment:

**CR Number: 2018365307** **Implementation Date:** 01-Feb-19 Related CR: 2018365259

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Vulvovaginal hypoaesthesia* | Approved as Requested | PT to merge | |
| To PT | *Genital hypoaesthesia* | | *Vulvovaginal hypoaesthesia* | 10075520 Current |
| | | | To PT | |
| | | | *Genital hypoaesthesia* | 10068912 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2018365260** **Implementation Date:** 01-Feb-19 Related CR: 2018365260

| Change Requested | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|
| Add a New Term | | | |
| Proposed Term *Penile hyperaesthesia* | Approved as Requested | Proposed LLT *Penile hyperaesthesia* | 10082680 Current |
| | | To PT *Genital hyperaesthesia* | 10073421 |

MSSO Comment: The proposal to add a new term Penile hyperaesthesia is approved as requested. Penile hyperaesthesia consists of increased sensitivity in the penile region, particularly referring to a painful sensation resulting from a normally painless touch stimulus. Penile hyperaesthesia and its American English counterpart Penile hyperesthesia will be as sub-concept LLTs to PT Genital hyperaesthesia.

**CR Number: 2018365308** **Implementation Date:** 01-Feb-19 Related CR: 2018365260

| Change Requested | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|
| Add a New LLT | | | |
| Proposed LLT *Penile hyperesthesia* | Approved as Requested | Proposed LLT *Penile hyperesthesia* | 10082694 Current |
| To PT *Genital hyperaesthesia* | | To PT *Genital hyperaesthesia* | 10073421 |

MSSO Comment:

**CR Number: 2018365261** **Implementation Date:** 01-Feb-19 Related CR: 2018365261

| Change Requested | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|
| Add a New Term | | | |
| Proposed Term *Penile hypoaesthesia* | Rejected | | |

MSSO Comment: The proposal to add a new term Penile hypoaesthesia is not approved. The proposed term can be represented by the existing LLT Hypoaesthesia of penis.

# Supplemental Update Report

**CR Number: 2018365262** **Implementation Date:** 01-Feb-19 Related CR: 2018365262

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Testicular hyperaesthesia* | Approved Not as Requested | Proposed LLT<br>*Scrotal hyperaesthesia*<br>To PT<br>*Genital hyperaesthesia* | 10082685 Current<br>10073421 |

MSSO Comment: The proposal to add a new term Testicular hyperaesthesia is approved but not as requested. Scrotal hyperaesthesia consists of increased sensitivity in the testicular region, particularly referring to a painful sensation resulting from a normally painless touch stimulus. Scrotal hyperaesthesia and the American English counterpart Scrotal hyperesthesia will be added as an LLTs to PT Genital hyperaesthesia.

**CR Number: 2018365309** **Implementation Date:** 01-Feb-19 Related CR: 2018365262

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT<br>To PT | *Scrotal hyperesthesia*<br>*Genital hyperaesthesia* | Approved as Requested | Proposed LLT<br>*Scrotal hyperesthesia*<br>To PT<br>*Genital hyperaesthesia* | <br>10082696 Current<br><br>10073421 |

MSSO Comment:

**CR Number: 2018365263** **Implementation Date:** 01-Feb-19 Related CR: 2018365263

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Testicular hypoaesthesia* | Approved Not as Requested | Proposed LLT<br>*Scrotal hypoaesthesia*<br>To PT<br>*Genital hypoaesthesia* | <br>10082679 Current<br><br>10068912 |

MSSO Comment: The proposal to add a new term Testicular hypoaesthesia is approved but not as requested. Testicular hypoaesthesia is a dysesthesia consisting of an abnormally decreased sensitivity in the testicles region, particularly to touch. Scrotal hypoaesthesia and it American English counterpart Scrotal hypoesthesia will be added as sub-concept LLTs to PT Genital hypoaesthesia.

# Supplemental Update Report

**CR Number: 2018365310** **Implementation Date:** 01-Feb-19 Related CR: 2018365263

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Scrotal hypoesthesia* | Approved as Requested | Proposed LLT | |
| To PT | *Genital hypoaesthesia* | | *Scrotal hypoesthesia* | 10082698 Current |
| | | | To PT | |
| | | | *Genital hypoaesthesia* | 10068912 |

MSSO Comment:

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**CR Number: 2018365264** **Implementation Date:** 01-Feb-19 Related CR: 2018365264

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Skin pain* | Approved as Requested | Proposed LLT | |
| To PT | *Pain of skin* | | *Skin pain* | 10082690 Current |
| | | | To PT | |
| | | | *Pain of skin* | 10033474 |

MSSO Comment: The proposal to add a new LLT Skin pain to PT Pain of skin is approved as requested to represent the concept in the natural word order.

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**CR Number: 2018365265** **Implementation Date:** 31-Jan-19 Related CR: 2018365265

| Change Requested | Rename PT/LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Term to modify | *Severe achondroplasia with developmental delay and acanthosis nigrican* | Approved as Requested | Term to modify | |
| | | | *Severe achondroplasia with developmental delay and acanthosis nigrican* | |
| Replacement term | *Severe achondroplasia with developmental delay and acanthosis nigricans* | | Replacement term | |
| | | | *Severe achondroplasia with developmental delay and acanthosis nigricans* | 10082394 Current |

MSSO Comment: The proposal to rename PT/LLT Severe achondroplasia with developmental delay and acanthosis nigrican to Severe achondroplasia with developmental delay and acanthosis nigricans is approved as requested. LLT Severe achondroplasia with developmental delay and acanthosis nigrican, added in version 22.0 to PT SADDAN syndrome, will be renamed as Severe achondroplasia with developmental delay and acanthosis nigricans, to represent the correct spelling of the term.

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# Supplemental Update Report

**CR Number: 2018365266** **Implementation Date:** 01-Feb-19 Related CR: 2018365266

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Pseudomonas peritonitis* | Approved Not as Requested | Proposed PT | |
| | | | *Pseudomonas peritonitis* | 10082669 |
| | | | HLT primary | |
| | | | *Pseudomonal infections* | 10037132 |
| | | | SOC primary | |
| | | | *Infections and infestations* | 10021881 |
| | | | HLT secondary | |
| | | | *Peritoneal infections* | 10034668 |
| | | | SOC secondary | |
| | | | *Gastrointestinal disorders* | 10017947 |

MSSO Comment: The proposal to add a new LLT Pseudomonas peritonitis is approved but not as requested. Peritonitis caused by Pseudomonas species is a serious complication in patients who are on continuous ambulatory peritoneal dialysis, and often is associated with poor response to conventional antibiotics and high rates of catheter removal. Pseudomonas peritonitis warrants addition as a PT to primary HLT Pseudomonal infections, secondary HLT Peritoneal infections and secondary HLT Dialysis related complications.

**CR Number: 2018365302** **Implementation Date:** 01-Feb-19 Related CR: 2018365266

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pseudomonas peritonitis* | Approved as Requested | Proposed PT | |
| To HLT | *Dialysis related complications* | | *Pseudomonas peritonitis* | 10082669 |
| | | | To HLT | |
| | | | *Dialysis related complications* | 10071945 |

MSSO Comment:

**CR Number: 2018365267** **Implementation Date:** 01-Feb-19 Related CR: 2018365267

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Artificial dental crown damage* | Approved Not as Requested | Proposed LLT | |
| To PT | *Dental restoration damage* | | *Artificial dental crown damage* | 10082672 Current |
| | | | To PT | |
| | | | *Device damage* | 10069870 Current |

MSSO Comment: The proposal to add a new LLT Artificial dental crown damage to PT Dental restoration damage is approved but not as requested. A crown is a type of fixed dental prosthesis that is a "tooth-shaped cap" placed over a natural tooth. Crowns replace parts of teeth that are damaged or decayed. Artificial dental crown damage will be placed as an LLT to PT Device damage.

# Supplemental Update Report

**CR Number: 2018365268** **Implementation Date:** 01-Feb-19 Related CR: 2018365268

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Dental filling damage* | Approved as Requested | Proposed LLT<br>*Dental filling damage*<br>To PT<br>*Device damage* | 10082673 Current<br>10069870 Current |

MSSO Comment: The proposal to add a new LLT Dental filling damage is approved as requested. Dental fillings are an effective treatment for restoring the health of teeth damaged by tooth decay. Dental fillings may be made of metal, including gold and silver amalgam, or tooth-colored composite resin. Although both metal and tooth-colored fillings can have a lifespan of over ten years, damage to dental fillings can cause them to fail early. Dental filling damage will be added as an LLT to PT Device damage.

**CR Number: 2018365269** **Implementation Date:** 01-Feb-19 Related CR: 2018365269

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Dental implant damage* | Approved as Requested | Proposed LLT<br>*Dental implant damage*<br>To PT<br>*Device damage* | 10082676 Current<br>10069870 Current |

MSSO Comment: The proposal to add a new term Dental implant damage is approved as requested. Dental implants have a high success rate, but some people experience dental implant failure. It's estimated that about 5 to 10 percent of dental implants fail, either shortly after a procedure or months or years later. Dental implant damage will be added as an LLT to PT Device damage.

**CR Number: 2018365270** **Implementation Date:** 01-Feb-19 Related CR: 2018365270

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Denture damage* | Approved as Requested | Proposed LLT<br>*Denture damage*<br>To PT<br>*Device damage* | 10082670 Current<br>10069870 Current |

MSSO Comment: The proposal to add a new LLT Denture damage is approved as requested. Denture damage, the damage to a removable plate or frame holding one or more artificial teeth, will be added as an LLT to PT Device damage.

# Supplemental Update Report

**CR Number: 2018365271** **Implementation Date:** 01-Feb-19 Related CR: 2018365271

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Dental prosthesis damage* | Approved as Requested | Proposed LLT | |
| | | | *Dental prosthesis damage* | 10082671 Current |
| | | | To PT | |
| | | | *Device damage* | 10069870 Current |

MSSO Comment: The proposal to add a new LLT Dental prosthesis damage is approved as requested. A dental prosthesis is an intraoral prosthesis used to restore intraoral defects such as missing teeth. Dental prosthesis damage will be added as an LLT to PT Device damage.

**CR Number: 2018365272** **Implementation Date:** 01-Feb-19 Related CR: 2018365272

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Artificial dental crown failure* | Approved as Requested | Proposed LLT | |
| | | | *Artificial dental crown failure* | 10082674 Current |
| | | | To PT | |
| | | | *Device failure* | 10056871 |

MSSO Comment: The proposal to add a new LLT Artificial dental crown failure is approved as requested. A dental prosthesis is an intraoral prosthesis used to restore intraoral defects such as missing teeth, missing parts of teeth, and missing soft or hard structures of the jaw and palate. Artificial dental crown failure will be added as an LLT to PT Device failure.

**CR Number: 2018365273** **Implementation Date:** 01-Feb-19 Related CR: 2018365273

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Dental prosthesis failure* | Approved as Requested | Proposed LLT | |
| | | | *Dental prosthesis failure* | 10082675 Current |
| | | | To PT | |
| | | | *Device failure* | 10056871 |

MSSO Comment: The proposal to add a new LLT Dental prosthesis failure is approved as requested. A dental prosthesis is an intraoral prosthesis used to restore intraoral defects such as missing teeth, missing parts of teeth, and missing soft or hard structures of the jaw and palate. A prosthesis may be fixed, such as a crown, or removable, such as a bridge. The proposed term, Dental prosthesis failure, will be added as a sub-concept LLT to PT Device failure.

# Supplemental Update Report

**CR Number: 2018365274** **Implementation Date:** 31-Jan-19 Related CR: 2018365274

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Scurf* | Rejected | | |
| From PT | *Dandruff* | | | |
| To PT | *Skin exfoliation* | | | |

MSSO Comment: The proposal to move the LLT Scurf from PT Dandruff to PT Skin exfoliation is not approved. Although scurf is defined as flakes on the surface of the skin that form as fresh skin develops below, it is mostly used in the context of dandruff, and therefore current placement is the most suitable one.

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**CR Number: 2018365275** **Implementation Date:** 31-Jan-19 Related CR: 2018365275

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Cough challenge test* | Approved as Requested | Proposed PT | |
| HLT primary | *Respiratory and pulmonary function diagnostic procedures* | | *Cough challenge test* | 10082668 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Respiratory and pulmonary function diagnostic procedures* | 10037385 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Cough challenge test to primary HLT Respiratory and pulmonary function diagnostic procedures in SOC Investigations is approved as requested. The cough challenge test is a useful tool in the physiological and pharmacological investigation of the cough reflex. The inhalation cough challenge relies on the delivery of tussive agents as aerosols from jet or ultrasonic nebulizers, and thus facilitates the quantification of cough and the assessment of the antitussive effects of the specific therapies. It can also have a diagnostic purpose, for example, sensory hyperresponsiveness to capsaicin was only seen in patients with asthma or gastroesophageal reflux.

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**CR Number: 2018365276** **Implementation Date:** 31-Jan-19 Related CR: 2018365276

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Renal fossa pain* | Rejected | | |

MSSO Comment: The proposal to add a new PT Renal fossa pain is not approved. The MSSO could not find in medical literature proof of existing concept. Please consider whether existing LLT Renal angle tenderness or LLT Costovertebral angle tenderness may represent your requested term.

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# Supplemental Update Report

**CR Number: 2018365278** **Implementation Date:** 01-Feb-19 Related CR: 2018365278

| Change Requested | | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Add a New LLT | | | | |
| Proposed LLT | *Anogenital warts aggravated* | Rejected | | |
| To PT | *Anogenital warts* | | | |

MSSO Comment: The proposal to add a new LLT Anogenital warts aggravated to PT Anogenital warts is not approved. As stated in Section 4.10 of the MedDRA Introductory Guide "The majority of terms expressing “aggravated” concepts (e.g., LLT Allergy aggravated) have been inherited from other terminologies." Because nearly all medical conditions and disorders may become aggravated, at this time, the MSSO refrains from adding new "aggravated" term concepts unless "aggravated" is part of the diagnostic term, or that such a term is universally recognized to be of major clinical significance. The requested term, Anogenital warts aggravated, can be represented by split coding with LLT Anogenital warts plus LLT Condition aggravated.

**CR Number: 2018365279** **Implementation Date:** 01-Feb-19 Related CR: 2018365279

| Change Requested | | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Add a New LLT | | | | |
| Proposed LLT | *Condyloma aggravated* | Rejected | | |
| To PT | *Anogenital warts* | | | |

MSSO Comment: The proposal to add a new LLT Condyloma aggravated to PT Anogenital warts is not approved. As stated in Section 4.10 of the MedDRA Introductory Guide "The majority of terms expressing “aggravated” concepts (e.g., LLT Allergy aggravated) have been inherited from other terminologies." Because nearly all medical conditions and disorders may become aggravated, at this time, the MSSO refrains from adding new "aggravated" term concepts unless "aggravated" is part of the diagnostic term, or that such a term is universally recognized to be of major clinical significance. The requested term, Condyloma aggravated, can be represented by split coding with LLT Condyloma plus LLT Condition aggravated.

**CR Number: 2018365280** **Implementation Date:** 08-Feb-19 Related CR: 2018365280

| Change Requested | | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Add a New PT | | | | |
| Proposed PT | *Urinary Neutrophil Gelatin-Associated Lipocalin* | Approved Not as Requested | Proposed LLT<br>*Urinary neutrophil gelatin-associated lipocalin*<br>To PT<br>*Neutrophil gelatin-associated lipocalin* | |

MSSO Comment: The proposal to add a new PT Urinary Neutrophil Gelatin-Associated Lipocalin is approved but not as requested. Neutrophil gelatinase-associated lipocalin (NGAL) is a member of the lipocalin family that is expressed at low levels in several human tissues, and rapidly released from renal tubular cells in response to various insults to the kidney. Serum and urinary NGAL are promising emerging biomarkers for early detection of acute kidney injury. Several recent studies have also defined the role of NGAL in chronic kidney disease and showed serum and urinary NGAL levels are a marker of kidney disease and severity in chronic kidney disease. The proposed term will be modified to comply with MedDRA capitalization conventions, and added as LLT Urinary neutrophil gelatin-associated lipocalin to a new PT Neutrophil gelatin-associated lipocalin. In a related change, Neutrophil gelatin-associated lipocalin will be added as a PT to HLT Renal function analyses. In addition, the acronym NGAL will be added as an LLT to PT Neutrophil gelatin-associated lipocalin.

# Supplemental Update Report

**CR Number: 2018365337** **Implementation Date:** 08-Feb-19 Related CR: 2018365280

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Neutrophil gelatin-associated lipocalin* | Approved as Requested | Proposed PT<br>*Neutrophil gelatin-associated lipocalin* | |
| HLT primary | *Renal function analyses* | | HLT primary<br>*Renal function analyses* | 10038454 |
| SOC primary | *Investigations* | | SOC primary<br>*Investigations* | 10022891 |

MSSO Comment:

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**CR Number: 2018365338** **Implementation Date:** 08-Feb-19 Related CR: 2018365280

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *NGAL* | Approved as Requested | Proposed LLT<br>*NGAL* | 10082701 Current |
| To PT | *Neutrophil gelatin-associated lipocalin* | | To PT<br>*Neutrophil gelatin-associated lipocalin* | |

MSSO Comment:

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**CR Number: 2018365281** **Implementation Date:** 08-Feb-19 Related CR: 2018365281

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Increased Urinary Neutrophil Gelatin-Associated Lipocalin* | Approved Not as Requested | Proposed LLT<br>*Urinary neutrophil gelatin-associated lipocalin increased*<br>To PT<br>*Neutrophil gelatin-associated lipocalin increased* | |

MSSO Comment: The proposal to add a new PT Increased Urinary Neutrophil Gelatin-Associated Lipocalin is approved but not as requested. Neutrophil gelatinase-associated lipocalin (NGAL) is a member of the lipocalin family that is expressed at low levels in several human tissues and rapidly released from renal tubular cells in response to various insults to the kidney. Elevated levels of serum and urinary NGAL are promising emerging biomarkers for early detection of acute kidney injury. Several recent studies have also defined the role of NGAL in chronic kidney disease and showed that elevated serum and urinary NGAL levels are a marker of kidney disease and severity in chronic kidney disease. The proposed term will be modified to comply with MedDRA conventions, and added as LLT Urinary neutrophil gelatin-associated lipocalin increased to new PT Neutrophil gelatin-associated lipocalin increased. In a related change, Neutrophil gelatin-associated lipocalin increased will be added as a PT to HLT Renal function analyses. Also the acronym NGAL increased will be added as an LLT to new PT Neutrophil gelatin-associated lipocalin increased.

# Supplemental Update Report

**CR Number: 2018365339** **Implementation Date:** 08-Feb-19 Related CR: 2018365281

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Neutrophil gelatin-associated lipocalin increased* | Approved as Requested | Proposed PT | |
| HLT primary | *Renal function analyses* | | *Neutrophil gelatin-associated lipocalin increased* | |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Renal function analyses* | 10038454 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment:

**CR Number: 2018365340** **Implementation Date:** 08-Feb-19 Related CR: 2018365281

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *NGAL increased* | Approved as Requested | Proposed LLT | |
| To PT | *Neutrophil gelatin-associated lipocalin increased* | | *NGAL increased* | 10082704 Current |
| | | | To PT | |
| | | | *Neutrophil gelatin-associated lipocalin increased* | |

MSSO Comment:

**CR Number: 2018365282** **Implementation Date:** 08-Feb-19 Related CR: 2018365282

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Urinary Osteopontin* | Approved Not as Requested | Proposed LLT | |
| | | | *Urinary osteopontin* | 10082707 Current |
| | | | To PT | |
| | | | *Osteopontin* | 10082706 |

MSSO Comment: The proposal to add a new PT Urinary Osteopontin is approved but not as requested. Osteopontin (OPN), also known as early T lymphocyte activation 1 (Eta-1), is a secreted multifunctional glycoprotein. OPN is expressed mainly by bone, kidney, and epithelial tissues but can also be found in endometrial tissues, endothelial cells, T cells, macrophages, smooth muscle cells, and many tumor types. It is upregulated in tissues during several pathological processes including atherosclerosis, valve stenosis, myocardial infarction, and rheumatoid arthritis. Higher urinary osteopontin has been demonstrated to predicts chronic kidney disease. The proposed term will be modified to comply with MedDRA capitalization conventions, and added as LLT Urinary osteopontin to PT Osteopontin. In a related change, PT Osteopontin will be added to HLT Protein analyses NEC.

# Supplemental Update Report

**CR Number: 2018365341** **Implementation Date:** 08-Feb-19 Related CR: 2018365282

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Osteopontin* | Approved as Requested | Proposed PT | |
| HLT primary | *Protein analyses NEC* | | *Osteopontin* | 10082706 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Protein analyses NEC* | 10036998 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment:

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**CR Number: 2018365283** **Implementation Date:** 08-Feb-19 Related CR: 2018365283

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Increased Urinary Osteopontin* | Approved Not as Requested | Proposed LLT | |
| | | | *Urinary osteopontin increased* | 10082709 Current |
| | | | To PT | |
| | | | *Osteopontin increased* | 10082708 |

MSSO Comment: The proposal to add a new PT Increased Urinary Osteopontin is approved but not as requested. Osteopontin (OPN), also known as early T lymphocyte activation 1 (Eta-1), is a secreted multifunctional glycoprotein. OPN is expressed mainly by bone, kidney, and epithelial tissues but can also be found in endometrial tissues, endothelial cells, T cells, macrophages, smooth muscle cells, and many tumor types. It is upregulated in tissues during several pathological processes including atherosclerosis, valve stenosis, myocardial infarction, and rheumatoid arthritis. Higher urinary osteopontin has been demonstrated to predicts chronic kidney disease. The proposed term will be modified to comply with MedDRA conventions, and added as LLT Urinary osteopontin increased to new PT Osteopontin increased. In a related change, Osteopontin increased will be added as a PT to HLT Protein analyses NEC.

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**CR Number: 2018365342** **Implementation Date:** 08-Feb-19 Related CR: 2018365283

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Osteopontin increased* | Approved as Requested | Proposed PT | |
| HLT primary | *Protein analyses NEC* | | *Osteopontin increased* | 10082708 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Protein analyses NEC* | 10036998 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment:

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# Supplemental Update Report

**CR Number: 2018365284** **Implementation Date:** 08-Feb-19 Related CR: 2018365284

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Myotonic chondrodystrophy* | Approved as Requested | Proposed LLT | |
| To PT | *Schwartz Jampel syndrome* | | *Myotonic chondrodystrophy* | 10082710 Current |
| | | | To PT | |
| | | | *Schwartz Jampel syndrome* | 10082378 |

MSSO Comment: The proposal to add a new LLT Myotonic chondrodystrophy to PT Schwartz Jampel syndrome is approved as requested. Myotonic chondrodystrophy is the medical synonym expression of Schwartz Jampel syndrome.

**CR Number: 2018365285** **Implementation Date:** 08-Feb-19 Related CR: 2018365285

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *XXXXX syndrome* | Approved as Requested | Proposed LLT | |
| To PT | *Penta X syndrome* | | *XXXXX syndrome* | 10082711 Current |
| | | | To PT | |
| | | | *Penta X syndrome* | 10082382 |

MSSO Comment: The proposal to add a new LLT XXXXX syndrome to PT Penta X syndrome is approved as requested. XXXXX syndrome is a frequently used synonym of PT Penta X syndrome and will be added as its LLT.

**CR Number: 2018365286** **Implementation Date:** 08-Feb-19 Related CR: 2018365286

| Change Requested | Rename PT/LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Term to modify | *Serous incision site discharge* | Approved as Requested | Term to modify | |
| Replacement term | *Incision site serous discharge* | | *Serous incision site discharge* | |
| | | | Replacement term | |
| | | | *Incision site serous discharge* | 10082301 Current |

MSSO Comment: The proposal to rename PT/LLT Serous incision site discharge to Incision site serous discharge is approved as requested to comply with the phrasing of other similar terms in MedDRA.

# Supplemental Update Report

**CR Number: 2018365287** **Implementation Date:** 08-Feb-19 Related CR: 2018365287

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Insufficiency fracture* | Rejected | | |
| From PT | *Stress fracture* | | | |
| To PT | *Pathological fracture* | | | |

MSSO Comment: The proposal to move the LLT Insufficiency fracture from PT Stress fracture to PT Pathological fracture is not approved. Insufficiency fractures are a type of stress fracture, which are the result of normal stresses on abnormal bone. Insufficiency fractures may occur in the absence of trauma or as a result of low-energy trauma, and occur due to a mismatch of the low osteoporotic bone strength and the presence of chronic mechanical stress. They are different than pathological fractures, which are the result of either focal pathology (such as tumors both malignant and benign) or the impact of an acute trauma in an osteoporotic bone.

**CR Number: 2018365288** **Implementation Date:** 08-Feb-19 Related CR: 2018365288

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Pelvic insufficiency fracture* | Rejected | | |
| From PT | *Stress fracture* | | | |
| To PT | *Pathological fracture* | | | |

MSSO Comment: The proposal to move the LLT Pelvic insufficiency fracture from PT Stress fracture to PT Pathological fracture is not approved. Pelvic insufficiency fractures are a type of stress fracture, which are the result of normal stresses on abnormal bone. Insufficiency fractures may occur in the absence of trauma or as a result of low-energy trauma, and occur due to a mismatch of the low osteoporotic bone strength and the presence of chronic mechanical stress. They are different than pathological fractures, which are the result of either focal pathology (such as tumors both malignant and benign) or the impact of an acute trauma in an osteoporotic bone.

**CR Number: 2018365289** **Implementation Date:** 08-Feb-19 Related CR: 2018365289

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Look alike packaging* | Approved as Requested | Proposed LLT | |
| To PT | *Product packaging confusion* | | *Look alike packaging* | 10082713 Current |
| | | | To PT | |
| | | | *Product packaging confusion* | 10074776 |

MSSO Comment: The proposal to add a new LLT Look alike packaging to PT Product packaging confusion is approved as requested. Look alike packaging, one that closely resembles another, may lead to packaging confusion and an important scenario for reporting to avoid potential errors.

# Supplemental Update Report

**CR Number: 2018365290** **Implementation Date:** 08-Feb-19 Related CR: 2018365290

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Product confusion* | Approved Not as Requested | Proposed PT | |
| To PT | *Product appearance confusion* | | *Product confusion* | 10082712 |
| | | | HLT primary | |
| | | | *Product confusion errors and issues* | 10079148 |
| | | | SOC primary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |

MSSO Comment: The proposal to add a new LLT Product confusion to PT Product appearance confusion is approved but not as requested. Product confusion is a broad meaning term to represent circumstances of confounding similarity between products, in which the element of confusion is not specified. Product confusion will be added as PT to HLT Product confusion errors and issues.

**CR Number: 2018365291** **Implementation Date:** 08-Feb-19 Related CR: 2018365291

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed PT | *Product commingling error* | Approved Not as Requested | Proposed LLT | | |
| | | | *Product commingling dispensing error* | 10082714 | Current |
| | | | To PT | | |
| | | | *Product dispensing error* | 10080359 | |

MSSO Comment: The proposal to add a new PT Product commingling error is approved but not as requested. Product commingling error is an accidental commingling of various prescription drugs at pharmacies. Product commingling error will be modified for clarification to Product commingling dispensing error and added a sub-concept LLT under PT Product dispensing error.

# Supplemental Update Report

**CR Number: 2018365292** **Implementation Date:** 28-Feb-19 Related CR: 2018365292

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Penile rash* | Approved Not as Requested After Suspension | Proposed LLT | |
| HLT primary | *Penile disorders NEC (excl erection and ejaculation)* | | *Penile rash* | 10082571 |
| SOC primary | *Reproductive system and breast disorders* | | From PT | |
| | | | *Genital rash* | 10018175 |
| | | | HLT primary | |
| | | | *Penile disorders NEC (excl erection and ejaculation)* | 10034304 |
| | | | SOC primary | |
| | | | *Reproductive system and breast disorders* | 10038604 |
| | | | HLT secondary | |
| | | | *Rashes, eruptions and exanthems NEC* | 10052566 |
| | | | SOC secondary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment: The proposal to add a new PT Penile rash to primary HLT Penile disorders NEC (excl erection and ejaculation) in SOC Reproductive system and breast disorders is approved but not as requested after suspension. After reconsideration the recently added LLT Penile rash to PT Genital rash will be promoted to PT and linked to primary HLT Penile disorders NEC (excl erection and ejaculation) and to secondary HLT Rashes, eruptions and exanthems NEC for consistency with other "penile" concepts. For similar reasons and in a related change, the recently added LLT Scrotal rash to PT Genital rash will also be promoted to a PT and linked primary HLT Scrotal disorders NEC and secondary HLT Rashes, eruptions and exanthems NEC.

# Supplemental Update Report

**CR Number: 2019059018** **Implementation Date:** 28-Feb-19 Related CR: 2018365292

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Scrotal rash* | Approved as Requested | Proposed LLT | |
| From PT | *Genital rash* | | *Scrotal rash* | 10082689 |
| HLT primary | *Scrotal disorders NEC* | | From PT | |
| | | | *Genital rash* | 10018175 |
| | | | HLT primary | |
| | | | *Scrotal disorders NEC* | 10039745 |
| | | | SOC primary | |
| | | | *Reproductive system and breast disorders* | 10038604 |
| | | | HLT secondary | |
| | | | *Rashes, eruptions and exanthems NEC* | 10052566 |
| | | | SOC secondary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment:

**CR Number: 2018365293** **Implementation Date:** 28-Feb-19 Related CR: 2018365293

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Rash acneiform* | Rejected After Suspension | | |
| From PT | *Dermatitis acneiform* | | | |

MSSO Comment: The proposal to promote the LLT Rash acneiform from PT Dermatitis acneiform is not approved after suspension. After reconsideration the MSSO still considers that the LLT Rash acneiform is best placed as quasi-synonym under PT Dermatitis acneiform which is defined as: Cutaneous eruptions resembling acne, characterized by the presence of papulonodules, pustules, comedones, or cysts in the face, trunk, and extremities. Causes include infections and the use of certain medications. Please note that there are many LLT "rash" terms which are not subordinate to PT rash terms, and linked to HLTs other than Rashes, eruptions and exanthems NEC; for example LLT Bullous rash under PT Dermatitis bullous is one out of many such examples.

# Supplemental Update Report

**CR Number: 2018365294** **Implementation Date:** 28-Feb-19 Related CR: 2018365294

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Testicular exfoliation* | Rejected After Suspension | | |

MSSO Comment: The proposal to add a new term Testicular exfoliation is not approved after suspension. Because the proposed term Testicular exfoliation appears to be incorrect wording as the testicles are inside the scrotal sac and exfoliation/peeling etc only can be seen on the scrotum, the concept can be represented by the existing LLT Scrotal exfoliation.

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**CR Number: 2018365295** **Implementation Date:** 28-Feb-19 Related CR: 2018365295

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Clamminess* | Rejected After Suspension | | |
| From PT | *Cold sweat* | | | |
| To PT | *Hyperhidrosis* | | | |

MSSO Comment: The proposal to move the LLT Clamminess from PT Cold sweat to PT Hyperhidrosis is not approved after suspension. It is the opinion of the MSSO that the rationale for the non-approval of this request previously submitted in CR 2018340015 remains valid. "Clammy refers to a surface covered with cold, sticky moisture, provoking a cold and damp sensation. The term is better represented in its current location, as a characteristic of the skin associated to normal sweating, rather than under the proposed hyperhidrosis, which is disorder term representing excessive sweating." Clamminess is not necessarily characterized by hyperhidrosis, and the current placement of LLT Clamminess is thus appropriate.

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**CR Number: 2018365296** **Implementation Date:** 28-Feb-19 Related CR: 2018365296

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Clammy* | Rejected After Suspension | | |
| From PT | *Cold sweat* | | | |
| To PT | *Hyperhidrosis* | | | |

MSSO Comment: The proposal to move the LLT Clammy from PT Cold sweat to PT Hyperhidrosis is not approved after suspension. It is the opinion of the MSSO that the rationale for the non-approval of this request previously submitted in CR 2018340015 remains valid. "Clammy refers to a surface covered with cold, sticky moisture, provoking a cold and damp sensation. The term is better represented in its current location, as a characteristic of the skin associated to normal sweating, rather than under the proposed hyperhidrosis, which is disorder term representing excessive sweating." Clamminess is not necessarily characterized by hyperhidrosis, and the current placement of LLT Clammy is thus appropriate.

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# Supplemental Update Report

**CR Number: 2018365297** **Implementation Date:** 28-Feb-19 Related CR: 2018365297

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Red spotty rash* | Approved After Suspension | Proposed LLT | |
| To PT | *Rash macular* | | *Red spotty rash* | 10082785 Current |
| | | | To PT | |
| | | | *Rash macular* | 10037867 |

MSSO Comment: The proposal to add a new LLT Red spotty rash to PT Rash macular is approved as requested after suspension. After reconsideration, the MSSO agrees to the colloquial descriptive term Red spotty rash to facilitate "user friendly" coding options for medical concepts.

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**CR Number: 2018365299** **Implementation Date:** 08-Feb-19 Related CR: 2018365299

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *JEJUNOJEJUNOSTOMY* | Approved Not as Requested | Proposed PT | |
| | | | *Jejunojejunostomy* | 10082699 |
| | | | HLT primary | |
| | | | *Gastrointestinal therapeutic procedures NEC* | 10018013 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment: The proposal to add a new LLT JEJUNOJEJUNOSTOMY is approved but not as requested. Jejunojejunostomy is a surgical technique used in an anastomosis between two portions of the jejunum. Jejunojejunostomy, in accordance with MedDRA capitalisation convention, will be added as PT to HLT Gastrointestinal therapeutic procedures NEC.

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**CR Number: 2018365300** **Implementation Date:** 28-Feb-19 Related CR: 2018365300

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Scurf* | Rejected After Suspension | | |
| From PT | *Dandruff* | | | |
| To PT | *Skin exfoliation* | | | |

MSSO Comment: The proposal to move the LLT Scurf from PT Dandruff to PT Skin exfoliation is not approved after suspension. In an unqualified clinical context scurf is usually used synonymously used with dandruff. Furthermore in Stedmen's medical dictionary defines Scurf as well as a synonym of dandruff. Please also note that LLT Scurf has been a sub-concept of PT Dandruff since version 5.0 and changing status to non-current may impact legacy data.

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# Supplemental Update Report

**CR Number: 2018365301** **Implementation Date:** 08-Feb-19 Related CR: 2018365301

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Ureterovaginal fistula* | Approved as Requested | Proposed LLT | |
| | | | *Ureterovaginal fistula* | 10082715 Current |
| | | | To PT | |
| | | | *Urogenital fistula* | 10046696 |

MSSO Comment: The proposal to add a new term Ureterovaginal fistula is approved as requested. Ureterovaginal fistula, a fistula from the ureter to the vagina, will be added as sub-concept LLT to PT Urogenital fistula.

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**CR Number: 2018365311** **Implementation Date:** 19-Feb-19 Related CR: 2018365311

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Forgot to take product* | Approved After Suspension | Proposed LLT | |
| To PT | *Product dose omission* | | *Forgot to take product* | 10082741 Current |
| | | | To PT | |
| | | | *Product dose omission* | 10081580 |

MSSO Comment: The proposal to add a new LLT Forgot to take product to PT Product dose omission is approved as requested after suspension. This term could help identify many reported cases of a patient forgetting to take the medication and missing a dose.

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**CR Number: 2018365312** **Implementation Date:** 11-Feb-19 Related CR: 2018365312

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Herpetic radiculopathy* | Approved as Requested | Proposed PT | |
| | | | *Herpetic radiculopathy* | 10082717 |
| | | | HLT primary | |
| | | | *Herpes viral infections* | 10019972 |
| | | | SOC primary | |
| | | | *Infections and infestations* | 10021881 |
| | | | HLT secondary | |
| | | | *Spinal cord and nerve root disorders NEC* | 10041544 |
| | | | SOC secondary | |
| | | | *Nervous system disorders* | 10029205 |

MSSO Comment: The proposal to add a new term Herpetic radiculopathy is approved as requested. Radiculopathy caused by Herpes simplex type 2 infection typically affects the lumbar or sacral nerve roots and is often recurrent. In addition to radicular pain, paresthesias, urinary retention, constipation, anogenital discomfort, and leg weakness may be observed. Herpetic radiculopathy will be added as a PT to primary HLT Herpes viral infections, and to secondary HLT Spinal cord and nerve root disorders NEC.

# Supplemental Update Report

**CR Number: 2018365313** **Implementation Date:** 11-Feb-19 Related CR: 2018365313

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Smegma increased* | Approved Not as Requested | Proposed PT | |
| | | | *Smegma accumulation* | 10082718 |
| | | | HLT primary | |
| | | | *Reproductive tract signs and symptoms NEC* | 10040674 |
| | | | SOC primary | |
| | | | *Reproductive system and breast disorders* | 10038604 |

MSSO Comment: The proposal to add a new term Smegma increased is approved but not as requested. Smegma is a combination of shed skin cells, skin oils, and moisture. It occurs in both male and female mammalian genitalia. In females, it collects around the clitoris and in the folds of the labia minora; in males, smegma collects under the foreskin. Inadequate hygiene of genitalia can result in an accumlation of smegma. Smegma increased will be modified to Smegma accumulation and added as PT to HLT Reproductive tract signs and symptoms NEC.

**CR Number: 2018365314** **Implementation Date:** 11-Feb-19 Related CR: 2018365314

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Menolipsis* | Approved as Requested | Proposed LLT | |
| | | | *Menolipsis* | 10082720 Current |
| | | | To PT | |
| | | | *Amenorrhoea* | 10001928 |

MSSO Comment: The proposal to add a new term Menolipsis is approved as requested. Menolipsis, a temporary cessation of menses, will be added as a sub-concept LLT to PT Amenorrhoea.

**CR Number: 2018365315** **Implementation Date:** 11-Feb-19 Related CR: 2018365315

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Benign paroxysmal nystagmus* | Approved as Requested | Proposed LLT | |
| To PT | *Vertigo positional* | | *Benign paroxysmal nystagmus* | 10082719 Current |
| | | | To PT | |
| | | | *Vertigo positional* | 10047348 |

MSSO Comment: The proposal to add a new LLT Benign paroxysmal nystagmus to PT Vertigo positional is approved as requested. Benign paroxysmal nystagmus, a synonym of Benign Paroxysmal Positional Vertigo (BPPV), is a common cause of vertigo. The condition is thought to be caused by displacement of otoconial crystals (calcium carbonate crystals normally embedded in the saccule and utricle). This displaced material stimulates hair cells most commonly in the posterior semicircular canal (and rarely in the superior semicircular canal), creating the illusion of motion. A variety of etiological factors have been proposed. Benign paroxysmal nystagmus will be added as a synonym LLT to PT Vertigo positional.

# Supplemental Update Report

**CR Number: 2018365316** **Implementation Date:** 11-Feb-19 Related CR: 2018365316

| Change Requested | Add a New PT |
|---|---|
| Proposed PT | *Congenital bilateral perisylvian syndrome* |
| HLT primary | *Cerebral disorders congenital* |
| SOC primary | *Congenital, familial and genetic disorders* |

| Final Disposition |
|---|
| Approved as Requested |

| Final Placement | MedDRA Code # |
|---|---|
| Proposed PT | |
| *Congenital bilateral perisylvian syndrome* | 10082716 |
| HLT primary | |
| *Cerebral disorders congenital* | 10052634 |
| SOC primary | |
| *Congenital, familial and genetic disorders* | 10010331 |
| HLT secondary | |
| *Congenital and peripartum cerebral disorders* | 10010334 |
| SOC secondary | |
| *Nervous system disorders* | 10029205 |

MSSO Comment: The proposal to add a new PT Congenital bilateral perisylvian syndrome to primary HLT Cerebral disorders congenital in SOC Congenital, familial and genetic disorders and secondary HLT Congenital and peripartum cerebral disorders in SOC Nervous system disorders is approved as requested. Congenital bilateral perisylvian syndrome is an extremely rare neurological disorder that may be apparent at birth, infancy, or later during childhood. It is characterized by partial paralysis of muscles on both sides of the face, tongue, jaws, and throat (pseudobulbar palsy); dysarthria, mastication dysphagia; and/or epilepsy. In most cases, mild to severe intellectual disability may also present. Symptoms and findings are thought to be due to improper development (neuronal dysmigration) of the outer surface of the cerebral cortex during embryonic growth In most cases, the disorder appears to occur sporadically for unknown reasons.

# Supplemental Update Report

**CR Number: 2018365317** **Implementation Date:** 11-Feb-19 Related CR: 2018365317

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Gastrointestinal mucormycosis* | Approved Not as Requested | Proposed PT | |
| To PT | *Mucormycosis* | | *Gastrointestinal mucormycosis* | 10082721 |
| | | | HLT primary | |
| | | | *Fungal infections NEC* | 10017536 |
| | | | SOC primary | |
| | | | *Infections and infestations* | 10021881 |
| | | | HLT secondary | |
| | | | *Gastrointestinal infections, site unspecified* | 10017968 |
| | | | SOC secondary | |
| | | | *Gastrointestinal disorders* | 10017947 |

MSSO Comment: The proposal to add a new LLT Gastrointestinal mucormycosis to PT Mucormycosis is approved but not as requested. In the past, gastrointestinal mucormycosis occurred primarily in premature neonates in association with disseminated disease and necrotizing enterocolitis. However, there has been a marked increase in case reports describing adults with neutropenia, glucocorticoid use, or other immunocompromising conditions. Gastrointestinal mucormycosis therefore will be added as a PT to primary HLT Fungal infections NEC and secondary HLT Gastrointestinal infections, site unspecified. In related changes, the following LLTs will be promoted from under PT Mucormycosis, to represent clinically relevant affected organs at the PT level: LLT Pulmonary mucormycosis, to primary HLT Fungal infections NEC, and secondary HLT Respiratory tract infections NEC; LLT Rhinocerebral mucormycosis to primary HLT Fungal infections NEC and secondary HLT Nervous system infections NEC. Furthermore, LLT Rhino-orbital-cerebral mucormycosis will be moved from PT Mucormycosis to newly promoted PT Rhinocerebral mucormycosis.

# Supplemental Update Report

**CR Number: 2018365343** **Implementation Date:** 11-Feb-19 Related CR: 2018365317

| Change Requested | Promote an LLT |
|---|---|
| Proposed LLT | *Pulmonary mucormycosis* |
| From PT | *Mucormycosis* |
| HLT primary | *Fungal infections NEC* |

Final Disposition: Approved as Requested

| Final Placement | MedDRA Code # |
|---|---|
| Proposed LLT | |
| *Pulmonary mucormycosis* | 10078354 |
| From PT | |
| *Mucormycosis* | 10028098 |
| HLT primary | |
| *Fungal infections NEC* | 10017536 |
| SOC primary | |
| *Infections and infestations* | 10021881 |
| HLT secondary | |
| *Respiratory tract infections NEC* | 10057190 |
| SOC secondary | |
| *Respiratory, thoracic and mediastinal disorders* | 10038738 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2018365344** **Implementation Date:** 11-Feb-19 Related CR: 2018365317

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Rhinocerebral mucormycosis* | Approved as Requested | Proposed LLT | |
| From PT | *Mucormycosis* | | *Rhinocerebral mucormycosis* | 10076959 |
| HLT primary | *Fungal infections NEC* | | From PT | |
| | | | *Mucormycosis* | 10028098 |
| | | | HLT primary | |
| | | | *Fungal infections NEC* | 10017536 |
| | | | SOC primary | |
| | | | *Infections and infestations* | 10021881 |
| | | | HLT secondary | |
| | | | *Nervous system infections NEC* | 10021888 |
| | | | SOC secondary | |
| | | | *Nervous system disorders* | 10029205 |

MSSO Comment:

**CR Number: 2018365345** **Implementation Date:** 11-Feb-19 Related CR: 2018365317

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Rhino-orbital-cerebral mucormycosis* | Approved as Requested | Proposed LLT | |
| From PT | *Mucormycosis* | | *Rhino-orbital-cerebral mucormycosis* | 10076960 Current |
| To PT | *Rhinocerebral mucormycosis* | | From PT | |
| | | | *Mucormycosis* | 10028098 |
| | | | To PT | |
| | | | *Rhinocerebral mucormycosis* | 10076959 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2018365318** **Implementation Date:** 11-Feb-19 Related CR: 2018365318

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Cutaneous mucormycosis* | Approved Not as Requested | Proposed PT | |
| To PT | *Mucormycosis* | | *Cutaneous mucormycosis* | 10082722 |
| | | | HLT primary | |
| | | | *Fungal infections NEC* | 10017536 |
| | | | SOC primary | |
| | | | *Infections and infestations* | 10021881 |
| | | | HLT secondary | |
| | | | *Skin and subcutaneous tissue fungal infections* | 10040791 |
| | | | SOC secondary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment: The proposal to add a new LLT Cutaneous mucormycosis to PT Mucormycosis is approved but not as requested. Cutaneous mucormycosis is an emerging fungal infection caused by opportunistic fungi of the phylum Glomeromycota. It is frequent in poorly controlled diabetic patients and individuals with immunosuppression. It is usually acquired by direct inoculation through trauma. Cutaneous mucormycosis will be added as a PT to primary HLT Fungal infections NEC and secondary HLT Skin and subcutaneous tissue fungal infections.

**CR Number: 2018365319** **Implementation Date:** 11-Feb-19 Related CR: 2018365319

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Gangrenous necrotizing cutaneous mucormycosis* | Approved Not as Requested | Proposed LLT | |
| | | | *Gangrenous necrotizing cutaneous mucormycosis* | 10082724 Current |
| | | | To PT | |
| | | | *Cutaneous mucormycosis* | 10082722 |

MSSO Comment: The proposal to add a new PT Gangrenous necrotizing cutaneous mucormycosis is approved but not as requested. Gangrenous necrotizing cutaneous mucormycosis is a severe complication of cutaneous mucormycosis, particulary seen in secondary cutaneous mucormycosis in immunocompromised patients and will be added as sub-concept LLT to the new PT Cutaneous mucormycosis. In a related change, the British English spelled counterpart Gangrenous necrotising cutaneous mucormycosis will be added as sub-concept LLT to PT Cutaneous mucormycosis, added in change request 2018365318.

# Supplemental Update Report

**CR Number: 2019039001** **Implementation Date:** 11-Feb-19 Related CR: 2018365319

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Gangrenous necrotising cutaneous mucormycosis* | Approved as Requested | Proposed LLT | |
| To PT | *Cutaneous mucormycosis* | | *Gangrenous necrotising cutaneous mucormycosis* | 10082723 Current |
| | | | To PT | |
| | | | *Cutaneous mucormycosis* | 10082722 |

MSSO Comment:

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**CR Number: 2018365320** **Implementation Date:** 11-Feb-19 Related CR: 2018365320

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Dissecting carotid artery aneurysm* | Approved Not as Requested | Proposed LLT | |
| HLT primary | *Aneurysms and dissections site specific NEC* | | *Dissecting carotid artery aneurysm* | 10082727 Current |
| SOC primary | *Vascular disorders* | | To PT | |
| | | | *Carotid artery dissection* | 10050403 |

MSSO Comment: The proposal to add a new PT Dissecting carotid artery aneurysm to primary HLT Aneurysms and dissections site specific NEC in SOC Vascular disorders is approved but not as requested. A dissecting aneurysm is a situation in which the inner wall of an artery has expanded and begun to rip. This allows blood to spill into the middle layer, or section, of the aorta. As a result, the middle and inner layers begin to separate or dissect, effectively widening the gap and impairing the function of the artery. As a result, Dissecting carotid artery aneurysm will be added as sub-concept LLT to PT Carotid artery dissection. In a related change, for consistency approach PT Dissecting coronary artery aneurysm will be demoted under PT Coronary artery dissection.

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**CR Number: 2019042001** **Implementation Date:** 11-Feb-19 Related CR: 2018365320

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Dissecting coronary artery aneurysm* | Approved as Requested | PT to merge | |
| To PT | *Coronary artery dissection* | | *Dissecting coronary artery aneurysm* | 10013428 Current |
| | | | To PT | |
| | | | *Coronary artery dissection* | 10048631 |

MSSO Comment:

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# Supplemental Update Report

**CR Number: 2018365321** **Implementation Date:** 11-Feb-19 Related CR: 2018365321

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *FIBROPAPILLOMAS* | Approved Not as Requested | Proposed LLT<br>*Fibropapilloma* | 10082728 Current |
| | | | To PT<br>*Acrochordon* | 10000591 |

MSSO Comment: The proposal to add a new term FIBROPAPILLOMAS is approved but not as requested. A fibropapilloma, or fibroepithelial papilloma, is a type of papilloma containing extensive fibrous tissue. LLT Fibropapilloma will be added as a sub-concept under PT Acrochordon. Per MedDRA naming conventions, this term will be added in singular form with only the first letter being upper case.

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**CR Number: 2018365322** **Implementation Date:** 19-Feb-19 Related CR: 2018365322

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Pseudoventricular tachycardia* | Rejected After Suspension | | |
| To PT | *Atrial fibrillation* | | | |

MSSO Comment: The proposal to add a new LLT Pseudoventricular tachycardia to PT Atrial fibrillation is not approved after suspension. The term is ambiguous and as described in the literature could represent either an ECG artifact or an actual arrhythmia that mimics ventricular tachycardia.

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**CR Number: 2018365323** **Implementation Date:** 11-Feb-19 Related CR: 2018365323

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Intentional product storage issue* | Rejected | | |
| To PT | *Intentional product use issue* | | | |

MSSO Comment: The proposal to add a new LLT Intentional product storage issue to PT Intentional product use issue is not approved. This is a multiple concept term which can be coded using more than one MedDRA term, for example, PT Intentional product use issue and LLT Incorrect product storage. Please refer to Section 3.5 of the MedDRA Term Selection: Points to Consider Document regarding the coding of combination terms.

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# Supplemental Update Report

**CR Number: 2018365324** **Implementation Date:** 11-Feb-19 Related CR: 2018365324

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Occupational exposure to product via skin contact* | Approved Not as Requested | Proposed LLT | |
| To PT | *Occupational exposure to product* | | *Occupational exposure via skin contact with product* | 10082732 Current |
| | | | To PT | |
| | | | *Occupational exposure to product* | 10073311 |

MSSO Comment: The proposal to add a new LLT Occupational exposure to product via skin contact to PT Occupational exposure to product is approved but not as requested. Occupational exposure to products may include skin contact in addition to the existing LLT concepts ingestion and inhalation. Occupational exposure via skin contact with product will be added as an LLT, formatted for consistency with existing occupational exposure LLTs and linked to PT Occupational exposure to product.

**CR Number: 2018365325** **Implementation Date:** 11-Feb-19 Related CR: 2018365325

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Astheno-depressive syndrome* | Approved Not as Requested | Proposed LLT | |
| To PT | *Mental disorder due to a general medical condition* | | *Astheno-depressive syndrome* | 10082733 Current |
| | | | To PT | |
| | | | *Depressed mood* | 10012374 |

MSSO Comment: The proposal to add a new LLT Astheno-depressive syndrome to PT Mental disorder due to a general medical condition is approved but not as requested. Astheno-depressive syndrome does not appear to be a well-defined, universally recognized concept in the scientific medical literature. However, to provide a specific coding option, Astheno-depressive syndrome will be added as an LLT to PT Depressed mood.

**CR Number: 2018365326** **Implementation Date:** 11-Feb-19 Related CR: 2018365326

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Diverticulitis resection* | Rejected | | |

MSSO Comment: The proposal to add a new LLT Diverticulitis resection is not approved. MedDRA cannot accommodate a unique term that combines every possible procedure with a respective indication. The requested term can be represented by split coding with LLT Diverticulitis and PT/LLT Diverticulectomy.

# Supplemental Update Report

**CR Number: 2018365327** **Implementation Date:** 11-Feb-19 Related CR: 2018365327

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Marisk surgery* | Approved Not as Requested | Proposed LLT | |
| | | | *Marisc surgery* | 10082734 Current |
| | | | To PT | |
| | | | *Anal skin tag excision* | 10002171 |

MSSO Comment: The proposal to add a new LLT Marisk surgery is approved but not as requested. The requested term will be modified to Marisc surgery and added as synonym LLT to PT Anal skin tag excision.

**CR Number: 2018365328** **Implementation Date:** 11-Feb-19 Related CR: 2018365328

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Lymph node rupture* | Approved as Requested | Proposed PT | |
| | | | *Lymph node rupture* | 10082725 |
| | | | HLT primary | |
| | | | *Lymphatic system disorders NEC* | 10025198 |
| | | | SOC primary | |
| | | | *Blood and lymphatic system disorders* | 10005329 |

MSSO Comment: The proposal to add a new term Lymph node rupture is approved as requested. If lymph nodes are swollen of an infection nearby they cannot burst. In case there's however an infection of the lymph nodes themselves (lymphadenitis) which can - if not treated right (usually with i.v. antibiotics) - lead to abscesses of the lymphnodes and surrounding structures. In these cases they could "burst". Lymph node rupture will be added as PT to HLT Lymphatic system disorders NEC.

**CR Number: 2018365329** **Implementation Date:** 11-Feb-19 Related CR: 2018365329

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Temple swelling* | Approved as Requested | Proposed LLT | |
| | | | *Temple swelling* | 10082726 Current |
| | | | To PT | |
| | | | *Swelling face* | 10042682 |

MSSO Comment: The proposal to add a new term Temple swelling is approved as requested. Temple indicates the side of the head behind the eyes. Swelling of the temple is a common condition and there may be different causes depending on the age and condition of a person. Temple swelling will be added as sub-concept LLT to PT Swelling face.

# Supplemental Update Report

**CR Number: 2018365330** **Implementation Date:** 11-Feb-19 Related CR: 2018365330

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Hypersensitive skin* | Approved as Requested | Proposed LLT | |
| | | | *Hypersensitive skin* | 10082735 Current |
| | | | To PT | |
| | | | *Sensitive skin* | 10081765 |

MSSO Comment: The proposal to add a new LLT Hypersensitive skin is approved as requested. The proposed term, is a general expression used in the context of skin that is hyper-reactive to different factors of varying harshness that are well-tolerated by normal skin. To provide this verbatim term coding option, Hypersensitive skin will be added as a sub-concept LLT to PT Sensitive skin.

**CR Number: 2018365331** **Implementation Date:** 11-Feb-19 Related CR: 2018365331

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Transverse Abdominis Plane Block (TAP Block)* | Approved Not as Requested | Proposed PT | |
| | | | *Transversus abdominis plane block* | 10082730 |
| | | | HLT primary | |
| | | | *Anaesthesia and allied procedures* | 10002092 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment: The proposal to add a new LLT Transverse Abdominis Plane Block (TAP Block) is approved but not as requested. The transversus abdominis plane (TAP) block is a peripheral nerve block designed to anesthetize the nerves supplying the anterior abdominal wall. The TAP block is a simple procedure that can be used as an adjunct for postoperative pain control in abdominal, gynecologic, or urologic surgery involving the T6 to L1 distribution. The requested term will be modified to Transversus abdominis plane block so that the full muscle name is consistently represented in Latin, and added as a PT Transversus abdominis plane block to HLT Anaesthesia and allied procedures. In a related change, the frequently used acroynm, TAP block will be added, as an LLT to PT Transversus abdominis plane block.

**CR Number: 2019042002** **Implementation Date:** 11-Feb-19 Related CR: 2018365331

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *TAP block* | Approved as Requested | Proposed LLT | |
| To PT | *Transversus abdominis plane block* | | *TAP block* | 10082731 Current |
| | | | To PT | |
| | | | *Transversus abdominis plane block* | 10082730 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2018365332** **Implementation Date:** 11-Feb-19 Related CR: 2018365332

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Soft tissue excision* | Approved as Requested | Proposed PT | |
| | | | *Soft tissue excision* | 10082729 |
| | | | HLT primary | |
| | | | *Soft tissue therapeutic procedures NEC* | 10052876 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment: The proposal to add a new term Soft tissue excision is approved as requested. Soft tissue refers to tissues that connect, support, or surround other structures and organs of the body, and includes muscles, tendons, ligaments, fascia, nerves, fibrous tissues, fat, blood vessels, and synovial membranes. The concept representing an excision of an unspecified soft tissue will be added as PT Soft tissue excision to HLT Soft tissue therapeutic procedures NEC.

**CR Number: 2018365333** **Implementation Date:** 28-Feb-19 Related CR: 2018365333

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Scalp discomfort* | Rejected After Suspension | | |
| To PT | *Skin discomfort* | | | |

MSSO Comment: The proposal to add a new LLT Scalp discomfort to PT Skin discomfort is not approved after suspension. "Scalp discomfort" appears to be a seldom used expression in clinical reports and in medical literature. In addition, PT Skin discomfort, a PT level term in MedDRA since version 4.0, has represented a concept that is not anatomically specific, as LLT Skin discomfort, the PT term counterpart, is the only subordinate LLT. Generally, a separate term for every anatomical location of a concept or disorder is not represented in MedDRA, unless it is of potential relevance to pharmacovigilance. Please consider a variety of existing MedDRA terms that represent symptoms pertaining to the scalp, including, but not limited to: LLT Scalp tenderness, LLT Scalp swelling, LLT Scalp pain, LLT Scalp irritation, LLT Scalp disorder, LLT Itchy scalp, LLT Dry scalp, LLT Burning sensation scalp, and LLT Paresthesia of scalp.

**CR Number: 2018365335** **Implementation Date:** 12-Feb-19 Related CR: 2018365335

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Lymph node rupture* | Rejected | | |

MSSO Comment: The proposal to add a new term Lymph node rupture is not approved. This is a technical rejection, because, the proposed term "Lymph node rupture" was also requested in change request 2018365328, and accepted for addition as PT to HLT Lymphatic system disorders NEC. PT Lymph node rupture will be added for MedDRA in version 22.1.

# Supplemental Update Report

**CR Number: 2018365336** **Implementation Date:** 12-Feb-19 Related CR: 2018365336

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Incision site paraesthesia* | Approved as Requested | Proposed PT | |
| HLT primary | *Non-site specific procedural complications* | | *Incision site paraesthesia* | 10082736 |
| SOC primary | *Injury, poisoning and procedural complications* | | HLT primary | |
| | | | *Non-site specific procedural complications* | 10029559 |
| | | | SOC primary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |
| | | | HLT secondary | |
| | | | *Paraesthesias and dysaesthesias* | 10033788 |
| | | | SOC secondary | |
| | | | *Nervous system disorders* | 10029205 |

MSSO Comment: The proposal to add a new PT Incision site paraesthesia to primary HLT Non-site specific procedural complications in SOC Injury, poisoning and procedural complications and secondary HLT Paraesthesias and dysaesthesias in SOC Nervous system disorders is approved as requested. The creation of an incision can result in numbness or paraesthesia due to temporary damage to sensory nerves. Incision site paraesthesia is not uncommon in surgery involving skin or mucus membrane incisions. Incision site paraesthesia will be added as a new PT to primary HLT Non-site specific procedural complications; to secondary HLT Paraesthesias and dysaesthesias. In a related change, the American English counterpart spelling, LLT Incision site paresthesia will be added to new PT Incision site paraesthesia.

**CR Number: 2019043002** **Implementation Date:** 12-Feb-19 Related CR: 2018365336

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Incision site paresthesia* | Approved as Requested | Proposed LLT | |
| To PT | *Incision site paraesthesia* | | *Incision site paresthesia* | 10082737 Current |
| | | | To PT | |
| | | | *Incision site paraesthesia* | 10082736 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019043001** **Implementation Date:** 20-Feb-19 Related CR: 2019043001

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Immediate hypersensitivity reaction* | Rejected | | |
| From PT | *Type I hypersensitivity* | | | |
| HLT primary | *Allergic conditions NEC* | | | |

MSSO Comment: The proposal to promote the LLT Immediate hypersensitivity reaction from PT Type I hypersensitivity to primary HLT Allergic conditions NEC in SOC Immune system disorders is not approved. Immediate hypersensitivity reaction generally represents Type I hypersensitivity and therefore promotion of LLT Immediate hypersensitivity reaction is not appropriate as the two terms are synonymously used. However to represent hypersensitivity reactions which are not involving immunoglobulin E (IgE)–mediated release of histamine and other mediators from mast cells and basophils, but represent other systemic inflammatory response mechanisms such as seen in cytokine release syndrome, the MSSO will do the following; adding a new PT Infusion related hypersensitivity reaction with supporting a new LLT Infusion related immediate hypersensitivity reaction to reflect the change request desired outcome. As a result, in a related change, Infusion related hypersensitivity reaction will be added as a PT to primary HLT Allergic conditions NEC and secondary HLT Non-site specific procedural complications. Also, LLT Infusion related immediate hypersensitivity reaction and LLT Infusion related delayed hypersensitivity reaction will be added as sub-concept LLTs to the new PT Infusion related hypersensitivity reaction.

**CR Number: 2019050001** **Implementation Date:** 20-Feb-19 Related CR: 2019043001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Infusion related immediate hypersensitivity reaction* | Approved as Requested | Proposed LLT | | |
| | | | *Infusion related immediate hypersensitivity reaction* | 10082743 | Current |
| To PT | *Infusion related hypersensitivity reaction* | | To PT | | |
| | | | *Infusion related hypersensitivity reaction* | 10082742 | |

MSSO Comment:

**CR Number: 2019050002** **Implementation Date:** 20-Feb-19 Related CR: 2019043001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Infusion related delayed hypersensitivity reaction* | Approved as Requested | Proposed LLT | | |
| To PT | *Infusion related hypersensitivity reaction* | | *Infusion related delayed hypersensitivity reaction* | 10082744 | Current |
| | | | To PT | | |
| | | | *Infusion related hypersensitivity reaction* | 10082742 | |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019051050** **Implementation Date:** 20-Feb-19 Related CR: 2019043001

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Infusion related hypersensitivity reaction* | Approved as Requested | Proposed PT | |
| HLT primary | *Allergic conditions NEC* | | *Infusion related hypersensitivity reaction* | 10082742 |
| SOC primary | *Immune system disorders* | | HLT primary | |
| | | | *Allergic conditions NEC* | 10027654 |
| | | | SOC primary | |
| | | | *Immune system disorders* | 10021428 |
| | | | HLT secondary | |
| | | | *Non-site specific procedural complications* | 10029559 |
| | | | SOC secondary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |

MSSO Comment:

**CR Number: 2019044001** **Implementation Date:** 19-Feb-19 Related CR: 2019044001

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Reflex test* | Approved as Requested | Proposed PT | |
| HLT primary | *Neurologic diagnostic procedures* | | *Reflex test* | 10082738 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Neurologic diagnostic procedures* | 10029285 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Reflex test to primary HLT Neurologic diagnostic procedures in SOC Investigations is approved as requested. Reflex testing incorporates an assessment of the function and interplay of both sensory and motor pathways. The addition of the unqualified PT Reflex test will provide a coding option to represent a report of one or more unspecified reflex tests performed.

# Supplemental Update Report

**CR Number: 2019046001** **Implementation Date:** 19-Feb-19 Related CR: 2019046001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Asymptomatic hypertension* | Approved Not as Requested | Proposed LLT | |
| To PT | *Hypertension* | | *Severe asymptomatic hypertension* | 10082740 Current |
| | | | To PT | |
| | | | *Hypertensive urgency* | 10058181 |

MSSO Comment: The proposal to add a new LLT Asymptomatic hypertension to PT Hypertension is approved but not as requested. Asympotomatic and symptomatic only is used in context of severe hypertensions such as in emergency/urgency. The entity of severe asymptomatic hypertension is sometimes called hypertensive urgency - relatively asymptomatic (mild headache) or completely asymptomatic. The requested term will be modified and added as LLT Severe asymptomatic hypertension to PT Hypertensive urgency.

**CR Number: 2019046002** **Implementation Date:** 19-Feb-19 Related CR: 2019046002

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Vascular access steal syndrome* | Approved as Requested | Proposed PT | |
| | | | *Vascular access steal syndrome* | 10082739 |
| | | | HLT primary | |
| | | | *Cardiac and vascular procedural complications* | 10007602 |
| | | | SOC primary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |
| | | | HLT secondary | |
| | | | *Non-site specific necrosis and vascular insufficiency NEC* | 10029558 |
| | | | SOC secondary | |
| | | | *Vascular disorders* | 10047065 |

MSSO Comment: The proposal to add a new term Vascular access steal syndrome is approved as requested. When an arteriovenous fistula is created using healthy vessels, dilatation of the proximal and distal arteries, as well as dilatation of the collaterals around the anastomosis, compensate for enhanced systolic arteriovenous flow and also for diastolic retrograde inflow into the fistula. Any vascular pathology affecting one or several of these adaptive mechanisms can cause distal ischaemia by a steal mechanism, and may carry severe morbidity including tissue or limb loss if not recognized. Three recognized etiologies include (1) blood flow restriction to the hand from arterial occlusive disease, (2) excess blood flow through the arteriovenous fistula conduit (true steal), and (3) lack of vascular (arterial) adaptation or collateral flow reserve (i.e., atherosclerosis) to the increased flow demand from the arteriovenous conduit. Vascular access steal syndrome will be added as a new PT to primary HLT Cardiac and vascular procedural complications, to secondary HLT Non-site specific necrosis and vascular insufficiency NEC, and to secondary HLT Complications associated with device NEC. In a related change, PT Subclavian steal syndrome will be moved from HLT Site specific vascular disorders NEC to HLT Site specific necrosis and vascular insufficiency NEC for consistent alignment with similar concepts.

# Supplemental Update Report

**CR Number: 2019050003** **Implementation Date:** 19-Feb-19 Related CR: 2019046002

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vascular access steal syndrome* | Approved as Requested | Proposed PT | |
| To HLT | *Complications associated with device NEC* | | *Vascular access steal syndrome* | 10082739 |
| | | | To HLT | |
| | | | *Complications associated with device NEC* | 10069785 |

MSSO Comment:

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**CR Number: 2019050004** **Implementation Date:** 19-Feb-19 Related CR: 2019046002

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Subclavian steal syndrome* | Approved as Requested | Proposed PT | |
| From HLT | *Site specific vascular disorders NEC* | | *Subclavian steal syndrome* | 10042335 |
| To HLT | *Site specific necrosis and vascular insufficiency NEC* | | From HLT | |
| | | | *Site specific vascular disorders NEC* | 10057188 |
| | | | To HLT | |
| | | | *Site specific necrosis and vascular insufficiency NEC* | 10052781 |

MSSO Comment:

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**CR Number: 2019048001** **Implementation Date:** 27-Mar-19 Related CR: 2019048001

| Change Requested | Change term status in a SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Early onset primary dystonia* | Approved as Requested | Proposed PT | |
| To SMQ | *Dystonia (SMQ)* | | *Early onset primary dystonia* | 10076668 |
| Status | *I* | | To SMQ | |
| | | | *Dystonia (SMQ)* | 20000098 |
| | | | Status | |
| | | | *I* | |

MSSO Comment: The proposal to change status of the term Early onset primary dystonia in Dystonia (SMQ) to Inactive is approved as requested. The PT Early onset primary dystonia was mistakenly added to this SMQ and should not have been since the Original Documentation for this SMQ states that disorders with a genetic basis should not be included. Making this PT inactive will allow the SMQ to identify the cases for which it was intended - potential cases of drug-related extrapyramidal disorders.

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# Supplemental Update Report

**CR Number: 2019048002** **Implementation Date:** 27-Mar-19 Related CR: 2019048002

| Change Requested | Change term status in a SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Dopa-responsive dystonia* | Approved as Requested | Proposed PT | |
| To SMQ | *Dystonia (SMQ)* | | *Dopa-responsive dystonia* | 10080034 |
| Status | *I* | | To SMQ | |
| | | | *Dystonia (SMQ)* | 20000098 |
| | | | Status | |
| | | | *I* | |

MSSO Comment: The proposal to change status of the term Dopa-responsive dystonia in Dystonia (SMQ) to Inactive is approved as requested. The PT Dopa-responsive dystonia was mistakenly added to this SMQ and should not have been since the original documentation for this SMQ states that disorders with a genetic basis should not be included. Making this PT inactive will allow the SMQ to identify the cases for which it was intended - potentially cases of drug-related extrapyramidal disorders.

**CR Number: 2019050005** **Implementation Date:** 27-Mar-19 Related CR: 2019050005

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Corneal toxicity* | Approved as Requested | Proposed PT | |
| To SMQ | *Corneal disorders (SMQ)* | | *Corneal toxicity* | 10082599 |
| Term scope | *Narrow* | | To SMQ | |
| | | | *Corneal disorders (SMQ)* | 20000156 |
| | | | Term scope | |
| | | | *Narrow* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Corneal toxicity to Corneal disorders (SMQ) as a narrow term is approved as requested. PT Corneal toxicity, added in version 22.1, is a concept that relates to potential or actual corneal tissue damage or injury associated with topical ocular medications, the use of contact lens solutions, exposure to occupational/industrial chemicals, etc. PT Corneal toxicity will be added as a narrow scope term to Corneal disorders (SMQ), fulfilling the inclusion criterion, "All terms involving the cornea."

# Supplemental Update Report

**CR Number: 2019050006** **Implementation Date:** 27-Mar-19 Related CR: 2019050006

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *New onset diabetes after transplantation* | Approved as Requested | Proposed PT | |
| To SMQ | *Hyperglycaemia/new onset diabetes mellitus (SMQ)* | | *New onset diabetes after transplantation* | 10082630 |
| Term scope | *Narrow* | | To SMQ | |
| | | | *Hyperglycaemia/new onset diabetes mellitus (SMQ)* | 20000041 |
| | | | Term scope | |
| | | | *Narrow* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT New onset diabetes after transplantation to Hyperglycaemia/new onset diabetes mellitus (SMQ) as a narrow term is approved as requested. PT New onset diabetes after transplantation, added in version 22.1, represents a recognized complication following organ transplantation, especially after solid organ transplantation, bone marrow and hematopoietic stem cells. It is not known why some patients develop early-onset (within 1-year after transplantation), late-onset (1-year after transplantation), or transient diabetes mellitus following transplantation. PT New onset diabetes after transplantation will be added as a narrow scope term to Hyperglycaemia/new onset diabetes mellitus (SMQ), as it fulfills the following inclusion criterion: "Narrow search terms were those considered to be very specifically related to a new diagnosis of, or manifestations, signs, or symptoms of new onset diabetes mellitus."

**CR Number: 2019050007** **Implementation Date:** 27-Mar-19 Related CR: 2019050007

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vitritis infective* | Approved as Requested | Proposed PT | |
| To SMQ | *Ocular infections (SMQ)* | | *Vitritis infective* | 10082583 |
| Term scope | *Narrow* | | To SMQ | |
| | | | *Ocular infections (SMQ)* | 20000183 |
| | | | Term scope | |
| | | | *Narrow* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Vitritis infective to Ocular infections (SMQ) as a narrow term is approved as requested. PT Vitritis infective, added in version 22.1, represents an inflammatory condition of the vitreous caused by viral, bacterial, fungal, helminthic, or parasitic organisms, and is one of the most common and visually devastating causes of uveitis. PT Vitritis infective will be added as a narrow scope term to Ocular infections (SMQ), as it fulfills the inclusion criterion, "All terms directly related to or describing an eye infection."

# Supplemental Update Report

**CR Number: 2019050008** **Implementation Date:** 27-Mar-19 Related CR: 2019050008

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Optic disc traction syndrome* | Approved as Requested | Proposed PT<br>*Optic disc traction syndrome* | 10082596 |
| To SMQ | *Optic nerve disorders (SMQ)* | | To SMQ<br>*Optic nerve disorders (SMQ)* | 20000148 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Optic disc traction syndrome to Optic nerve disorders (SMQ) as a narrow term is approved as requested. PT Optic disc traction syndrome, added in version 22.1, represents traction of the optic disc by a fibrocellular proliferating membrane or posterior vitreous detachment. This abnormality has been described in proliferative diabetic retinopathy and may be accompanied by intrapapillary and subretinal peripapillary hemorrhages, especially in young patients. PT Optic disc traction syndrome will be added to Optic nerve disorders (SMQ) as a narrow scope term, fulfilling the inclusion criterion for narrow terms, "Terms relating to the optic disc."

**CR Number: 2019050009** **Implementation Date:** 27-Mar-19 Related CR: 2019050009

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Optic disc traction syndrome* | Approved as Requested | Proposed PT<br>*Optic disc traction syndrome* | 10082596 |
| To SMQ | *Retinal disorders (SMQ)* | | To SMQ<br>*Retinal disorders (SMQ)* | 20000158 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Optic disc traction syndrome to Retinal disorders (SMQ) as a broad term is approved as requested. PT Optic disc traction syndrome, added in version 22.1, represents traction of the optic disc by a fibrocellular proliferating membrane or posterior vitreous detachment. This abnormality has been described in proliferative diabetic retinopathy and central vein occlusion, and may be accompanied by intrapapillary and subretinal peripapillary hemorrhages, especially in young patients. Because PT Optic disc traction syndrome may be associated with retinal pathology such as retinal hemorrhage, and retinal detachment, the term will be added to Retinal disorders (SMQ) as a broad scope term.

# Supplemental Update Report

**CR Number: 2019050010** **Implementation Date:** 27-Mar-19 Related CR: 2019050010

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pulmonary imaging procedure abnormal* | Approved as Requested | Proposed PT<br>*Pulmonary imaging procedure abnormal* | 10082582 |
| To SMQ | *Infective pneumonia (SMQ)* | | To SMQ<br>*Infective pneumonia (SMQ)* | 20000231 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Pulmonary imaging procedure abnormal to Infective pneumonia (SMQ) as a broad term is approved as requested. Pulmonary imaging procedure abnormal fits the inclusion criteria for this Infective pneumonia (SMQ) for terms for diagnostic imaging relating to infective pneumonia. A similar term, PT Chest X-ray abnormal, is included as a broad search term.

**CR Number: 2019050011** **Implementation Date:** 27-Mar-19 Related CR: 2019050011

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Coronary sinus dilatation* | Approved as Requested | Proposed PT<br>*Coronary sinus dilatation* | 10082615 |
| To SMQ | *Pulmonary hypertension (SMQ)* | | To SMQ<br>*Pulmonary hypertension (SMQ)* | 20000130 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Coronary sinus dilatation to Pulmonary hypertension (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ for signs highly related to pulmonary hypertension. Although rarely seen in healthy patients, the coronary sinus is often visualized on echocardiography in patients with right-sided heart disease. In one study, coronary sinus dilation has been observed in 81% of a selected group of patients with pulmonary hypertension in the absence of structural disease of the tricuspid valve.

# Supplemental Update Report

**CR Number: 2019050012** **Implementation Date:** 27-Mar-19 Related CR: 2019050012

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Bronchial mucosa hyperaemia* | Approved as Requested | Proposed PT | |
| To SMQ | *Asthma/bronchospasm (SMQ)* | | *Bronchial mucosa hyperaemia* | 10082575 |
| Term scope | *Broad* | | To SMQ | |
| | | | *Asthma/bronchospasm (SMQ)* | 20000025 |
| | | | Term scope | |
| | | | *Broad* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Bronchial mucosa hyperaemia to Asthma/bronchospasm (SMQ) as a broad term is approved as requested. Bronchial mucosa hyperaemia is a new term for version 22.1 which fits inclusion criteria as broad in scope for signs and symptoms. Consistent feature of tissue inflammation in asthma is bronchial mucosa hyperaemia and hyperperfusion.

**CR Number: 2019050013** **Implementation Date:** 27-Mar-19 Related CR: 2019050013

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Coronary sinus dilatation* | Approved as Requested | Proposed PT | |
| To SMQ | *Cardiac failure (SMQ)* | | *Coronary sinus dilatation* | 10082615 |
| Term scope | *Broad* | | To SMQ | |
| | | | *Cardiac failure (SMQ)* | 20000004 |
| | | | Term scope | |
| | | | *Broad* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Coronary sinus dilatation to Cardiac failure (SMQ) as a broad term is approved as requested. New term for version 22.1 which fits inclusion criteria as broad in scope. Coronary sinus dilatations can be related to right ventricular dysfunction in patients with pulmonary hypertension. Related PT Right ventricular dysfunction is included as broad term as well.

# Supplemental Update Report

**CR Number: 2019050014** **Implementation Date:** 27-Mar-19 Related CR: 2019050014

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Immune-mediated myocarditis* | Approved as Requested | Proposed PT<br>*Immune-mediated myocarditis* | 10082606 |
| To SMQ | *Cardiomyopathy (SMQ)* | | To SMQ<br>*Cardiomyopathy (SMQ)* | 20000150 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Immune-mediated myocarditis to Cardiomyopathy (SMQ) as a broad term is approved as requested. New term for version 22.1 which fits inclusion criteria as broad in scope as any type of myocarditis may lead to cardiomyopathy. All other myocarditis PTs are included as well with broad scope.

**CR Number: 2019050015** **Implementation Date:** 27-Mar-19 Related CR: 2019050015

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Musculoskeletal toxicity* | Approved as Requested | Proposed PT<br>*Musculoskeletal toxicity* | 10082578 |
| To SMQ | *Rhabdomyolysis/myopathy (SMQ)* | | To SMQ<br>*Rhabdomyolysis/myopathy (SMQ)* | 20000002 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Musculoskeletal toxicity to Rhabdomyolysis/myopathy (SMQ) as a broad term is approved as requested. New term for version 22.1 which fits inclusion criteria as broad in scope. Musculoskeletal toxicity is a broad umbrella term including toxic effects to muscle, bone or connective tissue injuries and reports may include serious and life-threatening cases, such as rhabdomyolysis. The more specific term for muscle toxicity, Myopathy toxic, is included as narrow PT.

# Supplemental Update Report

**CR Number: 2019050016** **Implementation Date:** 27-Mar-19 Related CR: 2019050016

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Abdominal wall oedema* | Approved as Requested | Proposed PT<br>*Abdominal wall oedema* | 10082609 |
| To SMQ | *Acute pancreatitis (SMQ)* | | To SMQ<br>*Acute pancreatitis (SMQ)* | 20000022 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*C* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Abdominal wall oedema to Acute pancreatitis (SMQ) as a broad term is approved as requested. Abdominal wall edema is frequently associated with acute pancreatitis and may be a supplementary indicator of disease severity. PT Abdominal wall oedema will be added to the broad scope of this SMQ in the category C, together with other abdominal signs and symptoms.

**CR Number: 2019050017** **Implementation Date:** 27-Mar-19 Related CR: 2019050017

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Apolipoprotein E e4 gene carrier* | Approved as Requested | Proposed PT<br>*Apolipoprotein E e4 gene carrier* | 10082637 |
| To SMQ | *Congenital, familial and genetic disorders (SMQ)* | | To SMQ<br>*Congenital, familial and genetic disorders (SMQ)* | 20000077 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Apolipoprotein E e4 gene carrier to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

# Supplemental Update Report

**CR Number: 2019050018** **Implementation Date:** 27-Mar-19 Related CR: 2019050018

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Connective tissue dysplasia* | Approved as Requested | Proposed PT<br>*Connective tissue dysplasia* | 10082604 |
| To SMQ | *Congenital, familial and genetic disorders (SMQ)* | | To SMQ<br>*Congenital, familial and genetic disorders (SMQ)* | 20000077 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Connective tissue dysplasia to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

**CR Number: 2019050019** **Implementation Date:** 27-Mar-19 Related CR: 2019050019

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Double inlet left ventricle* | Approved as Requested | Proposed PT<br>*Double inlet left ventricle* | 10082665 |
| To SMQ | *Congenital, familial and genetic disorders (SMQ)* | | To SMQ<br>*Congenital, familial and genetic disorders (SMQ)* | 20000077 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Double inlet left ventricle to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

# Supplemental Update Report

**CR Number: 2019050020** **Implementation Date:** 27-Mar-19 Related CR: 2019050020

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Familial glucocorticoid deficiency* | Approved as Requested | Proposed PT<br>*Familial glucocorticoid deficiency* | 10082603 |
| To SMQ | *Congenital, familial and genetic disorders (SMQ)* | | To SMQ<br>*Congenital, familial and genetic disorders (SMQ)* | 20000077 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Familial glucocorticoid deficiency to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

**CR Number: 2019050021** **Implementation Date:** 27-Mar-19 Related CR: 2019050021

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Neurodegeneration with brain iron accumulation disorder* | Approved as Requested | Proposed PT<br>*Neurodegeneration with brain iron accumulation disorder* | 10082633 |
| To SMQ | *Congenital, familial and genetic disorders (SMQ)* | | To SMQ<br>*Congenital, familial and genetic disorders (SMQ)* | 20000077 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Neurodegeneration with brain iron accumulation disorder to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

# Supplemental Update Report

**CR Number: 2019050022** **Implementation Date:** 27-Mar-19 Related CR: 2019050022

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Plasminogen activator inhibitor deficiency type 1* | Approved as Requested | Proposed PT<br>*Plasminogen activator inhibitor deficiency type 1* | |
| To SMQ | *Congenital, familial and genetic disorders (SMQ)* | | To SMQ<br>*Congenital, familial and genetic disorders (SMQ)* | 20000077 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Plasminogen activator inhibitor deficiency type 1 to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

**CR Number: 2019050023** **Implementation Date:** 27-Mar-19 Related CR: 2019050023

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Uterine cervix canal atresia* | Approved as Requested | Proposed PT<br>*Uterine cervix canal atresia* | 10082605 |
| To SMQ | *Congenital, familial and genetic disorders (SMQ)* | | To SMQ<br>*Congenital, familial and genetic disorders (SMQ)* | 20000077 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Uterine cervix canal atresia to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

# Supplemental Update Report

**CR Number: 2019050024** **Implementation Date:** 27-Mar-19 Related CR: 2019050024

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Immune-mediated myocarditis* | Approved as Requested | Proposed PT | |
| To SMQ | *Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)* | | *Immune-mediated myocarditis* | 10082606 |
| Term scope | *Broad* | | To SMQ | |
| | | | *Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)* | 20000225 |
| | | | Term scope | |
| | | | *Broad* | |
| | | | Term_category | |
| | | | *B* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Immune-mediated myocarditis to Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ) as a broad term is approved as requested. Terms for immune-mediated organ damage meet the criteria for inclusion in the Category B broad search terms of this SMQ. A similar term, PT Immune-mediated hepatitis, is already included in this SMQ.

**CR Number: 2019050025** **Implementation Date:** 27-Mar-19 Related CR: 2019050025

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Asynclitic presentation* | Approved as Requested | Proposed PT | |
| To SMQ | *Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)* | | *Asynclitic presentation* | 10082614 |
| Term scope | *Narrow* | | To SMQ | |
| | | | *Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)* | 20000186 |
| | | | Term scope | |
| | | | *Narrow* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Asynclitic presentation to Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ) as a narrow term is approved as requested. An asynclitic presentation refers to the position of a fetus in the uterus such that the head of the baby is presenting first and is tilted to the shoulder causing the fetal head to no longer be in line with the vagina. Persistence of asynclitism can cause problems with dystocia, and has often been associated with Cesarean birth. As it represents a specific condition which can negatively impact labor and delivery, it meets the criteria for inclusion in the narrow search terms of this SMQ.

# Supplemental Update Report

**CR Number: 2019050026** **Implementation Date:** 27-Mar-19 Related CR: 2019050026

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vulvar basal cell carcinoma* | Approved as Requested | Proposed PT<br>*Vulvar basal cell carcinoma* | 10082639 |
| To SMQ | *Non-haematological malignant tumours (SMQ)* | | To SMQ<br>*Non-haematological malignant tumours (SMQ)* | 20000228 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Vulvar basal cell carcinoma to Non-haematological malignant tumours (SMQ) as a narrow term is approved as requested. Basal cell carcinoma of the vulva is a cancerous tumor affecting the external opening around the vagina. With early detection and treatment, the prognosis is excellent. However, if it metastasizes to the local lymph nodes, the prognosis is guarded or unpredictable. All terms in this SMQ are narrow in scope.

**CR Number: 2019050027** **Implementation Date:** 27-Mar-19 Related CR: 2019050027

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Stress fracture* | Approved as Requested | Proposed PT<br>*Stress fracture* | 10042212 |
| To SMQ | *Osteoporosis/osteopenia (SMQ)* | | To SMQ<br>*Osteoporosis/osteopenia (SMQ)* | 20000178 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Stress fracture to Osteoporosis/osteopenia (SMQ) as a broad term is approved as requested. This term fits the inclusion criteria for this SMQ for fracture types that are characteristic of osteoporosis. The most common cause of stress fracture is osteoporosis. Similar fracture terms, including PT Pathological fracture, are already included as broad scope terms.

# Supplemental Update Report

**CR Number: 2019050028** **Implementation Date:** 27-Mar-19 Related CR: 2019050028

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Reversible splenial lesion syndrome* | Approved as Requested | Proposed PT<br>*Reversible splenial lesion syndrome* | 10082632 |
| To SMQ | *Noninfectious encephalopathy/delirium (SMQ)* | | To SMQ<br>*Noninfectious encephalopathy/delirium (SMQ)* | 20000133 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Reversible splenial lesion syndrome to Noninfectious encephalopathy/delirium (SMQ) as a narrow term is approved as requested. Reversible splenial lesion syndrome is characterized by the presence of transient lesions involving the splenium of the corpus callosum. It has been described in patients with encephalitis or encephalopathy of varied etiology including antiepileptic drug withdrawal, infection, high-altitude cerebral edema or metabolic disorders (hypoglycemia and hypernatremia). Complete resolution after a variable lapse is the rule. As it represents a specific syndrome which can be associated with encephalitis, it will be included in the narrow search terms of this SMQ.

**CR Number: 2019050029** **Implementation Date:** 27-Mar-19 Related CR: 2019050029

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Immune-mediated neuropathy* | Approved as Requested | Proposed PT<br>*Immune-mediated neuropathy* | 10078963 |
| To SMQ | *Demyelination (SMQ)* | | To SMQ<br>*Demyelination (SMQ)* | 20000154 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Immune-mediated neuropathy to Demyelination (SMQ) as a narrow term is approved as requested. PT Immune-mediated neuropathy was promoted from under PT Autoimmune neuropathy. Since most immune-mediated neuropathies are demyelinative rather than axonal in nature, this term will be added to the narrow search terms of this SMQ.

# Supplemental Update Report

**CR Number: 2019050030** **Implementation Date:** 27-Mar-19 Related CR: 2019050030

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Foville syndrome* | Approved as Requested | Proposed PT<br>*Foville syndrome* | 10082594 |
| To SMQ | *Ocular motility disorders (SMQ)* | | To SMQ<br>*Ocular motility disorders (SMQ)* | 20000184 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Foville syndrome to Ocular motility disorders (SMQ) as a narrow term is approved as requested. PT Foville syndrome, added in version 22.1, is an inferior medial pontine stroke syndrome of the brainstem characterized by contralateral hemiparesis or hemiplegia (due to corticospinal tract affection within the dorsal tegementum of the pons), peripheral ipsilateral facial nerve palsy, and conjugate gaze palsy with diplopia with inability to look to the side of the lesion. Because Foville syndrome usually manifests as a conjugate gaze palsy, PT Foville syndrome will be added to Ocular motility disorders (SMQ) as a narrow scope term.

**CR Number: 2019050031** **Implementation Date:** 27-Mar-19 Related CR: 2019050031

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Enterovirus myocarditis* | Approved as Requested | Proposed PT<br>*Enterovirus myocarditis* | 10075553 |
| To SMQ | *Cardiomyopathy (SMQ)* | | To SMQ<br>*Cardiomyopathy (SMQ)* | 20000150 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Enterovirus myocarditis to Cardiomyopathy (SMQ) as a broad term is approved as requested. Old term which may have been overlooked since it was as added in MedDRA version 18.0. Any type of myocarditis may lead to cardiomyopathy. All other myocarditis PTs are included as well with broad scope.

# Supplemental Update Report

**CR Number: 2019050032** **Implementation Date:** 27-Mar-19 Related CR: 2019050032

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Myocardial hypoperfusion* | Approved as Requested | Proposed PT | |
| To SMQ | *Other ischaemic heart disease (SMQ)* | | *Myocardial hypoperfusion* | 10082580 |
| Term scope | *Narrow* | | To SMQ | |
| | | | *Other ischaemic heart disease (SMQ)* | 20000168 |
| | | | Term scope | |
| | | | *Narrow* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Myocardial hypoperfusion to Other ischaemic heart disease (SMQ) as a narrow term is approved as requested. New term for version 22.1 which fits inclusion criteria as narrow in scope, i.e. all types of conditions related to myocardial ischemia. Mocardial hypoperfusion due to an inadequate coronary arterial supply may lead to myocardial ischaemia and infarction.

**CR Number: 2019050033** **Implementation Date:** 27-Mar-19 Related CR: 2019050033

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Uterine atony* | Approved as Requested | Proposed PT | |
| To SMQ | *Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)* | | *Uterine atony* | 10046763 |
| Term scope | *Narrow* | | To SMQ | |
| | | | *Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)* | 20000186 |
| | | | Term scope | |
| | | | *Narrow* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Uterine atony to Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ) as a narrow term is approved as requested. In version 22.1, PT Uterine atony had its primary SOC changed from SOC Reproductive system and breast disorders to SOC Pregnancy, puerperium and perinatal conditions. Uterine atony is associated with increased risk for severe hemorrhagic complications following delivery. It meets the criteria for inclusion in the narrow search terms of this SMQ

# Supplemental Update Report

**CR Number: 2019050034** **Implementation Date:** 27-Mar-19 Related CR: 2019050034

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Foville syndrome* | Approved as Requested | Proposed PT<br>*Foville syndrome* | 10082594 |
| To SMQ | *Haemorrhagic central nervous system vascular conditions (SMQ)* | | To SMQ<br>*Haemorrhagic central nervous system vascular conditions (SMQ)* | 20000064 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Foville syndrome to Haemorrhagic central nervous system vascular conditions (SMQ) as a narrow term is approved as requested. Foville syndrome is a pontine stroke syndrome of the dorsal tegmentum characterized by contralateral hemiplegia, ipsilateral peripheral-type facial palsy and the inability to move the eyes conjugately to the ipsilateral side due to paramedian pontine reticular formation and/or abducens nerve nucleus involvement. It can be related to either ischemic or hemorrhagic lesions of the pons and, as a specific type of stroke, meets the criteria for inclusion in the narrow search terms of this SMQ.

**CR Number: 2019050035** **Implementation Date:** 27-Mar-19 Related CR: 2019050035

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Foville syndrome* | Approved as Requested | Proposed PT<br>*Foville syndrome* | 10082594 |
| To SMQ | *Ischaemic central nervous system vascular conditions (SMQ)* | | To SMQ<br>*Ischaemic central nervous system vascular conditions (SMQ)* | 20000063 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Foville syndrome to Ischaemic central nervous system vascular conditions (SMQ) as a narrow term is approved as requested. Foville syndrome is a pontine stroke syndrome of the dorsal tegmentum characterized by contralateral hemiplegia, ipsilateral peripheral-type facial palsy and the inability to move the eyes conjugately to the ipsilateral side due to paramedian pontine reticular formation and/or abducens nerve nucleus involvement. It can be related to either ischemic or hemorrhagic lesions of the pons and, as a specific type of stroke, meets the criteria for inclusion in the narrow search terms of this SMQ.

# Supplemental Update Report

**CR Number: 2019050036** **Implementation Date:** 27-Mar-19 Related CR: 2019050036

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Reversible splenial lesion syndrome* | Approved as Requested | Proposed PT<br>*Reversible splenial lesion syndrome* | 10082632 |
| To SMQ | *Noninfectious encephalitis (SMQ)* | | To SMQ<br>*Noninfectious encephalitis (SMQ)* | 20000132 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Reversible splenial lesion syndrome to Noninfectious encephalitis (SMQ) as a narrow term is approved as requested. Reversible splenial lesion syndrome is characterized by the presence of transient lesions involving the splenium of the corpus callosum. It has been described in patients with encephalitis or encephalopathy of varied etiology including antiepileptic drug withdrawal, infection, high-altitude cerebral edema or metabolic disorders (hypoglycemia and hypernatremia). Complete resolution after a variable lapse is the rule. As it represents a specific syndrome which can be associated with encephalitis, it will be included in the narrow search terms of this SMQ.

**CR Number: 2019050037** **Implementation Date:** 27-Mar-19 Related CR: 2019050037

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Diabulimia* | Approved as Requested | Proposed PT<br>*Diabulimia* | 10082635 |
| To SMQ | *Hyperglycaemia/new onset diabetes mellitus (SMQ)* | | To SMQ<br>*Hyperglycaemia/new onset diabetes mellitus (SMQ)* | 20000041 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Diabulimia to Hyperglycaemia/new onset diabetes mellitus (SMQ) as a broad term is approved as requested. PT Diabulimia, added in version 22.1, represents an eating disorder in a person with diabetes mellitus, typically type I diabetes, wherein the person purposefully restricts insulin in order to lose weight. Although this condition may be related to bulimia, the term may be useful in the identification of cases of hyperglycemia, and/or diabetes mellitus. PT Diabulimia fulfills more that one of the inclusion criteria for Hyperglycaemia/new onset diabetes mellitus (SMQ), including, "Terms with roots of “diabet-," and will thus be added as a broad scope term to this SMQ.

# Supplemental Update Report

**CR Number: 2019051001** **Implementation Date:** 26-Feb-19 Related CR: 2019051001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Myopic macular degeneration* | Approved as Requested | Proposed LLT | |
| | | | *Myopic macular degeneration* | 10082754 Current |
| | | | To PT | |
| | | | *Myopic chorioretinal degeneration* | 10079959 |

MSSO Comment: The proposal to add a new term Myopic macular degeneration is approved as requested. People with high myopia (more than -6.00 dioptres) are at risk of pathological myopia where permanent degenerative changes can occur to the retina at the back of the eye. The stretching of the retina in myopia causes the retina to become thinner which can lead to areas of retinal atrophy. Retinal atrophy can occur anywhere on the retina and if it happens in the central macula area, it can affect central vision. Myopic macular degeneration will be added as a sub-concept LLT to the PT Myopic chorioretinal degeneration.

**CR Number: 2019051002** **Implementation Date:** 26-Feb-19 Related CR: 2019051002

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Cardiosclerosis* | Approved as Requested | Proposed LLT | |
| | | | *Cardiosclerosis* | 10082755 Current |
| | | | To PT | |
| | | | *Myocardial fibrosis* | 10028594 |

MSSO Comment: The proposal to add a new LLT Cardiosclerosis is approved as requested. Cardiosclerosis is a condition in which scar tissue is formed inside the heart muscle. This condition is clinically characterized by a degeneration of the muscle fibers which get subsequently substituted with connective tissue. Cardiosclerosis will be added as a sub-element LLT of PT Myocardial fibrosis.

**CR Number: 2019051003** **Implementation Date:** 26-Feb-19 Related CR: 2019051003

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Pulsed signal therapy* | Approved as Requested | Proposed LLT | |
| | | | *Pulsed signal therapy* | 10082758 Current |
| | | | To PT | |
| | | | *Magnetic therapy* | 10065343 |

MSSO Comment: The proposal to add a new LLT Pulsed signal therapy is approved as requested. Pulsed signal therapy is a unique form of pulsed electromagnetic field therapy for stimulating healing of damaged structures such as cartilage, bones and soft tissues. The magnetic wave-pulse induces a tiny electrical signal that mimics the physiological signaling normally occurring in healthy joints, mainly through chondrocytes stimulation. In this way, it exerts its therapeutic effects by stimulating cellular repair. Pulsed signal therapy is used to treat diseases from the skeletal system, such as arthritis and osteoporosis, and will be added a sub-concept LLT to PT Magnetic therapy.

# Supplemental Update Report

**CR Number: 2019051004** **Implementation Date:** 26-Feb-19 Related CR: 2019051004

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Cold coagulation* | Approved as Requested | Proposed LLT | |
| | | | *Cold coagulation* | 10082756 Current |
| | | | To PT | |
| | | | *Cervix cautery* | 10008349 |

MSSO Comment: The proposal to add a new LLT Cold coagulation is approved as requested. Cold coagulation is a procedure used to treat women with abnormal cells on their cervix. It may be indicated for all grades of cervix intraepithelial neoplasia, and is safe, quick and acceptable as an outpatient procedure. Cold coagulation will be added as a sub-concept LLT under PT Cervix cautery.

**CR Number: 2019051005** **Implementation Date:** 26-Feb-19 Related CR: 2019051005

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Bridle procedure* | Approved as Requested | Proposed LLT | |
| | | | *Bridle procedure* | 10082759 Current |
| | | | To PT | |
| | | | *Tendon transfer* | 10043253 |

MSSO Comment: The proposal to add a new term Bridle procedure is approved as requested. The Bridle procedure consists of a posterior tibial tendon transfer through the interosseous membrane to the dorsum of the foot with a dual anastomosis to the tendon of the anterior tibial and a rerouted peroneus longus in front of the lateral malleolus. This procedure is performed to restore loss of dorsiflexion and to balance the foot, preventing a secondary varus or valgus deformity. Bridle procedure will be added as a sub-element LLT of PT Tendon transfer.

**CR Number: 2019051006** **Implementation Date:** 26-Feb-19 Related CR: 2019051006

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Proprioceptive excercise* | Approved Not as Requested | Proposed PT | |
| | | | *Proprioceptive exercise* | 10082752 |
| | | | HLT primary | |
| | | | *Nervous system therapeutic procedures NEC* | 10052731 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment: The proposal to add a new LLT Proprioceptive exercise is approved but not as requested. Proprioceptive and balance exercises are meant to control the position of a deficient or an injured joint thorough the re-education of the proprioceptive subconscious reactions to the wobbly movements of normal life in an automatic way. Proprioceptive exercise is a well defined therapy which warrants addition to PT level and will be added, with corrected spelling, as PT Proprioceptive exercise to the HLT Nervous system therapeutic procedures NEC.

# Supplemental Update Report

**CR Number:** **2019051007** **Implementation Date:** 26-Feb-19 Related CR: 2019051007

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed Term | *Ovarian fibrothecoma* | Approved as Requested | Proposed LLT | | |
| | | | *Ovarian fibrothecoma* | 10082757 | Current |
| | | | To PT | | |
| | | | *Ovarian granulosa cell tumour* | 10073260 | |

MSSO Comment: The proposal to add a new term Ovarian fibrothecoma is approved as requested. Ovarian fibrothecomas comprise tumors in the spectrum of ovarian sex cord/stromal tumors where there are components of both an ovarian fibroma and an ovarian thecoma. Ovarian fibrothecoma is classified as a variety of granulose tumors in the WHO classification of ovarian neoplasms, and consequently will be added as a sub-concept LLT to PT Ovarian granulosa cell tumour.

**CR Number:** **2019051008** **Implementation Date:** 26-Feb-19 Related CR: 2019051008

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Scarf osteotomy* | Approved as Requested | Proposed LLT | | |
| | | | *Scarf osteotomy* | 10082760 | Current |
| | | | To PT | | |
| | | | *Bunion operation* | 10006586 | |

MSSO Comment: The proposal to add a new LLT Scarf osteotomy is approved as requested. Scarf osteotomy is an operation to correct a severe bunion (hallux valgus) deformity consisting on making small cuts in the bones (osteotomy) and moving them into a more normal position. Scarf osteotomy is a type of bunion surgery and consequently will be placed as a sub-element LLT under PT Bunion operation.

**CR Number:** **2019051009** **Implementation Date:** 26-Feb-19 Related CR: 2019051009

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Passive leg raise assessment* | Approved as Requested | Proposed PT | |
| | | | *Passive leg raise assessment* | 10082753 |
| | | | HLT primary | |
| | | | *Cardiac function diagnostic procedures* | 10007566 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new term Passive leg raise assessment is approved as requested. Passive leg raise assessment is a simple bedside technique that can be used to assess fluid responsiveness. This maneuver can be used as a pseudo-fluid challenge of an approximately of 150–300 mL by placing patient head down flat and feet up at a 45° angle. Blood from the lower extremities translocate to intrathoracic compartment where increases right and left ventricular preload and if the patient is responsive increases stroke volume and cardiac output. An increase in stroke volume of more than 10% indicates the patient is preload responsive with the high sensitivity and specificity. Passive leg raise assessment will be added as a PT to the HLT Cardiac function diagnostic procedures.

# Supplemental Update Report

**CR Number: 2019051010** **Implementation Date:** 27-Mar-19 Related CR: 2019051010

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Toxic shock syndrome streptococcal* | Approved as Requested | Proposed PT<br>*Toxic shock syndrome streptococcal* | 10044251 |
| To SMQ | *Toxic-septic shock conditions (SMQ)* | | To SMQ<br>*Toxic-septic shock conditions (SMQ)* | 20000070 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Toxic shock syndrome streptococcal to Toxic-septic shock conditions (SMQ) as a narrow term is approved as requested. Toxic shock syndrome is a toxin-mediated acute life-threatening illness, usually precipitated by infection with either Staphylococcus aureus or group A Streptococcus. PTs with "shock" in general fulfill inclusion criteria as narrow in scope for any of the 6 Level 2 sub-searches. The broad PT Toxic shock syndrome is included when this SMQ was developed and released in version 9.1. However, the two agent specific PTs for treptococcal/staphylococcal have been overseen as both PTs, PT Toxic shock syndrome streptococcal and PT Toxic shock syndrome staphyolococcal, are in MedDRA since version 2.1 as well.

**CR Number: 2019051011** **Implementation Date:** 27-Mar-19 Related CR: 2019051011

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Toxic shock syndrome staphylococcal* | Approved as Requested | Proposed PT<br>*Toxic shock syndrome staphylococcal* | 10044250 |
| To SMQ | *Toxic-septic shock conditions (SMQ)* | | To SMQ<br>*Toxic-septic shock conditions (SMQ)* | 20000070 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Toxic shock syndrome staphylococcal to Toxic-septic shock conditions (SMQ) as a narrow term is approved as requested. Toxic shock syndrome is a toxin-mediated acute life-threatening illness, usually precipitated by infection with either Staphylococcus aureus or group A Streptococcus. PTs with "shock" in general fulfill inclusion criteria as narrow in scope for any of the 6 Level 2 sub-searches. The broad PT Toxic shock syndrome is included when this SMQ was developed and released in version 9.1. However, the two agent specific PTs for streptococcal/staphylococcal have been overseen as both PTs, PT Toxic shock syndrome streptococcal and PT Toxic shock syndrome staphyolococcal, are in MedDRA since version 2.1 as well.

# Supplemental Update Report

**CR Number: 2019051012** **Implementation Date:** 28-Feb-19 Related CR: 2019051012

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Product damaged* | Approved as Requested | Proposed LLT<br>*Product damaged* | 10082777 Current |
| | | | To PT<br>*Product physical issue* | 10071134 |

MSSO Comment: The proposal to add a new term Product damaged is approved as requested. Product damaged will be added as LLT to PT Product physical issue grouped together with LLT Tablet damaged. In a related change, PT Device damage will be demoted as a sub-concept LLT under PT Device physical property issue, for better placement.

**CR Number: 2019059005** **Implementation Date:** 28-Feb-19 Related CR: 2019051012

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Device damage* | Approved as Requested | PT to merge<br>*Device damage* | 10069870 Current |
| To PT | *Device physical property issue* | | To PT<br>*Device physical property issue* | 10069880 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019051013** **Implementation Date:** 28-Feb-19 Related CR: 2019051013

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Administration site acne* | Approved as Requested | Proposed PT | |
| HLT primary | *Administration site reactions NEC* | | *Administration site acne* | 10082766 |
| SOC primary | *General disorders and administration site conditions* | | HLT primary | |
| | | | *Administration site reactions NEC* | 10057196 |
| | | | SOC primary | |
| | | | *General disorders and administration site conditions* | 10018065 |
| | | | HLT secondary | |
| | | | *Acnes* | 10000497 |
| | | | SOC secondary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment: The proposal to add a new PT Administration site acne to primary HLT Administration site reactions NEC in SOC General disorders and administration site conditions is approved as requested. Acne may occur after the administration of topical or systemic drugs such as corticosteroids. PT Administration site acne will also be linked to secondary HLT Acnes.

**CR Number: 2019051014** **Implementation Date:** 28-Feb-19 Related CR: 2019051014

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Medical device site acne* | Rejected | | |
| HLT primary | *Complications associated with device NEC* | | | |
| SOC primary | *General disorders and administration site conditions* | | | |

MSSO Comment: The proposal to add a new PT Medical device site acne to primary HLT Complications associated with device NEC in SOC General disorders and administration site conditions is not approved. Referencing existing terms in MedDRA is not sufficient justification for addition of similar new terms. Medical device site acne is not a term that appears to be referenced in Medical literature. Please consider split coding LLT Acne and LLT Medical device site reaction.

# Supplemental Update Report

**CR Number: 2019051015** **Implementation Date:** 28-Feb-19 Related CR: 2019051015

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Oral mucosal scab* | Approved as Requested | Proposed PT | |
| | | | *Oral mucosal scab* | 10082769 |
| | | | HLT primary | |
| | | | *Oral soft tissue signs and symptoms* | 10031021 |
| | | | SOC primary | |
| | | | *Gastrointestinal disorders* | 10017947 |

MSSO Comment: The proposal to add a new term Oral mucosal scab is approved as requested. Healing processes in the oral cavity may include crust or scab building. Oral mucosal scab will be placed as PT to HLT Oral soft tissue signs and symptoms.

**CR Number: 2019051016** **Implementation Date:** 28-Feb-19 Related CR: 2019051016

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Lip scab* | Approved as Requested | Proposed PT | |
| | | | *Lip scab* | 10082767 |
| | | | HLT primary | |
| | | | *Oral soft tissue signs and symptoms* | 10031021 |
| | | | SOC primary | |
| | | | *Gastrointestinal disorders* | 10017947 |

MSSO Comment: The proposal to add a new term Lip scab is approved as requested. During healing processes on the lip e.g. after Herpes scab or crusts may be seen on the lip. Lip scab will be added as PT to HLT Oral soft tissue signs and symptoms.

**CR Number: 2019051017** **Implementation Date:** 28-Feb-19 Related CR: 2019051017

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Periorbital erythema* | Rejected | | |
| HLT primary | *Ocular disorders NEC* | | | |
| SOC primary | *Eye disorders* | | | |

MSSO Comment: The proposal to add a new PT Periorbital erythema to primary HLT Ocular disorders NEC in SOC Eye disorders and secondary HLT Erythemas in SOC Skin and subcutaneous tissue disorders is not approved. LLT Erythema periorbital in change request 2019051018 is best placed under the PT Erythema and there is no need to create a new PT Periorbital erythema to host the LLT Erythema periorbital. Erythema in the periorbital/periocular area usually only affects the skin and cannot be compared with e.g. swelling, inflammation in this region in respect of consistent representation on PT level as those concepts affect other tissues than skin and may have specific clinical relvance.

# Supplemental Update Report

**CR Number: 2019051018** **Implementation Date:** 28-Feb-19 Related CR: 2019051018

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Erythema periorbital* | Rejected | | |
| From PT | *Erythema* | | | |
| To PT | *Periorbital erythema* | | | |

MSSO Comment: The proposal to move the LLT Erythema periorbital from PT Erythema to PT Periorbital erythema is not approved. This is a technical rejection as change request 2019051017 has been rejected.

**CR Number: 2019051019** **Implementation Date:** 28-Feb-19 Related CR: 2019051019

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Periorbital redness* | Rejected | | |
| To PT | *Periorbital erythema* | | | |

MSSO Comment: The proposal to add a new LLT Periorbital redness to PT Periorbital erythema is not approved. Periorbital erythema was not added in change request 2019051017 since periorbital/periocular area usually only affects the skin. Furthermore, it is not feasible to add a redness synonym for each anatomical site specific erythema LLT.

**CR Number: 2019051020** **Implementation Date:** 28-Feb-19 Related CR: 2019051020

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Perirobital burning sensation* | Approved Not as Requested | Proposed LLT *Perirobital burning sensation* | |
| HLT primary | *Ocular disorders NEC* | | To PT *Skin burning sensation* | 10054786 |
| SOC primary | *Eye disorders* | | | |

MSSO Comment: The proposal to add a new PT Perirobital burning sensation to primary HLT Ocular disorders NEC in SOC Eye disorders and secondary HLT Dermal and epidermal conditions NEC in SOC Skin and subcutaneous tissue disorders is approved but not as requested. Periocular/periorbital area is confined to the skin around the eyes and burning sensations often is related to it. Periorbital burning sensation will be added as sub-concept LLT to PT Skin burning sensation.

# Supplemental Update Report

**CR Number: 2019051021** **Implementation Date:** 28-Feb-19 Related CR: 2019051021

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Eyelid burning sensation* | Rejected | | |
| From PT | *Eyelid irritation* | | | |
| HLT primary | *Ocular disorders NEC* | | | |

MSSO Comment: The proposal to promote the LLT Eyelid burning sensation from PT Eyelid irritation to primary HLT Ocular disorders NEC in SOC Eye disorders and secondary HLT Dermal and epidermal conditions NEC in SOC Skin and subcutaneous tissue disorders is not approved. Eyelid burning sensation is best placed as sub-concept LLT to PT Eyelid irritation, since burning sensation is one of the possible manifestations of tissue irritation. This alignment is frequently found in MedDRA, such as LLT Burning eyes under PT Eye irritation. Please note that in MedDRA only 8 burning sensations are placed as PTs - most others are subordinated to PTs, either irritation or discomfort.

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**CR Number: 2019051022** **Implementation Date:** 28-Feb-19 Related CR: 2019051022

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Periorbital discomfort* | Rejected | | |
| HLT primary | *Ocular disorders NEC* | | | |
| SOC primary | *Eye disorders* | | | |

MSSO Comment: The proposal to add a new PT Periorbital discomfort to primary HLT Ocular disorders NEC in SOC Eye disorders is not approved. Referencing existing terms in MedDRA is not sufficient justification for addition of similar new terms. Furthermore, the requested term is represented by LLT Discomfort around orbit.

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**CR Number: 2019051023** **Implementation Date:** 28-Feb-19 Related CR: 2019051023

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Periocular rash* | Rejected | | |
| From PT | *Rash* | | | |
| HLT primary | *Lid, lash and lacrimal infections, irritations and inflammations* | | | |

MSSO Comment: The proposal to promote the LLT Periocular rash from PT Rash to primary HLT Lid, lash and lacrimal infections, irritations and inflammations in SOC Eye disorders and secondary HLT Rashes, eruptions and exanthems NEC in SOC Skin and subcutaneous tissue disorders is not approved. Similarly to erythema in the periocular area, rash is limited to the skin and therefore LLT Periocular rash is best placed as sub-concept LLT to the PT Rash. This subordination for anatomical specificity under a broad PT concept avoids overgranulation on PT Level and dilution of concepts. Please note, that the eyelid is classified as structure of the eye as stated in the MedDRA Introductory Guide 4.8 Body site consideration but this Statement does not include the periocular area. The proposed concept can be represented by existing LLT/PT Eyelid rash.

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# Supplemental Update Report

**CR Number: 2019051024** **Implementation Date:** 28-Feb-19 Related CR: 2019051024

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Periorbital irritation* | Approved Not as Requested | Proposed LLT | |
| HLT primary | *Orbital infections, inflammations and irritations* | | *Periorbital irritation* | 10082774 Current |
| SOC primary | *Eye disorders* | | To PT | |
| | | | *Skin irritation* | 10040880 |

MSSO Comment: The proposal to add a new PT Periorbital irritation to primary HLT Orbital infections, inflammations and irritations in SOC Eye disorders and secondary HLT Dermatitis and eczema in SOC Skin and subcutaneous tissue disorders is approved but not as requested. Please note that Orbital concepts are different from periorbital terms. Periorbital irriation indicates a sensation of the skin in the particular area around the eyes. Periorbital irritation will be added as sub-concept LLT to PT Skin irritation.

**CR Number: 2019051025** **Implementation Date:** 28-Feb-19 Related CR: 2019051025

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Periorbital pruritus* | Approved Not as Requested | Proposed LLT | |
| HLT primary | *Ocular disorders NEC* | | *Periorbital pruritus* | 10082778 Current |
| SOC primary | *Eye disorders* | | To PT | |
| | | | *Pruritus* | 10037087 |

MSSO Comment: The proposal to add a new PT Periorbital pruritus to primary HLT Ocular disorders NEC in SOC Eye disorders and secondary HLT Pruritus NEC in SOC Skin and subcutaneous tissue disorders is approved but not as requested. Terms of the periorbital area affecting the skin only are considered to be sub-concepts to skin PTs. Periorbital pruritus will be added as an LLT to PT Pruritus.

**CR Number: 2019051026** **Implementation Date:** 28-Feb-19 Related CR: 2019051026

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Periorbital itching* | Rejected | | |
| To PT | *Periorbital pruritus* | | | |

MSSO Comment: The proposal to add a new LLT Periorbital itching to PT Periorbital pruritus is not approved. MedDRA cannot accommodate a separate term for every synonym of each medical concept PT. LLT Itching is an existing synonym LLT under to PT Pruritus. The addition of a counterpart "itching" synonym LLT to each of the more than 30 existing Preferred Terms pertaining to pruritus would unnecessarily overpopulate MedDRA.

# Supplemental Update Report

**CR Number: 2019051027** **Implementation Date:** 28-Feb-19 Related CR: 2019051027

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Periorbital anaesthesia* | Approved Not as Requested | Proposed LLT<br>*Periorbital anaesthesia* | 10082773 Current |
| SOC primary | *Eye disorders* | | To PT<br>*Anaesthesia* | 10002091 |

MSSO Comment: The proposal to add a new PT Periorbital anaesthesia in SOC Eye disorders and secondary HLT Paraesthesias and dysaesthesias in SOC Nervous system disorders is approved but not as requested. Periorbital anaesthesia, is the lack of sensation of structures near or around the orbit, frequently pertains to the skin, and is not usually an eye disorder, per se. Periorbital anaesthesia and its American English spelled counterpart Periorbital anesthesia will be added as sub-concept LLTs to PT Anaesthesia.

**CR Number: 2019059009** **Implementation Date:** 28-Feb-19 Related CR: 2019051027

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Periorbital anesthesia* | Approved as Requested | Proposed LLT<br>*Periorbital anesthesia* | 10082782 Current |
| To PT | *Anaesthesia* | | To PT<br>*Anaesthesia* | 10002091 |

MSSO Comment:

**CR Number: 2019051028** **Implementation Date:** 28-Feb-19 Related CR: 2019051028

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Periorbital hyperaesthesia* | Approved Not as Requested | Proposed LLT<br>*Periorbital hyperaesthesia* | 10082775 Current |
| SOC primary | *Eye disorders* | | To PT<br>*Hyperaesthesia* | 10020568 |

MSSO Comment: The proposal to add a new PT Periorbital hyperaesthesia in SOC Eye disorders and secondary HLT Paraesthesias and dysaesthesias in SOC Nervous system disorders is approved but not as requested. Periorbital hyperaesthesia, the increased sensitivity of structures near or around the orbit, can present as a painful sensation from a normally painless touch stimulus. This symptom may be a manifestation of neurologic conditions such as pathology of the trigeminal nerve. Because periorbital hyperaesthesia generally pertains to skin sensation, and is not usually an eye disorder, per se, new LLT Periorbital hyperaesthesia will be added as a sub-concept LLT to PT Hyperaesthesia. In a related change, the American English spelling counterpart LLT Periorbital hyperesthesia will also be added to PT Hyperaesthesia.

# Supplemental Update Report

**CR Number: 2019059010** **Implementation Date:** 28-Feb-19 Related CR: 2019051028

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Periorbital hyperesthesia* | Approved as Requested | Proposed LLT | |
| To PT | *Hyperaesthesia* | | *Periorbital hyperesthesia* | 10082779 Current |
| | | | To PT | |
| | | | *Hyperaesthesia* | 10020568 |

MSSO Comment:

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**CR Number: 2019051029** **Implementation Date:** 28-Feb-19 Related CR: 2019051029

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Periorbital hypoaesthesia* | Approved Not as Requested | Proposed LLT | |
| | | | *Periorbital hypoaesthesia* | 10082776 Current |
| SOC primary | *Eye disorders* | | To PT | |
| | | | *Hypoaesthesia* | 10020937 |

MSSO Comment: The proposal to add a new PT Periorbital hypoaesthesia in SOC Eye disorders and secondary HLT Paraesthesias and dysaesthesias in SOC Nervous system disorders is approved but not as requested. Periorbital hypoaesthesia, is an abnormally decreased sensitivity of structures near or around the orbit, particularly to touch. This symptom may be a manifestation of neurologic conditions such as pathology of the trigeminal nerve. Because periorbital hypoaesthesia generally pertains to skin sensation, and is not usually an eye disorder, per se, new LLT Periorbital hypoaesthesia will be added as a sub-concept LLT to PT Hypoaesthesia. In a related change, the American English spelling counterpart LLT Periorbital hypoesthesia will also be added to PT Hypoaesthesia.

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**CR Number: 2019059011** **Implementation Date:** 28-Feb-19 Related CR: 2019051029

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Periorbital hypoesthesia* | Approved as Requested | Proposed LLT | |
| To PT | *Hypoaesthesia* | | *Periorbital hypoesthesia* | 10082783 Current |
| | | | To PT | |
| | | | *Hypoaesthesia* | 10020937 |

MSSO Comment:

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# Supplemental Update Report

**CR Number: 2019051030** **Implementation Date:** 28-Feb-19 Related CR: 2019051030

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Periorbital paraesthesia* | Approved Not as Requested | Proposed LLT | |
| | | | *Periorbital paraesthesia* | 10082771 Current |
| SOC primary | *Eye disorders* | | To PT | |
| | | | *Paraesthesia* | 10033775 |

MSSO Comment: The proposal to add a new PT Periorbital paraesthesia in SOC Eye disorders and secondary HLT Paraesthesias and dysaesthesias in SOC Nervous system disorders is approved but not as requested. Periorbital paraesthesia, is an abnormal touch sensation, such as burning, prickling, or formication, often in the absence of an external stimulus of structures near or around the orbit. This symptom may be a manifestation of neurologic conditions such as pathology of the trigeminal nerve, or a malignancy which compresses an adjacent nerve. Because periorbital paraesthesia generally pertains to skin sensation, and is not usually an eye disorder, per se, new LLT Periorbital paraesthesia will be added as a sub-concept LLT to PT Paraesthesia. In a related change, the American English spelling counterpart LLT Periorbital paresthesia will also be added to PT Paraesthesia.

**CR Number: 2019059012** **Implementation Date:** 28-Feb-19 Related CR: 2019051030

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Periorbital paresthesia* | Approved as Requested | Proposed LLT | |
| To PT | *Paraesthesia* | | *Periorbital paresthesia* | 10082780 Current |
| | | | To PT | |
| | | | *Paraesthesia* | 10033775 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019051031** **Implementation Date:** 28-Feb-19 Related CR: 2019051031

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Anaesthesia eye* | Approved as Requested | Proposed PT | |
| HLT primary | *Ocular sensation disorders* | | *Anaesthesia eye* | 10082764 |
| SOC primary | *Eye disorders* | | HLT primary | |
| | | | *Ocular sensation disorders* | 10030063 |
| | | | SOC primary | |
| | | | *Eye disorders* | 10015919 |
| | | | HLT secondary | |
| | | | *Paraesthesias and dysaesthesias* | 10033788 |
| | | | SOC secondary | |
| | | | *Nervous system disorders* | 10029205 |

MSSO Comment: The proposal to add a new PT Anaesthesia eye to primary HLT Ocular sensation disorders in SOC Eye disorders and secondary HLT Paraesthesias and dysaesthesias in SOC Nervous system disorders is approved as requested. Anaesthesia of the eye is a broad concept that relates to a loss of sensation of the eye. Usually, the concept pertains to corneal anesthesia caused by impairment to the ophthalmic division of the trigeminal nerve, which provides sensation to the cornea. Corneal anesthesia is commonly caused by infection (such as Herpes Zoster), diabetes, trauma or surgery. In a related change, the American English spelling counterpart LLT Anesthesia eye will be added to PT Anaesthesia eye. Furthermore, to differentiate PT Anaesthesia eye from a procedural concept which is also related to the eye new PT Anaesthesic ophthalmic procedure will be added to HLT Eye therapeutic procedures NEC. In addition the American English counterpart LLT Anesthesic ophthalmic procedure to PT Anaesthesic ophthalmic procedure.

**CR Number: 2019059006** **Implementation Date:** 28-Feb-19 Related CR: 2019051031

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Anesthesia eye* | Approved as Requested | Proposed LLT | |
| To PT | *Anaesthesia eye* | | *Anesthesia eye* | 10082781 Current |
| | | | To PT | |
| | | | *Anaesthesia eye* | 10082764 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019059013** **Implementation Date:** 28-Feb-19 Related CR: 2019051031

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Anaesthesic ophthalmic procedure* | Approved as Requested | Proposed PT | |
| HLT primary | *Eye therapeutic procedures NEC* | | *Anaesthesic ophthalmic procedure* | 10082763 |
| SOC primary | *Surgical and medical procedures* | | HLT primary | |
| | | | *Eye therapeutic procedures NEC* | 10027675 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment:

**CR Number: 2019059014** **Implementation Date:** 28-Feb-19 Related CR: 2019051031

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Anesthesic ophthalmic procedure* | Approved as Requested | Proposed LLT | |
| To PT | *Anaesthesic ophthalmic procedure* | | *Anesthesic ophthalmic procedure* | 10082784 Current |
| | | | To PT | |
| | | | *Anaesthesic ophthalmic procedure* | 10082763 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019051032** **Implementation Date:** 28-Feb-19 Related CR: 2019051032

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Hyperaesthesia eye* | Approved as Requested | Proposed PT | |
| HLT primary | *Ocular sensation disorders* | | *Hyperaesthesia eye* | 10082768 |
| SOC primary | *Eye disorders* | | HLT primary | |
| | | | *Ocular sensation disorders* | 10030063 |
| | | | SOC primary | |
| | | | *Eye disorders* | 10015919 |
| | | | HLT secondary | |
| | | | *Paraesthesias and dysaesthesias* | 10033788 |
| | | | SOC secondary | |
| | | | *Nervous system disorders* | 10029205 |

MSSO Comment: The proposal to add a new PT Hyperaesthesia eye to primary HLT Ocular sensation disorders in SOC Eye disorders and secondary HLT Paraesthesias and dysaesthesias in SOC Nervous system disorders is approved as requested. Hyperaesthesia, or an abnormal increase in sensation of the eye, is a non-specific concept, which usually refers to increased sensitivity of the cornea, for example after Herpes Zoster Ophthalmicus.

**CR Number: 2019051033** **Implementation Date:** 28-Feb-19 Related CR: 2019051033

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Hypoaesthesia eyelid* | Rejected | | |
| HLT primary | *Ocular sensation disorders* | | | |
| SOC primary | *Eye disorders* | | | |

MSSO Comment: The proposal to add a new PT Hypoaesthesia eyelid to primary HLT Ocular sensation disorders in SOC Eye disorders and secondary HLT Paraesthesias and dysaesthesias in SOC Nervous system disorders is not approved. It is not feasible to add to all possible anatomical sites, terms for an-,dys-, hyper-,hypo-, paraesthesia as this may lead to overgranulation at PT level and signal dilution. In a related change, LLT Numbness of eyelid and LLT Numbness of eyelids will be moved from PT Hypoaesthesia eye to PT Eyelid sensory disorder for better alignment.

# Supplemental Update Report

**CR Number: 2019059015** **Implementation Date:** 28-Feb-19 Related CR: 2019051033

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Numbness of eyelid* | Approved as Requested | Proposed LLT | |
| From PT | *Hypoaesthesia eye* | | *Numbness of eyelid* | 10029843 Current |
| To PT | *Eyelid sensory disorder* | | From PT | |
| | | | *Hypoaesthesia eye* | 10020939 |
| | | | To PT | |
| | | | *Eyelid sensory disorder* | 10015999 |

MSSO Comment:

**CR Number: 2019059016** **Implementation Date:** 28-Feb-19 Related CR: 2019051033

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Numbness of eyelids* | Approved as Requested | Proposed LLT | |
| From PT | *Hypoaesthesia eye* | | *Numbness of eyelids* | 10029844 Current |
| To PT | *Eyelid sensory disorder* | | From PT | |
| | | | *Hypoaesthesia eye* | 10020939 |
| | | | To PT | |
| | | | *Eyelid sensory disorder* | 10015999 |

MSSO Comment:

**CR Number: 2019051034** **Implementation Date:** 28-Feb-19 Related CR: 2019051034

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Numbness of eyelids* | Rejected | | |
| From PT | *Hypoaesthesia eye* | | | |
| To PT | *Hypoaesthesia eyelid* | | | |

MSSO Comment: The proposal to move the LLT Numbness of eyelids from PT Hypoaesthesia eye to PT Hypoaesthesia eyelid is not approved. This is a technical rejection please see change request 2019051033 for the move of LLT Numbness of eyelids.

# Supplemental Update Report

**CR Number: 2019051035** **Implementation Date:** 28-Feb-19 Related CR: 2019051035

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Numbness of eyelid* | Rejected | | |
| From PT | *Hypoaesthesia eye* | | | |
| To PT | *Hypoaesthesia eyelid* | | | |

MSSO Comment: The proposal to move the LLT Numbness of eyelid from PT Hypoaesthesia eye to PT Hypoaesthesia eyelid is not approved. This is a technical rejection please see change request 2019051033 for the move of LLT Numbness of eyelid.

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**CR Number: 2019051036** **Implementation Date:** 28-Feb-19 Related CR: 2019051036

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Anaesthesia eyelid* | Rejected | | |
| HLT primary | *Ocular sensation disorders* | | | |
| SOC primary | *Eye disorders* | | | |

MSSO Comment: The proposal to add a new PT Anaesthesia eyelid to primary HLT Ocular sensation disorders in SOC Eye disorders and secondary HLT Paraesthesias and dysaesthesias in SOC Nervous system disorders is not approved. It is not feasible to add to any possible anatomical sites, terms for an-,dys-, hyper-,hypo-, paraesthesia as this may lead to overgranulation at PT level and signal dilution. The requested term can be represented by split coding with LLT Eyelid sensory disorder and LLT Anaesthesia.

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**CR Number: 2019051037** **Implementation Date:** 28-Feb-19 Related CR: 2019051037

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Hyperaesthesia eyelid* | Rejected | | |
| HLT primary | *Ocular sensation disorders* | | | |
| SOC primary | *Eye disorders* | | | |

MSSO Comment: The proposal to add a new PT Hyperaesthesia eyelid to primary HLT Ocular sensation disorders in SOC Eye disorders and secondary HLT Paraesthesias and dysaesthesias in SOC Nervous system disorders is not approved. It is not feasible to add to any possible anatomical sites, terms for an-,dys-, hyper-,hypo-, paraesthesia as this may lead to overgranulation at PT level and signal dilution. The requested term can be represented by split coding with LLT Eyelid sensory disorder and LLT Hyperaesthesia skin or LLT Hyperaesthesia.

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# Supplemental Update Report

**CR Number: 2019051038** **Implementation Date:** 28-Feb-19 Related CR: 2019051038

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Paraesthesia eyelid* | Rejected | | |
| HLT primary | *Ocular sensation disorders* | | | |
| SOC primary | *Eye disorders* | | | |

MSSO Comment: The proposal to add a new PT Paraesthesia eyelid to primary HLT Ocular sensation disorders in SOC Eye disorders and secondary HLT Paraesthesias and dysaesthesias in SOC Nervous system disorders is not approved. It is not feasible to add to any possible anatomical sites, terms for an-,dys-, hyper-,hypo-, paraesthesia as this may lead to overgranulation at PT level and signal dilution. The requested term can be represented by split coding with LLT Eyelid sensory disorder and LLT Paraesthesia.

**CR Number: 2019051039** **Implementation Date:** 28-Feb-19 Related CR: 2019051039

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Medication too hard to chew* | Approved as Requested | Proposed LLT | | |
| | | | *Medication too hard to chew* | 10073761 | Current |
| From PT | *Product physical consistency issue* | | From PT | | |
| | | | *Product physical consistency issue* | 10073760 | |
| To PT | *Product use complaint* | | To PT | | |
| | | | *Product use complaint* | 10079400 | |

MSSO Comment: The proposal to move the LLT Medication too hard to chew from PT Product physical consistency issue to PT Product use complaint is approved as requested for better alignment with similar LLT Product difficult to swallow. Medication too hard to chew in a report rather refers to a patient perception/complaint and does not indicate a quality issue in first instance.

# Supplemental Update Report

**CR Number: 2019051040** **Implementation Date:** 28-Feb-19 Related CR: 2019051040

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Scrotal eczema* | Approved as Requested | Proposed LLT | |
| From PT | *Eczema* | | *Scrotal eczema* | 10050178 |
| HLT primary | *Scrotal disorders NEC* | | From PT | |
| | | | *Eczema* | 10014184 |
| | | | HLT primary | |
| | | | *Scrotal disorders NEC* | 10039745 |
| | | | SOC primary | |
| | | | *Reproductive system and breast disorders* | 10038604 |
| | | | HLT secondary | |
| | | | *Dermatitis and eczema* | 10012435 |
| | | | SOC secondary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment: The proposal to promote the LLT Scrotal eczema from PT Eczema to primary HLT Scrotal disorders NEC in SOC Reproductive system and breast disorders and secondary HLT Dermatitis and eczema in SOC Skin and subcutaneous tissue disorders is approved as requested for better representation of this skin condition with primary link to its site of manifestation SOC.

# Supplemental Update Report

**CR Number: 2019051041** **Implementation Date:** 28-Feb-19 Related CR: 2019051041

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Scrotal haemorrhage* | Approved as Requested | Proposed LLT | |
| From PT | *Scrotal haematocoele* | | *Scrotal haemorrhage* | 10061361 |
| HLT primary | *Scrotal disorders NEC* | | From PT | |
| | | | *Scrotal haematocoele* | 10061517 |
| | | | HLT primary | |
| | | | *Scrotal disorders NEC* | 10039745 |
| | | | SOC primary | |
| | | | *Reproductive system and breast disorders* | 10038604 |
| | | | HLT secondary | |
| | | | *Reproductive system haemorrhages* | 10052743 |
| | | | SOC secondary | |
| | | | *Vascular disorders* | 10047065 |

MSSO Comment: The proposal to promote the LLT Scrotal haemorrhage from PT Scrotal haematocoele to primary HLT Scrotal disorders NEC in SOC Reproductive system and breast disorders and secondary HLT Reproductive system haemorrhages in SOC Vascular disorders is approved as requested. Scrotal haemorrhage and scrotal haematocoele are two distinct concepts as scrotal haemorrhage can be caused by a superficial bleeding of the scrotal skin only. In a related change, the American spelled LLT Scrotal hemorrhage will be moved from PT Scrotal haematocoele to the newly promoted PT Scrotal haemorrhage.

**CR Number: 2019059008** **Implementation Date:** 28-Feb-19 Related CR: 2019051041

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Scrotal hemorrhage* | Approved as Requested | Proposed LLT | |
| From PT | *Scrotal haematocoele* | | *Scrotal hemorrhage* | 10061362 Current |
| To PT | *Scrotal haemorrhage* | | From PT | |
| | | | *Scrotal haematocoele* | 10061517 |
| | | | To PT | |
| | | | *Scrotal haemorrhage* | 10061361 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019051042** **Implementation Date:** 28-Feb-19 Related CR: 2019051042

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Scrotum erosion* | Approved as Requested | Proposed LLT | |
| From PT | *Scrotal ulcer* | | *Scrotum erosion* | 10039763 |
| HLT primary | *Scrotal disorders NEC* | | From PT | |
| | | | *Scrotal ulcer* | 10039760 |
| | | | HLT primary | |
| | | | *Scrotal disorders NEC* | 10039745 |
| | | | SOC primary | |
| | | | *Reproductive system and breast disorders* | 10038604 |
| | | | HLT secondary | |
| | | | *Skin and subcutaneous tissue ulcerations* | 10040796 |
| | | | SOC secondary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment: The proposal to promote the LLT Scrotum erosion from PT Scrotal ulcer to primary HLT Scrotal disorders NEC in SOC Reproductive system and breast disorders and secondary HLT Skin and subcutaneous tissue ulcerations in SOC Skin and subcutaneous tissue disorders is approved as requested. Often it is very difficult to distinguish between ulcer and erosion as they are often used in the same context. Ulcer is defined as a lesion that is eroding the skin or mucous membrane so that subordinating erosion terms as LLTs under ulcer PTs could be defendable. However, in MedDRA as a coding dictionary, erosions and ulcers are represented both on PT level for most existing anatomical sites. In a related change and for similar reasons, LLT Penile erosion will be promoted from under PT Penile ulceration and linked to primary HLT Penile disorders NEC (excl erection and ejaculation) and secondary HLT Skin and subcutaneous tissue ulcerations.

# Supplemental Update Report

**CR Number: 2019059007** **Implementation Date:** 28-Feb-19 Related CR: 2019051042

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Penile erosion* | Approved as Requested | Proposed LLT | |
| From PT | *Penile ulceration* | | *Penile erosion* | 10064061 |
| HLT primary | *Penile disorders NEC (excl erection and ejaculation)* | | From PT | |
| | | | *Penile ulceration* | 10034322 |
| | | | HLT primary | |
| | | | *Penile disorders NEC (excl erection and ejaculation)* | 10034304 |
| | | | SOC primary | |
| | | | *Reproductive system and breast disorders* | 10038604 |
| | | | HLT secondary | |
| | | | *Skin and subcutaneous tissue ulcerations* | 10040796 |
| | | | SOC secondary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment:

**CR Number: 2019051043** **Implementation Date:** 28-Feb-19 Related CR: 2019051043

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Scrotal injury* | Approved as Requested | Proposed PT | |
| HLT primary | *Reproductive system and breast injuries* | | *Scrotal injury* | 10082770 |
| SOC primary | *Injury, poisoning and procedural complications* | | HLT primary | |
| | | | *Reproductive system and breast injuries* | 10057193 |
| | | | SOC primary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |
| | | | HLT secondary | |
| | | | *Scrotal disorders NEC* | 10039745 |
| | | | SOC secondary | |
| | | | *Reproductive system and breast disorders* | 10038604 |

MSSO Comment: The proposal to add a new PT Scrotal injury to primary HLT Reproductive system and breast injuries in SOC Injury, poisoning and procedural complications and secondary HLT Scrotal disorders NEC in SOC Reproductive system and breast disorders is approved as requested. A wide variety of mechanisms can result in scrotal trauma, with a common endpoint of blunt and/or penetrating trauma to the scrotal area. In all cases but avulsion, this trauma manifests as scrotal swelling with intratesticular and scrotal hematoma and various degrees of scrotal wall ecchymosis.

# Supplemental Update Report

**CR Number: 2019051044** **Implementation Date:** 28-Feb-19 Related CR: 2019051044

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Scrotal discomfort* | Approved as Requested | Proposed PT | |
| HLT primary | *Scrotal disorders NEC* | | *Scrotal discomfort* | 10082765 |
| SOC primary | *Reproductive system and breast disorders* | | HLT primary | |
| | | | *Scrotal disorders NEC* | 10039745 |
| | | | SOC primary | |
| | | | *Reproductive system and breast disorders* | 10038604 |

MSSO Comment: The proposal to add a new PT Scrotal discomfort to primary HLT Scrotal disorders NEC in SOC Reproductive system and breast disorders is approved as requested. Scrotal discomfort is usually used to describe a dull, aching, or throbbing sensation of the scrotum or its contents, the testicles and their supporting structures.

**CR Number: 2019051045** **Implementation Date:** 26-Feb-19 Related CR: 2019051045

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Acquired Factor IX deficiency* | Approved Not as Requested | Proposed PT | |
| | | | *Acquired factor IX deficiency* | 10082747 |
| SOC primary | *Blood and lymphatic system disorders* | | HLT primary | |
| | | | *Coagulation factor deficiencies* | 10009737 |
| | | | SOC primary | |
| | | | *Blood and lymphatic system disorders* | 10005329 |

MSSO Comment: The proposal to add a new PT Acquired Factor IX deficiency in SOC Blood and lymphatic system disorders is approved but not as requested. Acquired factor IX deficiency can occur in a number of situations. One possibility is the presence of a spontaneously developed specific inhibitor to factor IX. Such an antibody can also appear in a patient with hemophilia B (factor IX deficiency) following treatment with factor IX, either prophylactically or to treat a bleeding episode. In this situation, the patient already has factor IX deficiency, but it can be made more severe by the presence of an antibody to factor IX. Factor IX deficiency can also be acquired in patients who have vitamin K deficiency. In this situation, there is also an accompanying deficiency of factor II, factor VII, factor X, protein C, and protein S. Acquired Factor IX deficiency will be modified in accordance with MedDRA capitalisation conventions and added as PT Acquired factor IX deficiency to HLT Coagulation factor deficiencies.

# Supplemental Update Report

**CR Number: 2019051046** **Implementation Date:** 26-Feb-19 Related CR: 2019051046

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Acquired Factor VIII deficiency* | Approved Not as Requested | Proposed PT<br>*Acquired factor VIII deficiency* | 10082745 |
| SOC primary | *Blood and lymphatic system disorders* | | HLT primary<br>*Coagulation factor deficiencies* | 10009737 |
| | | | SOC primary<br>*Blood and lymphatic system disorders* | 10005329 |

MSSO Comment: The proposal to add a new PT Acquired Factor VIII deficiency in SOC Blood and lymphatic system disorders is approved but not as requested. Hemophilia A is classically caused by a congenital deficiency of factor VIII, but an acquired form due to inhibitors to factor VIII (FVIII) typically presents later in life. Patients who develop such acquired factor VIII inhibitors may present with catastrophic bleeding episodes, despite having no prior history of a bleeding disorder. Though the disorder is rare, it is known to cause significant morbidity and mortality. Acquired factor VIII deficiency, will be modified in accordance with MedDRA capitalisation conventions and added as a PT to HLT Coagulation factor deficiencies.

**CR Number: 2019051047** **Implementation Date:** 26-Feb-19 Related CR: 2019051047

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Acquired Factor XI deficiency* | Approved Not as Requested | Proposed PT<br>*Acquired factor XI deficiency* | 10082746 |
| SOC primary | *Blood and lymphatic system disorders* | | HLT primary<br>*Coagulation factor deficiencies* | 10009737 |
| | | | SOC primary<br>*Blood and lymphatic system disorders* | 10005329 |

MSSO Comment: The proposal to add a new PT Acquired Factor XI deficiency in SOC Blood and lymphatic system disorders is approved but not as requested. Development of autoantibodies against coagulation factors is an uncommon bleeding disorder associated with cancer, autoimmune conditions, pregnancy, or no apparent disease. Spontaneous FVIII inhibitors are the most frequently encountered. Few cases of acquired FXI inhibitor have been reported in association with connective tissue disease, cancer, or surgery. Acquired factor XI deficiency, in accordance with MedDRA capitalisation conventions will be added as PT to HLT Coagulation factor deficiencies.

# Supplemental Update Report

**CR Number: 2019051048** **Implementation Date:** 26-Feb-19 Related CR: 2019051048

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed PT | *Acquired Haemophilia A with anti factor VIII* | Approved Not as Requested | Proposed LLT | | |
| | | | *Acquired haemophilia A with anti factor VIII* | 10082749 | Current |
| SOC primary | *Blood and lymphatic system disorders* | | To PT | | |
| | | | *Acquired haemophilia* | 10053745 | |

MSSO Comment: The proposal to add a new PT Acquired Haemophilia A with anti factor VIII in SOC Blood and lymphatic system disorders is approved but not as requested. Acquired hemophilia A is a rare bleeding diathesis caused by autoantibodies directed against clotting factor VIII and associated with an increased morbidity and mortality. Acquired haemophilia A with anti factor VIII, modified in accordance with MedDRA capitalisation conventions, will be added as a sub-concept LLT to PT Acquired haemophilia. In a related change, the American English counterpart LLT Acquired hemophilia A with anti factor VIII will be added to the PT Acquired haemophilia. Furthermore, PT Acquired haemophilia with anti FVIII, XI, or XIII will be demoted under PT Acquired haemophilia for better alignment of related concepts.

**CR Number: 2019057001** **Implementation Date:** 26-Feb-19 Related CR: 2019051048

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| PT to merge | *Acquired haemophilia with anti FVIII, XI, or XIII* | Approved as Requested | PT to merge | | |
| To PT | *Acquired haemophilia* | | *Acquired haemophilia with anti FVIII, XI, or XIII* | 10056496 | Current |
| | | | To PT | | |
| | | | *Acquired haemophilia* | 10053745 | |

MSSO Comment:

**CR Number: 2019057003** **Implementation Date:** 26-Feb-19 Related CR: 2019051048

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Acquired hemophilia A with anti factor VIII* | Approved as Requested | Proposed LLT | | |
| To PT | *Acquired haemophilia* | | *Acquired hemophilia A with anti factor VIII* | 10082751 | Current |
| | | | To PT | | |
| | | | *Acquired haemophilia* | 10053745 | |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019051049** **Implementation Date:** 26-Feb-19 Related CR: 2019051049

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Acquired Haemophilia B with anti factor IX* | Approved Not as Requested | Proposed LLT<br>*Acquired haemophilia B with anti factor IX* | 10082748 Current |
| SOC primary | *Blood and lymphatic system disorders* | | To PT<br>*Acquired haemophilia* | 10053745 |

MSSO Comment: The proposal to add a new PT Acquired Haemophilia B with anti factor IX in SOC Blood and lymphatic system disorders is approved but not as requested. Acquired hemophilia B is associated with the presence in non-hemophiliac subjects of antibodies directed against factor IX. This is a rare disease that can occur in particular in women during or at the end of pregnancy, in patients with autoimmune disease, and in elderly subjects. Acquired haemophilia B with anti factor IX, modified in accordance with MedDRA capitalisation conventions, will be added as a sub-concept LLT to PT Acquired haemophilia. In a related change, the American English counterpart LLT Acquired hemophilia B with anti factor IX will be added to the PT Acquired haemophilia.

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**CR Number: 2019057002** **Implementation Date:** 26-Feb-19 Related CR: 2019051049

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Acquired hemophilia B with anti factor IX* | Approved as Requested | Proposed LLT<br>*Acquired hemophilia B with anti factor IX* | 10082750 Current |
| To PT | *Acquired haemophilia* | | To PT<br>*Acquired haemophilia* | 10053745 |

MSSO Comment:

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**CR Number: 2019052001** **Implementation Date:** 26-Feb-19 Related CR: 2019052001

| Change Requested | Rename PT/LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Term to modify | *Plasminogen activator inhibitor deficiency type 1* | Approved as Requested | Term to modify<br>*Plasminogen activator inhibitor deficiency type 1* | |
| Replacement term | *Plasminogen activator inhibitor type 1 deficiency* | | Replacement term<br>*Plasminogen activator inhibitor type 1 deficiency* | 10082567 |

MSSO Comment: The proposal to rename PT/LLT Plasminogen activator inhibitor deficiency type 1 to Plasminogen activator inhibitor type 1 deficiency is approved as requested. The proposed replacement term is more frequently used in medical searches.

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# Supplemental Update Report

**CR Number: 2019052002** **Implementation Date:** 26-Feb-19 Related CR: 2019052002

| Change Requested | Rename PT/LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Term to modify | *Urinary neutrophil gelatin-associated lipocalin increased* | Approved as Requested | Term to modify<br>*Urinary neutrophil gelatin-associated lipocalin increased* | |
| Replacement term | *Urinary neutrophil gelatinase-associated lipocalin increased* | | Replacement term<br>*Urinary neutrophil gelatinase-associated lipocalin increased* | 10082705 Current |

MSSO Comment: The proposal to rename PT/LLT Urinary neutrophil gelatin-associated lipocalin increased to Urinary neutrophil gelatinase-associated lipocalin increased is approved as requested. The proposed replacement term is the medically accepted name for this molecule.

**CR Number: 2019052003** **Implementation Date:** 26-Feb-19 Related CR: 2019052003

| Change Requested | Rename PT/LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Term to modify | *Neutrophil gelatin-associated lipocalin increased* | Approved as Requested | Term to modify<br>*Neutrophil gelatin-associated lipocalin increased* | |
| Replacement term | *Neutrophil gelatinase-associated lipocalin increased* | | Replacement term<br>*Neutrophil gelatinase-associated lipocalin increased* | 10082703 |

MSSO Comment: The proposal to rename PT/LLT Neutrophil gelatin-associated lipocalin increased to Neutrophil gelatinase-associated lipocalin increased is approved as requested. The proposed replacement term is the medically accepted name for this molecule.

**CR Number: 2019052004** **Implementation Date:** 26-Feb-19 Related CR: 2019052004

| Change Requested | Rename PT/LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Term to modify | *Urinary neutrophil gelatin-associated lipocalin* | Approved as Requested | Term to modify<br>*Urinary neutrophil gelatin-associated lipocalin* | |
| Replacement term | *Urinary neutrophil gelatinase-associated lipocalin* | | Replacement term<br>*Urinary neutrophil gelatinase-associated lipocalin* | 10082702 Current |

MSSO Comment: The proposal to rename PT/LLT Urinary neutrophil gelatin-associated lipocalin to Urinary neutrophil gelatinase-associated lipocalin is approved as requested. The proposed replacement term is the medically accepted name for this molecule.

# Supplemental Update Report

**CR Number: 2019052005** **Implementation Date:** 26-Feb-19 Related CR: 2019052005

| Change Requested | Rename PT/LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Term to modify | *Neutrophil gelatin-associated lipocalin* | Approved as Requested | Term to modify | |
| Replacement term | *Neutrophil gelatinase-associated lipocalin* | | *Neutrophil gelatin-associated lipocalin* | |
| | | | Replacement term | |
| | | | *Neutrophil gelatinase-associated lipocalin* | 10082700 |

MSSO Comment: The proposal to rename PT/LLT Neutrophil gelatin-associated lipocalin to Neutrophil gelatinase-associated lipocalin is approved as requested. The proposed replacement term is the medically accepted name for this molecule.

**CR Number: 2019052006** **Implementation Date:** 26-Feb-19 Related CR: 2019052006

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Mee's line* | Approved as Requested | Proposed LLT | |
| From PT | *Metal poisoning* | | *Mee's line* | 10027108 Current |
| To PT | *Leukonychia* | | From PT | |
| | | | *Metal poisoning* | 10027439 |
| | | | To PT | |
| | | | *Leukonychia* | 10050658 |

MSSO Comment: The proposal to move the LLT Mee's line from PT Metal poisoning to PT Leukonychia is approved as requested. The LLT Mee's line will be moved from its current PT Metal poisoning to PT Leukonychia since Mee's lines can also be seen in conditions other than heavy metals (such as renal failure and exposure to certain chemotherapeutic agents).

# Supplemental Update Report

**CR Number: 2019052007** **Implementation Date:** 26-Feb-19 Related CR: 2019052007

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Phrenic nerve injury* | Approved as Requested | Proposed PT | |
| | | | *Phrenic nerve injury* | 10082761 |
| | | | HLT primary | |
| | | | *Nerve injuries NEC* | 10052639 |
| | | | SOC primary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |
| | | | HLT secondary | |
| | | | *Paralysis and paresis (excl cranial nerve)* | 10033800 |
| | | | SOC secondary | |
| | | | *Nervous system disorders* | 10029205 |

MSSO Comment: The proposal to add a new term Phrenic nerve injury is approved as requested. The phrenic nerve provides the primary motor supply to the diaphragm, the major respiratory muscle. Phrenic nerve injury may present as diaphragmatic dysfunction, unilateral diaphragmatic paralysis, or bilateral diaphragmatic paralysis. Etiologies include: complication of thoracic and cardiac surgery, blunt or penetrating trauma, metabolic diseases such as diabetes, infectious causes such as Lyme disease and herpes zoster, direct invasion by tumor, neurological diseases, and immunological diseases. Phrenic nerve injury will be added as a new PT to primary HLT Nerve injuries NEC, and to secondary HLT Paralysis and paresis (excl cranial nerve). In a related change, HLT for PT Phrenic nerve paralysis will be changed from HLT Mononeuropathies to HLT Paralysis and paresis (excl cranial nerve) for better alignment.

**CR Number: 2019057004** **Implementation Date:** 26-Feb-19 Related CR: 2019052007

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Phrenic nerve paralysis* | Approved as Requested | Proposed PT | |
| From HLT | *Mononeuropathies* | | *Phrenic nerve paralysis* | 10064964 |
| To HLT | *Paralysis and paresis (excl cranial nerve)* | | From HLT | |
| | | | *Mononeuropathies* | 10027917 |
| | | | To HLT | |
| | | | *Paralysis and paresis (excl cranial nerve)* | 10033800 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019052008** **Implementation Date:** 27-Mar-19 Related CR: 2019052008

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Burkholderia cepacia complex sepsis* | Approved as Requested | Proposed PT<br>*Burkholderia cepacia complex sepsis* | 10069684 |
| To SMQ | *Agranulocytosis (SMQ)* | | To SMQ<br>*Agranulocytosis (SMQ)* | 20000023 |
| Term scope | *Broad* | | Term scope<br>*Broad*<br>Term_category<br>*A*<br>Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Burkholderia cepacia complex sepsis to Agranulocytosis (SMQ) as a broad term is approved as requested. Species-specific forms of sepsis are currently captured as broad search terms in this SMQ.

**CR Number: 2019052009** **Implementation Date:** 27-Mar-19 Related CR: 2019052009

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Capnocytophaga sepsis* | Approved as Requested | Proposed PT<br>*Capnocytophaga sepsis* | 10081740 |
| To SMQ | *Agranulocytosis (SMQ)* | | To SMQ<br>*Agranulocytosis (SMQ)* | 20000023 |
| Term scope | *Broad* | | Term scope<br>*Broad*<br>Term_category<br>*A*<br>Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Capnocytophaga sepsis to Agranulocytosis (SMQ) as a broad term is approved as requested. Species-specific forms of sepsis are currently captured as broad search terms in this SMQ.

# Supplemental Update Report

**CR Number: 2019052010** **Implementation Date:** 27-Mar-19 Related CR: 2019052010

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Toxic shock syndrome* | Approved as Requested | Proposed PT<br>*Toxic shock syndrome* | 10044248 |
| To SMQ | *Agranulocytosis (SMQ)* | | To SMQ<br>*Agranulocytosis (SMQ)* | 20000023 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Toxic shock syndrome to Agranulocytosis (SMQ) as a broad term is approved as requested. This is a life-threatening syndrome associated with an overwhelming infection. As the presence and degree of neutropenia is variable, it will be included in the broad search terms of this SMQ.

**CR Number: 2019052011** **Implementation Date:** 27-Mar-19 Related CR: 2019052011

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Toxic shock syndrome staphylococcal* | Approved as Requested | Proposed PT<br>*Toxic shock syndrome staphylococcal* | 10044250 |
| To SMQ | *Agranulocytosis (SMQ)* | | To SMQ<br>*Agranulocytosis (SMQ)* | 20000023 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Toxic shock syndrome staphylococcal to Agranulocytosis (SMQ) as a broad term is approved as requested. This is a life-threatening syndrome associated with an overwhelming infection. As the presence and degree of neutropenia is variable, it will be included in the broad search terms of this SMQ.

# Supplemental Update Report

**CR Number: 2019052012** **Implementation Date:** 27-Mar-19 Related CR: 2019052012

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Toxic shock syndrome streptococcal* | Approved as Requested | Proposed PT<br>*Toxic shock syndrome streptococcal* | 10044251 |
| To SMQ | *Agranulocytosis (SMQ)* | | To SMQ<br>*Agranulocytosis (SMQ)* | 20000023 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Toxic shock syndrome streptococcal to Agranulocytosis (SMQ) as a broad term is approved as requested. This is a life-threatening syndrome associated with an overwhelming infection. As the presence and degree of neutropenia is variable, it will be included in the broad search terms of this SMQ.

**CR Number: 2019052013** **Implementation Date:** 27-Mar-19 Related CR: 2019052013

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Endotoxic shock* | Approved as Requested | Proposed PT<br>*Endotoxic shock* | 10014824 |
| To SMQ | *Agranulocytosis (SMQ)* | | To SMQ<br>*Agranulocytosis (SMQ)* | 20000023 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Endotoxic shock to Agranulocytosis (SMQ) as a broad term is approved as requested. This type of shock, caused by the effect of endotoxins, is a life-threatening event. As the presence and degree of neutropenia is variable, it will be included in the broad search terms of this SMQ.

# Supplemental Update Report

**CR Number: 2019052014** **Implementation Date:** 27-Mar-19 Related CR: 2019052014

| Change Requested | Update MedDRA term_scope | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Shigella sepsis* | Approved as Requested | Proposed PT *Shigella sepsis* | 10074481 |
| To SMQ | *Agranulocytosis (SMQ)* | | To SMQ *Agranulocytosis (SMQ)* | 20000023 |
| Term scope | *Broad* | | Term scope *Broad* | |

MSSO Comment: The proposal to change the scope of the PT Shigella sepsis in Agranulocytosis (SMQ) to Broad is approved as requested. Species-specific forms of sepsis are currently captured as broad search terms of this SMQ.

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**CR Number: 2019052015** **Implementation Date:** 27-Mar-19 Related CR: 2019052015

| Change Requested | Update MedDRA term_scope | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Intestinal sepsis* | Approved as Requested | Proposed PT *Intestinal sepsis* | 10075622 |
| To SMQ | *Agranulocytosis (SMQ)* | | To SMQ *Agranulocytosis (SMQ)* | 20000023 |
| Term scope | *Broad* | | Term scope *Broad* | |

MSSO Comment: The proposal to change the scope of the PT Intestinal sepsis in Agranulocytosis (SMQ) to Broad is approved as requested. Organ-specific sepsis terms are currently included in the broad search terms of this SMQ.

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**CR Number: 2019053001** **Implementation Date:** 26-Feb-19 Related CR: 2019053001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Panic anxiety syndrome* | Rejected | | |

MSSO Comment: The proposal to add a new term Panic anxiety syndrome is not approved. Panic disorder, also called episodic paroxysmal anxiety, is a type of anxiety disorder and best represented by LLT/PT Panic disorder.

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# Supplemental Update Report

**CR Number: 2019053002** **Implementation Date:** 26-Feb-19 Related CR: 2019053002

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Pleural nodules* | Rejected | | |

MSSO Comment: The proposal to add a new term Pleural nodules is not approved. The MSSO generally refrains from adding additional “nodule” terms except when a nodule represents a full diagnostic expression e.g. PT Milker’s nodules. Please consider existing terms LLT Pleural mass, or LLT Pleural disorder. In a related change PT Pleural mass will be linked to HLT Pleural conditions NEC. In addition, the primary SOC for PT Pleural mass will be re-assigned from SOC Musculoskeletal and connective tissue disorders to SOC Respiratory, thoracic and mediastinal disorders and the PT Pleural mass will be de-linked from HLT Musculoskeletal and connective tissue conditions NEC.

**CR Number: 2019057005** **Implementation Date:** 26-Feb-19 Related CR: 2019053002

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pleural mass* | Approved as Requested | Proposed PT | |
| To HLT | *Pleural conditions NEC* | | *Pleural mass* | 10082101 |
| | | | To HLT | |
| | | | *Pleural conditions NEC* | 10035594 |

MSSO Comment:

**CR Number: 2019057006** **Implementation Date:** 26-Feb-19 Related CR: 2019053002

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pleural mass* | Approved as Requested | Proposed PT | |
| Old Primary SOC | *Musculoskeletal and connective tissue disorders* | | *Pleural mass* | 10082101 |
| | | | Old Primary SOC | |
| New Primary SOC | *Respiratory, thoracic and mediastinal disorders* | | *Musculoskeletal and connective tissue disorders* | 10028395 |
| | | | New Primary SOC | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019057007** **Implementation Date:** 26-Feb-19 Related CR: 2019053002

| Change Requested | Unlink a PT from a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pleural mass* | Approved as Requested | Proposed PT | |
| From HLT | *Musculoskeletal and connective tissue conditions NEC* | | *Pleural mass* | 10082101 |
| | | | From HLT | |
| | | | *Musculoskeletal and connective tissue conditions NEC* | 10080711 |

MSSO Comment:

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**CR Number: 2019053003** **Implementation Date:** 26-Feb-19 Related CR: 2019053003

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Redness of inner eyelids* | Approved Not as Requested | Proposed LLT | |
| | | | *Redness of eyelid conjunctiva* | 10082762 Current |
| | | | To PT | |
| | | | *Conjunctival hyperaemia* | 10051625 |

MSSO Comment: The proposal to add a new term Redness of inner eyelids is approved but not as requested. Conjunctival hyperaemia is commonly associated with infectious, allergic, and other inflammatory conditions, and may occur in the bulbar (eye) conjunctiva and/or the palpebral (lid) conjunctiva. Redness of inner eyelids will be rephrased as Redness of eyelid conjunctiva, and added as a sub-concept LLT to PT Conjunctival hyperaemia.

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**CR Number: 2019059001** **Implementation Date:** 07-Mar-19 Related CR: 2019059001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Asynclitism* | Approved as Requested | Proposed LLT | |
| To PT | *Asynclitic presentation* | | *Asynclitism* | 10082789 Current |
| | | | To PT | |
| | | | *Asynclitic presentation* | 10082614 |

MSSO Comment: The proposal to add a new LLT Asynclitism to PT Asynclitic presentation is approved as requested. Asynclitism, synonym to PT Asynclitic presentation, refers to the position of a fetus in the uterus such that the head of the baby is presenting first and is tilted to the shoulder, causing the fetal head to no longer be in line with the birth canal.

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# Supplemental Update Report

**CR Number: 2019059002** **Implementation Date:** 07-Mar-19 Related CR: 2019059002

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Hemophilia B* | Approved as Requested | Proposed LLT | |
| To PT | *Factor IX deficiency* | | *Hemophilia B* | 10082786 Current |
| | | | To PT | |
| | | | *Factor IX deficiency* | 10016077 |

MSSO Comment: The proposal to add a new LLT Hemophilia B to PT Factor IX deficiency is approved as requested. Hemophilia B, also called factor IX deficiency or Christmas disease, is a genetic disorder caused by missing or defective factor IX, a clotting protein. In a related change, the British English counterpart spelling, LLT Haemophilia B will also be added to PT Factor IX deficiency.

**CR Number: 2019066015** **Implementation Date:** 07-Mar-19 Related CR: 2019059002

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Haemophilia B* | Approved as Requested | Proposed LLT | |
| To PT | *Factor IX deficiency* | | *Haemophilia B* | 10082788 Current |
| | | | To PT | |
| | | | *Factor IX deficiency* | 10016077 |

MSSO Comment:

**CR Number: 2019059003** **Implementation Date:** 07-Mar-19 Related CR: 2019059003

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Diabetic osteoarthropathy* | Approved as Requested | Proposed LLT | |
| | | | *Diabetic osteoarthropathy* | 10082787 Current |
| | | | To PT | |
| | | | *Neuropathic arthropathy* | 10029326 |

MSSO Comment: The proposal to add a new term Diabetic osteoarthropathy is approved as requested. Diabetic neuropathic arthropathy, also called diabetic osteoarthropathy, is the loss of sensation to a joint in diabetic patients which may result in a chronic, progressive, and destructive arthropathy. Diabetic osteoarthropathy will be added as a sub-concept LLT to PT Neuropathic arthropathy. In a related change, PT Diabetic arthropathy will be demoted under PT Neuropathic arthropathy as a sub-concept LLT as diabetes is the most common cause of neuropathic arthropathy. Furthermore, HLT in primary SOC for PT Neuropathic arthropathy will be changed from HLT Arthropathies NEC to HLT Osteoarthropathies. In an addition, secondary HLT Diabetic complications neurological will be added to PT Neuropathic arthropathy.

# Supplemental Update Report

**CR Number: 2019066016** **Implementation Date:** 07-Mar-19 Related CR: 2019059003

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Diabetic arthropathy* | Approved as Requested | PT to merge | |
| | | | *Diabetic arthropathy* | 10012644 Current |
| To PT | *Neuropathic arthropathy* | | To PT | |
| | | | *Neuropathic arthropathy* | 10029326 |

MSSO Comment:

**CR Number: 2019066017** **Implementation Date:** 07-Mar-19 Related CR: 2019059003

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Neuropathic arthropathy* | Approved as Requested | Proposed PT | |
| | | | *Neuropathic arthropathy* | 10029326 |
| From HLT | *Arthropathies NEC* | | From HLT | |
| | | | *Arthropathies NEC* | 10003284 |
| To HLT | *Osteoarthropathies* | | To HLT | |
| | | | *Osteoarthropathies* | 10057178 |

MSSO Comment:

**CR Number: 2019066018** **Implementation Date:** 07-Mar-19 Related CR: 2019059003

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Neuropathic arthropathy* | Approved as Requested | Proposed PT | |
| | | | *Neuropathic arthropathy* | 10029326 |
| To HLT | *Diabetic complications neurological* | | To HLT | |
| | | | *Diabetic complications neurological* | 10012656 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019059004** **Implementation Date:** 07-Mar-19 Related CR: 2019059004

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Peritonitis perforative* | Rejected | | |
| From PT | *Peritonitis* | | | |
| HLT primary | *Abdominal and gastrointestinal infections* | | | |

MSSO Comment: The proposal to promote the LLT Peritonitis perforative from PT Peritonitis to primary HLT Abdominal and gastrointestinal infections in SOC Infections and infestations and secondary HLT Gastrointestinal ulcers and perforation, site unspecified in SOC Gastrointestinal disorders is not approved. To avoid overpopulation at the PT level, the different etiologies of peritonitis are represented at the LLT level (e.g.: Infectious peritonitis; Peritonitis suppurative; Septic peritonitis; Stercoral peritonitis). To represent the perforation etiology in a given case, a second term may be selected from these specific LLTs grouped under Gastrointestinal ulceration and perforation HLGT.

**CR Number: 2019059017** **Implementation Date:** 07-Mar-19 Related CR: 2019059017

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Chest pain atypical* | Rejected | | |

MSSO Comment: The proposal to add a new LLT Chest pain atypical is not approved. The qualifier "atypical" could be applied to any condition whose clinical appearance is not as expected or coincidental with a classic medical description. Appliance of such modifier would lead to overpopulation of MedDRA, and should be used only in those cases where it has a clear diagnostic value (e.g. Atypical mycobacterial infection; Atypical fracture; etc). Please consider PT/LLT Chest pain, or another appropriate LLT subordinate to this PT for your coding needs.

**CR Number: 2019060001** **Implementation Date:** 07-Mar-19 Related CR: 2019060001

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *ROS1 gene rearrangement* | Approved as Requested | Proposed PT | |
| HLT primary | *Acquired gene mutations and other alterations* | | *ROS1 gene rearrangement* | 10082790 |
| SOC primary | *General disorders and administration site conditions* | | HLT primary | |
| | | | *Acquired gene mutations and other alterations* | 10071951 |
| | | | SOC primary | |
| | | | *General disorders and administration site conditions* | 10018065 |

MSSO Comment: The proposal to add a new PT ROS1 gene rearrangement to primary HLT Acquired gene mutations and other alterations in SOC General disorders and administration site conditions is approved as requested. In non-small cell lung Cancer (NSCLC) and other tumors, the ROS1 gene can undergo rearrangement, resulting in a fusion protein. ROS1 fusion proteins are oncogenic drivers, which constitutively activate multiple signaling pathways that promote tumor growth and survival. ROS1 rearrangements occur in 1%-2% of patients with NSCLC.

# Supplemental Update Report

**CR Number: 2019060002** **Implementation Date:** 07-Mar-19 Related CR: 2019060002

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vaginal dilation procedure* | Approved as Requested | Proposed PT | |
| | | | *Vaginal dilation procedure* | 10082791 |
| HLT primary | *Vaginal therapeutic procedures* | | HLT primary | |
| | | | *Vaginal therapeutic procedures* | 10046936 |
| SOC primary | *Surgical and medical procedures* | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment: The proposal to add a new PT Vaginal dilation procedure to primary HLT Vaginal therapeutic procedures in SOC Surgical and medical procedures is approved as requested. Vaginal dilatation is used to restore vaginal capacity, to expand the vagina in width and depth, to provide elasticity to the tissues, and to allow for comfortable sexual activity. Several medical conditions may warrant the use of vaginal dilation, including dyspareunia, high-tone pelvic floor dysfunction, vaginismus, vaginal atrophy, vulvar dermatoses, vaginal agenesis, and postradiation adhesions.

**CR Number: 2019060003** **Implementation Date:** 07-Mar-19 Related CR: 2019060003

| Change Requested | Rename PT/LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Term to modify | *Perirobital burning sensation* | Approved as Requested | Term to modify | |
| | | | *Perirobital burning sensation* | |
| Replacement term | *Periorbital burning sensation* | | Replacement term | |
| | | | *Periorbital burning sensation* | 10082772 Current |

MSSO Comment: The proposal to rename PT/LLT Perirobital burning sensation to Periorbital burning sensation is approved as requested. In change request 2019051020, the newly added LLT Periorbital burning sensation, was misspelled. As a result, LLT Perirobital burning sensation will be renamed as LLT Periorbital burning sensation to correct the misspelling.

**CR Number: 2019064001** **Implementation Date:** 07-Mar-19 Related CR: 2019064001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Anal fistula repair* | Approved as Requested | Proposed PT | |
| | | | *Anal fistula repair* | 10082792 |
| | | | HLT primary | |
| | | | *Anorectal therapeutic procedures* | 10002580 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment: The proposal to add a new term Anal fistula repair is approved as requested. The goals of surgical repair of an anal fistula includes a variety of options and approaches, including: fistulotomy, rectal flap, seton placement, fibrin glue and collagen plug, ligation of the intersphincteric fistula tract, ostomy and stoma, and muscle flap. Anal fistula repair will be added as a new PT to HLT Anorectal therapeutic procedures. In a related change, PT Anal fistula excision will be demoted as a sub-concept LLT of the newly added PT Anal fistula repair.

# Supplemental Update Report

**CR Number: 2019066020** **Implementation Date:** 07-Mar-19 Related CR: 2019064001

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Anal fistula excision* | Approved as Requested | PT to merge | |
| To PT | *Anal fistula repair* | | *Anal fistula excision* | 10002157 Current |
| | | | To PT | |
| | | | *Anal fistula repair* | 10082792 |

MSSO Comment:

**CR Number: 2019064002** **Implementation Date:** 07-Mar-19 Related CR: 2019064002

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Agenesis depressor anguli oris muscle* | Approved as Requested | Proposed LLT | |
| | | | *Agenesis depressor anguli oris muscle* | 10082794 Current |
| | | | To PT | |
| | | | *Congenital hypoplasia of depressor angularis oris muscle* | 10080879 |

MSSO Comment: The proposal to add a new term Agenesis depressor anguli oris muscle is approved as requested. Congenital unilateral hypoplasia of depressor anguli oris is a congenital anomaly, characterized by the unilateral hypoplasia/agenesis of the depressor anguli oris muscle, resulting in an asymmetric crying facies in neonatal period/ infancy (drooping of one corner of the mouth during crying. Agenesis depressor anguli oris muscle will be added as a sub-concept LLT to PT Congenital hypoplasia of depressor angularis oris muscle.

**CR Number: 2019064003** **Implementation Date:** 07-Mar-19 Related CR: 2019064003

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Uterine vessel ligation* | Approved as Requested | Proposed PT | |
| | | | *Uterine vessel ligation* | 10082793 |
| | | | HLT primary | |
| | | | *Uterine therapeutic procedures* | 10046808 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment: The proposal to add a new term Uterine vessel ligation is approved as requested. Uterine blood vessel ligation is performed during total laparoscopic hysterectomy. Uterine and ovarian artery ligation for post partum haemorrhage also is a life saving procedure with preservation of the uterus. Uterine vessel ligation will be added as a new PT to HLT Uterine therapeutic procedures.

# Supplemental Update Report

**CR Number:** **2019066001** **Implementation Date:** 14-Mar-19 Related CR: 2019066001

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Marion disease* | Approved Not as Requested | Proposed LLT | |
| HLT primary | *Renal and urinary tract disorders congenital NEC* | | *Marion disease* | 10082806 Current |
| SOC primary | *Congenital, familial and genetic disorders* | | To PT | |
| | | | *Congenital bladder neck obstruction* | 10010382 |

MSSO Comment: The proposal to add a new PT Marion disease to primary HLT Renal and urinary tract disorders congenital NEC in SOC Congenital, familial and genetic disorders is approved but not as requested. Primary bladder neck obstruction was first described by Marion as a condition wherein the bladder neck fails to open adequately during voiding, resulting in increased striated sphincter activity or obstruction of urinary flow in the absence of another anatomic obstruction. Marion disease can be considered a eponym synonym of PT Congenital bladder neck obstruction, and will be added as its LLT. In a related change, Primary bladder neck obstruction will be added as a synonym LLT under PT Congenital bladder neck obstruction.

**CR Number:** **2019073003** **Implementation Date:** 14-Mar-19 Related CR: 2019066001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Primary bladder neck obstruction* | Approved as Requested | Proposed LLT | |
| To PT | *Congenital bladder neck obstruction* | | *Primary bladder neck obstruction* | 10082808 Current |
| | | | To PT | |
| | | | *Congenital bladder neck obstruction* | 10010382 |

MSSO Comment:

**CR Number:** **2019066002** **Implementation Date:** 14-Mar-19 Related CR: 2019066002

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Solitary fibrous tumour* | Approved as Requested | Proposed PT | |
| HLT primary | *Soft tissue neoplasms malignant and unspecified NEC (excl sarcomas)* | | *Solitary fibrous tumour* | 10082804 |
| SOC primary | *Neoplasms benign, malignant and unspecified (incl cysts and polyps)* | | HLT primary | |
| | | | *Soft tissue neoplasms malignant and unspecified NEC (excl sarcomas)* | 10041293 |
| | | | SOC primary | |
| | | | *Neoplasms benign, malignant and unspecified (incl cysts and polyps)* | 10029104 |

MSSO Comment: The proposal to add a new PT Solitary fibrous tumour to primary HLT Soft tissue neoplasms malignant and unspecified NEC (excl sarcomas) in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) is approved as requested. Solitary fibrous tumor are known to be a rare soft tissue tumor, which usually behaves nonaggressively. Histologically, there are dilated vessels, sometimes staghorn (some consider solitary fibrous tumor and hemangiopericytoma to be part of a spectrum), with interspersed spindle cells that are arranged in a “patternless” pattern. In a related change, US English spelled counterpart LLT Solitary fibrous tumor will be added to new PT Solitary fibrous tumour.

# Supplemental Update Report

**CR Number: 2019073004** **Implementation Date:** 14-Mar-19 Related CR: 2019066002

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Solitary fibrous tumor* | Approved as Requested | Proposed LLT | |
| To PT | *Solitary fibrous tumour* | | *Solitary fibrous tumor* | 10082807 Current |
| | | | To PT | |
| | | | *Solitary fibrous tumour* | 10082804 |

MSSO Comment:

**CR Number: 2019066003** **Implementation Date:** 14-Mar-19 Related CR: 2019066003

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Cardiofaciocutaneous syndrome* | Approved as Requested | Proposed PT | |
| HLT primary | *Musculoskeletal disorders congenital NEC* | | *Cardiofaciocutaneous syndrome* | 10082805 |
| SOC primary | *Congenital, familial and genetic disorders* | | HLT primary | |
| | | | *Musculoskeletal disorders congenital NEC* | 10029513 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary | |
| | | | *Dermal and epidermal conditions NEC* | 10012424 |
| | | | SOC secondary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment: The proposal to add a new PT Cardiofaciocutaneous syndrome to primary HLT Musculoskeletal disorders congenital NEC in SOC Congenital, familial and genetic disorders is approved as requested. Cardiofaciocutaneous syndrome is a multiple congenital anomaly disorder characterized by a distinctive facial appearance, heart defects, and mental retardation. The heart defects include pulmonic stenosis, atrial septal defect, and hypertrophic cardiomyopathy. Some patients have ectodermal abnormalities such as sparse and friable hair, hyperkeratotic skin lesions, and a generalized ichthyosis-like condition. PT Cardiofaciocutaneous syndrome will be additionally linked to secondary HLT Dermal and epidermal conditions NEC and secondary bi-axial HLT Intellectual disabilities.

# Supplemental Update Report

**CR Number: 2019073005** **Implementation Date:** 14-Mar-19 Related CR: 2019066003

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Cardiofaciocutaneous syndrome* | Approved as Requested | Proposed PT | |
| To HLT | *Intellectual disabilities* | | *Cardiofaciocutaneous syndrome* | 10082805 |
| | | | To HLT | |
| | | | *Intellectual disabilities* | 10077548 |

MSSO Comment:

**CR Number: 2019066004** **Implementation Date:** 14-Mar-19 Related CR: 2019066004

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *General physical condition decreased* | Approved as Requested | PT to merge | |
| To PT | *General physical health deterioration* | | *General physical condition decreased* | 10081195 Current |
| | | | To PT | |
| | | | *General physical health deterioration* | 10049438 |

MSSO Comment: The proposal to demote the PT General physical condition decreased under PT General physical health deterioration is approved as requested. General physical condition decreased and general physical health deterioration are used synonymously.

**CR Number: 2019066005** **Implementation Date:** 14-Mar-19 Related CR: 2019066005

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Urinary CD4 lymphocytes increased* | Approved as Requested | Proposed PT | |
| HLT primary | *Urinalysis NEC* | | *Urinary CD4 lymphocytes increased* | 10082809 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Urinalysis NEC* | 10046512 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Urinary CD4 lymphocytes increased to primary HLT Urinalysis NEC in SOC Investigations is approved as requested. Increased urinary CD4 cells are a useful biomarker and indicator of treatment response for proliferative lupus nephritis a in patients with systemic lupus erythematosus.

# Supplemental Update Report

**CR Number: 2019066006** **Implementation Date:** 14-Mar-19 Related CR: 2019066006

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Urinary CD4 lymphocytes decreased* | Approved as Requested | Proposed PT | |
| HLT primary | *Urinalysis NEC* | | *Urinary CD4 lymphocytes decreased* | 10082810 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Urinalysis NEC* | 10046512 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Urinary CD4 lymphocytes decreased to primary HLT Urinalysis NEC in SOC Investigations is approved as requested. Increased urinary CD4 cells are a useful biomarker and indicator of treatment response for proliferative lupus nephritis a in patients with systemic lupus erythematosus.

**CR Number: 2019066007** **Implementation Date:** 14-Mar-19 Related CR: 2019066007

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Corticetomy* | Approved Not as Requested | Proposed LLT | |
| To PT | *Topectomy* | | *Corticectomy* | 10082800 Current |
| | | | To PT | |
| | | | *Topectomy* | 10073488 |

MSSO Comment: The proposal to add a new LLT Corticetomy to PT Topectomy is approved but not as requested. Corticectomy, synonymous with topectomy, is the ablation of a small and specific area of the frontal cortex, for the treatment of certain forms of epilepsy and psychiatric disorders. The spelling of proposed term Corticetomy will be corrected to Corticectomy and added as a synonym LLT to PT Topectomy.

# Supplemental Update Report

**CR Number: 2019066008** **Implementation Date:** 14-Mar-19 Related CR: 2019066008

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Simultanagnosia* | Approved as Requested | Proposed PT | |
| | | | *Simultanagnosia* | 10082795 |
| | | | HLT primary | |
| | | | *Cortical dysfunction NEC* | 10011168 |
| | | | SOC primary | |
| | | | *Nervous system disorders* | 10029205 |
| | | | HLT secondary | |
| | | | *Specific cognitive ability disturbances* | 10041427 |
| | | | SOC secondary | |
| | | | *Psychiatric disorders* | 10037175 |

MSSO Comment: The proposal to add a new term Simultanagnosia is approved as requested. Simultanagnosia (or simultagnosia) is a rare neurological disorder characterized by the inability of an individual to perceive more than a single object at a time. Simultanagnosia can be divided into two categories: dorsal and ventral. Ventral occipito-temporal lesions cause a mild form of the disorder, while dorsal occipito-parietal lesions cause a more severe form of the disorder. Simultanagnosia will be added as a new PT to primary HLT Cortical dysfunction NEC and secondary HLT Specific cognitive ability disturbances.

**CR Number: 2019066009** **Implementation Date:** 14-Mar-19 Related CR: 2019066009

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Skin lesion infection* | Rejected | | |
| HLT primary | *Skin structures and soft tissue infections* | | | |
| SOC primary | *Infections and infestations* | | | |

MSSO Comment: The proposal to add a new PT Skin lesion infection to primary HLT Skin structures and soft tissue infections in SOC Infections and infestations and secondary HLT Skin and subcutaneous tissue infections NEC in SOC Skin and subcutaneous tissue disorders is not approved. The proposed term is a combination of the two existing LLT/PTs Skin infection and Skin lesion. The requested term may be represented by split coding using these two terms.

# Supplemental Update Report

**CR Number: 2019066010** **Implementation Date:** 14-Mar-19 Related CR: 2019066010

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Extradural haematoma evacuation* | Approved as Requested | Proposed PT | |
| HLT primary | *Skull and brain therapeutic procedures* | | *Extradural haematoma evacuation* | 10082797 |
| SOC primary | *Surgical and medical procedures* | | HLT primary | |
| | | | *Skull and brain therapeutic procedures* | 10040957 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment: The proposal to add a new PT Extradural haematoma evacuation to primary HLT Skull and brain therapeutic procedures in SOC Surgical and medical procedures is approved as requested. Although successful conservative management of epidural hematoma has been described, surgical evacuation constitutes definitive treatment of this condition. Craniotomy or laminectomy is followed by evacuation of the hematoma, coagulation of bleeding sites, and inspection of the dura. In a related change, the American English spelling counterpart LLT Extradural hematoma evacuation will be added to new PT Extradural haematoma evacuation.

**CR Number: 2019073001** **Implementation Date:** 14-Mar-19 Related CR: 2019066010

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Extradural hematoma evacuation* | Approved as Requested | Proposed LLT | |
| To PT | *Extradural haematoma evacuation* | | *Extradural hematoma evacuation* | 10082801 Current |
| | | | To PT | |
| | | | *Extradural haematoma evacuation* | 10082797 |

MSSO Comment:

**CR Number: 2019066011** **Implementation Date:** 14-Mar-19 Related CR: 2019066011

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Clavicle operation* | Rejected | | |

MSSO Comment: The proposal to add a new term Clavicle operation is not approved. MedDRA cannot accommodate a separate non-specific "operation" term for every possible bone or region of bone, unless the term represents a specific recognized medical concept. The requested term may be represented by LLT Bone operation, and if specified, a term for the reason for the surgery, such as LLT Clavicle fracture, LLT Congenital deformity of clavicle, etc.

# Supplemental Update Report

**CR Number: 2019066012** **Implementation Date:** 14-Mar-19 Related CR: 2019066012

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Anorectal malformation* | Approved as Requested | Proposed PT | |
| HLT primary | *Anorectal disorders congenital* | | *Anorectal malformation* | 10082798 |
| SOC primary | *Congenital, familial and genetic disorders* | | HLT primary | |
| | | | *Anorectal disorders congenital* | 10002577 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary | |
| | | | *Anal and rectal stenosis and obstruction* | 10002117 |
| | | | SOC secondary | |
| | | | *Gastrointestinal disorders* | 10017947 |

MSSO Comment: The proposal to add a new PT Anorectal malformation to primary HLT Anorectal disorders congenital in SOC Congenital, familial and genetic disorders is approved as requested. Anorectal malformations include a wide spectrum of defects in the development of the lowest portion of the intestinal and urogenital tracts. PT Anorectal malformation will also be linked to secondary HLT Anal and rectal stenosis and obstruction.

**CR Number: 2019066013** **Implementation Date:** 14-Mar-19 Related CR: 2019066013

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Muscle strength abnormal* | Approved as Requested | Proposed PT | |
| HLT primary | *Physical examination procedures and organ system status* | | *Muscle strength abnormal* | 10082799 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Physical examination procedures and organ system status* | 10071941 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Muscle strength abnormal to primary HLT Physical examination procedures and organ system status in SOC Investigations is approved as requested. Muscle strength can be assessed, manually, functionally or mechanically through the exploration of several horizontal and antigravity maneuvers against progressive resistance, which defines different gradings on several existing recognized scales.

# Supplemental Update Report

**CR Number: 2019066014** **Implementation Date:** 14-Mar-19 Related CR: 2019066014

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Muscle strength normal* | Approved as Requested | Proposed PT | |
| HLT primary | *Physical examination procedures and organ system status* | | *Muscle strength normal* | 10082796 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Physical examination procedures and organ system status* | 10071941 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Muscle strength normal to primary HLT Physical examination procedures and organ system status in SOC Investigations is approved as requested. Muscle strength can be assessed, manually, functionally or mechanically through the exploration of several horizontal and antigravity maneuvers against progressive resistance, which defines different gradings on several existing recognized scales.

**CR Number: 2019066019** **Implementation Date:** 14-Mar-19 Related CR: 2019066019

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nasal inflammation* | Approved Not as Requested | PT to merge | |
| To PT | *Noninfective rhinitis* | | *Noninfective rhinitis* | 10081942 Current |
| | | | To PT | |
| | | | *Nasal inflammation* | 10028741 |

MSSO Comment: The proposal to demote the PT Nasal inflammation under PT Noninfective rhinitis is approved but not as requested. Nasal inflammation is broader concept than Noninfective rhinitis. Thus PT Noninfective rhinitis will be demoted under PT Nasal inflammation.

**CR Number: 2019066021** **Implementation Date:** 14-Mar-19 Related CR: 2019066021

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Soft tissue repair* | Rejected | | |

MSSO Comment: The proposal to add a new LLT Soft tissue repair is not approved. Soft tissue repair is ambiguous as it can refer to the healing process of injured tissue and to a procedural process. Consider to use LLT Promotion of wound healing and for the underlying causality e.g. LLT Soft tissue injury or LLT Soft tissue necrosis.

# Supplemental Update Report

**CR Number: 2019070001** **Implementation Date:** 14-Mar-19 Related CR: 2019070001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Disruption of the photoreceptor inner segment-outer segment* | Approved as Requested | Proposed PT<br>*Disruption of the photoreceptor inner segment-outer segment*<br>HLT primary<br>*Retinal structural change, deposit and degeneration*<br>SOC primary<br>*Eye disorders* | <br>10082802<br><br>10038896<br><br>10015919 |

MSSO Comment: The proposal to add a new term Disruption of the photoreceptor inner segment-outer segment is approved as requested. Photoreceptors are exquisitely adapted to transform light stimuli into electrical signals that modulate neurotransmitter release. These cells are organized into several compartments including the unique outer segment (OS). Its whole function is to absorb light and transduce this signal into a change of membrane potential. Another compartment is the inner segment where much of metabolism and regulation of membrane potential takes place and that connects the OS and synapse. Disruption of the photoreceptor IS/OS junction is a statistically significant predictor of poor visual acuity among patients with epiretinal membranes and is most useful when combined with central retinal thickness measurement. Disruption of the photoreceptor inner segment-outer segment will be placed as PT to HLT Retinal structural change, deposit and degeneration. In a related change, furthermore, the synonym LLT Inner segment ellipsoid band dysruption will be added to the new PT Disruption of the photoreceptor inner segment-outer segment.

**CR Number: 2019073002** **Implementation Date:** 14-Mar-19 Related CR: 2019070001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Inner segment ellipsoid band dysruption* | Approved as Requested | Proposed LLT<br>*Inner segment ellipsoid band dysruption* | |
| To PT | *Disruption of the photoreceptor inner segment-outer segment* | | To PT<br>*Disruption of the photoreceptor inner segment-outer segment* | <br>10082802 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019070002** **Implementation Date:** 14-Mar-19 Related CR: 2019070002

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *IGF-1 Abnormal* | Approved Not as Requested | Proposed LLT | |
| | | | *IGF-1 abnormal* | 10082817 Current |
| | | | To PT | |
| | | | *Insulin-like growth factor abnormal* | 10082816 |

MSSO Comment: The proposal to add a new PT IGF-1 Abnormal is approved but not as requested. Insulin-like growth factor-1 (IGF-1) is a hormone that, along with growth hormone, helps promote normal bone and tissue growth and development. The test measures the amount of IGF-1 in the blood. IGF-1 abnormal will be added as an LLT under a new PT named Insulin-like growth factor abnormal, in line with other existing terms of this test, and with the aim to represent those measurements of IGF-1 where the actual result is not known or lacks correspondence with the clinical findings. IGF-1 abnormal, modified according to MedDRA capitalisation conventions, will be added as an LLT to a new PT Insulin-like growth factor abnormal. In related change, PT Insulin-like growth factor abnormal will be added to HLT Endocrine analyses and imaging NEC.

**CR Number: 2019073006** **Implementation Date:** 14-Mar-19 Related CR: 2019070002

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Insulin-like growth factor abnormal* | Approved as Requested | Proposed PT | |
| HLT primary | *Endocrine analyses and imaging NEC* | | *Insulin-like growth factor abnormal* | 10082816 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Endocrine analyses and imaging NEC* | 10014693 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment:

**CR Number: 2019070003** **Implementation Date:** 14-Mar-19 Related CR: 2019070003

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Difficulty in injection* | Rejected | | |

MSSO Comment: The proposal to add a new term Difficulty in injection is not approved. The proposed term is a broad concept that may relate to technique or product design, quality or human factors. Please submit a change request if you are looking for a term representing a self administration issue.

# Supplemental Update Report

**CR Number: 2019070004** **Implementation Date:** 14-Mar-19 Related CR: 2019070004

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Self injection* | Approved as Requested | Proposed LLT<br>*Self injection*<br>To PT<br>*Self-medication* | 10082815 Current<br><br>10050729 |

MSSO Comment: The proposal to add a new term Self injection is approved as requested. Many medications that treat complex conditions require injections that should be administered by the patient himself. Parenteral self-administration (especially when getting started) can be sometimes a daunting practice, which may hamper adherence to treatment if the patient is not adequately trained and informed about the administration procedure. Self injection will be added as an LLT to the PT Self-medication.

**CR Number: 2019070005** **Implementation Date:** 14-Mar-19 Related CR: 2019070005

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pituitary scan* | Approved as Requested | Proposed PT<br>*Pituitary scan*<br>HLT primary<br>*Endocrine analyses and imaging NEC*<br>SOC primary<br>*Investigations* | <br>10082813<br><br>10014693<br><br>10022891 |

MSSO Comment: The proposal to add a new PT Pituitary scan is approved as requested. Pituitary scan, a broad imagine procedure term of the pituitary gland and surrounding structures, will be added as PT to HLT Endocrine analyses and imaging NEC.

**CR Number: 2019070006** **Implementation Date:** 14-Mar-19 Related CR: 2019070006

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pituitary scan abnormal* | Approved as Requested | Proposed PT<br>*Pituitary scan abnormal*<br>HLT primary<br>*Endocrine analyses and imaging NEC*<br>SOC primary<br>*Investigations* | <br>10082812<br><br>10014693<br><br>10022891 |

MSSO Comment: The proposal to add a new PT Pituitary scan abnormal is approved as requested. Pituitary scan abnormal will be added as a PT under HLT Endocrine analyses and imaging NEC to represent the abnormal imagine finding of the pituitary gland and to complement the PT Pituitary scan added in CR 2019070005.

# Supplemental Update Report

**CR Number: 2019070007** **Implementation Date:** 14-Mar-19 Related CR: 2019070007

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Secondary tuberculosis* | Approved Not as Requested | Proposed LLT | |
| | | | *Secondary tuberculosis* | 10082814 Current |
| | | | To PT | |
| | | | *Tuberculosis* | 10044755 |

MSSO Comment: The proposal to add a new PT Secondary tuberculosis is approved but not as requested. Secondary tuberculosis is seen mostly in adults as a reactivation of previous infection (or reinfection), particularly when health status declines. The granulomatous inflammation is much more florid and widespread. Typically, the upper lung lobes are most affected, and cavitation can occur. Secondary tuberculosis will be added as a sub-element LLT of PT Tuberculosis, in parallel with the very closely related existing LLTs Tuberculosis reactivated and Mycobacterium tuberculosis infection reactivated.

**CR Number: 2019070008** **Implementation Date:** 14-Mar-19 Related CR: 2019070008

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Refusal of vaccination* | Approved as Requested | Proposed PT | |
| | | | *Refusal of vaccination* | 10082811 |
| | | | HLT primary | |
| | | | *Social issues NEC* | 10070967 |
| | | | SOC primary | |
| | | | *Social circumstances* | 10041244 |

MSSO Comment: The proposal to add a new term Refusal of vaccination is approved as requested. Vaccines are among the most effective prevention tools available to clinicians. However, the success of an immunization program depends on high rates of acceptance and coverage. There is evidence of an increase in vaccine refusal that results in outbreaks. Children with exemptions from school immunization requirements are at increased risk to suffer infections traditionally controlled by adequate vaccination programs. Refusal of vaccination will be added as a PT to HLT Social issues NEC.

**CR Number: 2019072001** **Implementation Date:** 19-Mar-19 Related CR: 2019072001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Diffuse Polyalgic Syndrome* | Approved Not as Requested | Proposed LLT | |
| | | | *Diffuse polyalgic syndrome* | 10082821 Current |
| | | | To PT | |
| | | | *Fibromyalgia* | 10048439 |

MSSO Comment: The proposal to add a new term Diffuse Polyalgic Syndrome is approved but not as requested. Fibromyalgia is defined as a chronic and diffuse polyalgic syndrome characterized by musculoskeletal pain (axially distributed, including pain on both left and right sides of the body and pain above and below the waist) for more than 3 months. Diffuse Polyalgic Syndrome will be modified according to MedDRA capitalisation conventions and added as synonym LLT Diffuse polyalgic syndrome to PT Fibromyalgia.

# Supplemental Update Report

**CR Number: 2019072002** **Implementation Date:** 19-Mar-19 Related CR: 2019072002

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Forehead Flap* | Approved Not as Requested | Proposed LLT | |
| | | | *Forehead flap* | 10082822 Current |
| | | | To PT | |
| | | | *Plastic surgery to the face* | 10035509 |

MSSO Comment: The proposal to add a new term Forehead Flap is approved but not as requested. The forehead flap is a commonly used technique in maxillofacial surgery to reconstruct the deep and large nasal defects. As the gold standard for nasal soft tissue reconstruction, the forehead flap provides a reconstructive surgeon with a robust pedicle and large amount of tissue to reconstruct almost any defect. Forehead flap, corrected in accordance with MedDRA capitalisation conventions, and will be added as sub-concept LLT to PT Plastic surgery to the face.

**CR Number: 2019072003** **Implementation Date:** 19-Mar-19 Related CR: 2019072003

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Panhematopenia* | Approved as Requested | Proposed LLT | |
| | | | *Panhematopenia* | 10082823 Current |
| | | | To PT | |
| | | | *Pancytopenia* | 10033661 |

MSSO Comment: The proposal to add a new term Panhematopenia is approved as requested. Panhematopenia, listed in Dorland's Medical Dictionary as synonym of pancytopenia - deficiency of all cellular elements of the blood, will be added together with its British English counterpart Panhaematopenia as synonym LLTs to PT Pancytopenia.

**CR Number: 2019078004** **Implementation Date:** 19-Mar-19 Related CR: 2019072003

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Panhaematopenia* | Approved as Requested | Proposed LLT | |
| To PT | *Pancytopenia* | | *Panhaematopenia* | 10082824 Current |
| | | | To PT | |
| | | | *Pancytopenia* | 10033661 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019072004** **Implementation Date:** 19-Mar-19 Related CR: 2019072004

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *M protein increase* | Approved Not as Requested | Proposed LLT | |
| | | | *M-protein increased* | 10082826 Current |
| | | | To PT | |
| | | | *Monoclonal immunoglobulin increased* | 10082825 |

MSSO Comment: The proposal to add a new term M protein increase is approved but not as requested. The requested term will be modified in accordance with MedDRA naming conventions and added as synonym LLT M-protein increased to a new PT Monoclonal immunoglobulin increased. In a related change, PT Monoclonal immunoglobulin increased will be added to HLT Immunoglobulin analyses. A myeloma protein is an abnormal immunoglobulin fragment, such as an immunoglobulin light chain, that is produced in excess by an abnormal monoclonal proliferation of plasma cells, typically in multiple myeloma. Other terms for such a protein are M protein, M component, M spike, spike protein, or paraprotein.

**CR Number: 2019078005** **Implementation Date:** 19-Mar-19 Related CR: 2019072004

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Monoclonal immunoglobulin increased* | Approved as Requested | Proposed PT | |
| HLT primary | *Immunoglobulin analyses* | | *Monoclonal immunoglobulin increased* | 10082825 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Immunoglobulin analyses* | 10021477 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment:

**CR Number: 2019072005** **Implementation Date:** 19-Mar-19 Related CR: 2019072005

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Thoracoabdominal aortic aneurysm enlargement* | Approved as Requested | Proposed LLT | |
| | | | *Thoracoabdominal aortic aneurysm enlargement* | 10082829 Current |
| | | | To PT | |
| | | | *Aortic aneurysm* | 10002882 |

MSSO Comment: The proposal to add a new term Thoracoabdominal aortic aneurysm enlargement is approved as requested. Thoracoabdominal aortic aneurysm enlargement represents an enlargement of an aneurysm of the aorta in the thoracoabdominal region. Thoracoabdominal aortic aneurysm enlargement will be added as a new sub-concept LLT to PT Aortic aneurysm.

# Supplemental Update Report

**CR Number: 2019072006** **Implementation Date:** 19-Mar-19 Related CR: 2019072006

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Intraoperative blood loss* | Approved as Requested | Proposed LLT | |
| | | | *Intraoperative blood loss* | 10082830 Current |
| | | | To PT | |
| | | | *Procedural haemorrhage* | 10071229 |

MSSO Comment: The proposal to add a new term Intraoperative blood loss is approved as requested. Acute blood loss is a common, but often challenging, problem facing emergency physicians. Inadequate or delay in treatment can lead to morbidity or mortality. Standard classifications to quantify blood loss, as well as vital signs alone, are inadequate for guiding therapy. Intraoperative blood loss will be added as a sub-concept LLT to PT Procedural haemorrhage.

**CR Number: 2019072007** **Implementation Date:** 19-Mar-19 Related CR: 2019072007

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Peripheral artery restenosis* | Rejected | | |
| Old Primary SOC | *Injury, poisoning and procedural complications* | | | |
| New Primary SOC | *Vascular disorders* | | | |

MSSO Comment: The proposal to reassign the primary SOC of PT Peripheral artery restenosis from current SOC Injury, poisoning and procedural complications to SOC Vascular disorders is not approved. Reocclusion and re-stenosis terms, for purposes of MedDRA, are generally considered to be post procedural complication events with primary mapping to SOC Injury, poisoning and procedural complications and secondary to the SOC of the site of manifestation.

**CR Number: 2019072008** **Implementation Date:** 19-Mar-19 Related CR: 2019072008

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Iliac artery restenosis* | Approved as Requested | Proposed LLT | |
| | | | *Iliac artery restenosis* | 10082827 |
| | | | To PT | |
| | | | *Peripheral artery restenosis* | 10072557 |

MSSO Comment: The proposal to add a new term Iliac artery restenosis is approved as requested. Following angioplasty and stent placement, the local vasculature often reacts with an inflammatory response that precipitates neointimal proliferation and tissue ingrowth. Despite recent advances in angioplasty and stent technology, restenosis of the iliac artery remains to be a potential clinical problem. Iliac artery restenosis will be added as a sub-concept LT to PT Peripheral artery restenosis. In a related change, PT Post angioplasty restenosis and PT Vascular graft restenosis will be linked to HLT Vascular complications associated with device for consistent representation with other "restenosis" concepts.

# Supplemental Update Report

**CR Number: 2019078006** **Implementation Date:** 19-Mar-19 Related CR: 2019072008

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Post angioplasty restenosis* | Approved as Requested | Proposed PT | |
| To HLT | *Vascular complications associated with device* | | *Post angioplasty restenosis* | 10077146 |
| | | | To HLT | |
| | | | *Vascular complications associated with device* | 10069789 |

MSSO Comment:

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**CR Number: 2019078007** **Implementation Date:** 19-Mar-19 Related CR: 2019072008

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vascular graft restenosis* | Approved as Requested | Proposed PT | |
| To HLT | *Vascular complications associated with device* | | *Vascular graft restenosis* | 10077331 |
| | | | To HLT | |
| | | | *Vascular complications associated with device* | 10069789 |

MSSO Comment:

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**CR Number: 2019072009** **Implementation Date:** 19-Mar-19 Related CR: 2019072009

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Femoral artery restenosis* | Approved as Requested | Proposed LLT | |
| | | | *Femoral artery restenosis* | 10082828 Current |
| | | | To PT | |
| | | | *Peripheral artery restenosis* | 10072557 |

MSSO Comment: The proposal to add a new term Femoral artery restenosis is approved as requested. Following angioplasty and stent placement, the local vasculature often reacts with an inflammatory response that precipitates neointimal proliferation and tissue ingrowth. Despite recent advances in angioplasty and stent technology, restenosis of the femoral artery remains to be a potential clinical problem. Femoral artery restenosis will be added as a sub-concept LLT to PT Peripheral artery restenosis.

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# Supplemental Update Report

**CR Number: 2019073012** **Implementation Date:** 20-Mar-19 Related CR: 2019073012

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Lung miliary opacities in thoracic CT* | Approved Not as Requested | Proposed LLT<br>*Lung miliary opacities* | 10082838 Current |
| | | | To PT<br>*Lung opacity* | 10081792 |

MSSO Comment: The proposal to add a new term Lung miliary opacities in thoracic CT is approved but not as requested. Lung miliary opacities in thoracic CT represents an imaging CT finding of multiple tiny soft-tissue density nodules presenting throughout both lungs with an upper- and middle-zone predominance. The pattern of disease suggests an inhalational cause for the underlying pathology. Lung miliary opacities in thoracic CT will be shortened to pertain to any imaging technique, and added as LLT Lung miliary opacities under a newly promoted PT Lung opacity. Imaging findings are treated as conditions in MedDRA. Therefore, in a related change, the LLT Lung opacity will be promoted from PT Chest X-ray abnormal to PT level and linked to HLT Lower respiratory tract signs and symptoms. Furthermore, LLT Ground glass opacity on chest X-ray will be moved from PT Chest X-ray abnormal and moved under newly promoted PT Lung opacity. In addition, LLT Ground glass opacity in thoracic CT will be moved from PT Computerised tomogram thorax abnormal to newly promoted PT Lung opacity for better alignment.

**CR Number: 2019079013** **Implementation Date:** 20-Mar-19 Related CR: 2019073012

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Lung opacity* | Approved as Requested | Proposed LLT<br>*Lung opacity* | 10081792 |
| From PT | *Chest X-ray abnormal* | | From PT<br>*Chest X-ray abnormal* | 10008499 |
| HLT primary | *Lower respiratory tract signs and symptoms* | | HLT primary<br>*Lower respiratory tract signs and symptoms* | 10024976 |
| | | | SOC primary<br>*Respiratory, thoracic and mediastinal disorders* | 10038738 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019079014** **Implementation Date:** 20-Mar-19 Related CR: 2019073012

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Ground glass opacity on chest X-ray* | Approved as Requested | Proposed LLT | | |
| From PT | *Chest X-ray abnormal* | | *Ground glass opacity on chest X-ray* | 10072880 | Current |
| To PT | *Lung opacity* | | From PT | | |
| | | | *Chest X-ray abnormal* | 10008499 | |
| | | | To PT | | |
| | | | *Lung opacity* | 10081792 | |

MSSO Comment:

**CR Number: 2019079015** **Implementation Date:** 20-Mar-19 Related CR: 2019073012

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Ground glass opacity in thoracic CT* | Approved as Requested | Proposed LLT | | |
| From PT | *Computerised tomogram thorax abnormal* | | *Ground glass opacity in thoracic CT* | 10072879 | Current |
| To PT | *Lung opacity* | | From PT | | |
| | | | *Computerised tomogram thorax abnormal* | 10057799 | |
| | | | To PT | | |
| | | | *Lung opacity* | 10081792 | |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019073013** **Implementation Date:** 20-Mar-19 Related CR: 2019073013

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Glycated albumin decreased* | Approved as Requested | Proposed PT | |
| | | | *Glycated albumin decreased* | 10082837 |
| | | | HLT primary | |
| | | | *Carbohydrate tolerance analyses (incl diabetes)* | 10007217 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new term Glycated albumin decreased is approved as requested. Glycated albumin reflects short-term (2–3 weeks) mean glycemic levels. Glycated albumin values are not affected by changes in erythrocyte lifespan and thus measurement of glycated albumin is not influenced by anemia or other conditions which invalidate HbA1c measurements in the diagnosis of diabetes. Furthermore, glycated albumin is reported to serve as a better indicator of glycemic control than HbA1c in diabetic patients on dialysis. Glycated albumin decreased will be added as PT under HLT Carbohydrate tolerance analyses (incl diabetes). In a related change, the synonym LLT Blood glycoalbumin decreased will be moved from PT Fructosamine decreased to the new PT Glycated albumin decreased. Furthermore, PT Glycated albumin increased, PT Glycated albumin normal, and PT Glycated albumin, will be added to HLT Carbohydrate tolerance analyses (incl diabetes). Also, LLT Blood glycoalbumin will be moved from PT Fructosamine to new PT Glycated albumin, LLT Blood glycoalbumin increased will be moved from PT Fructosamine increased to new PT Glycated albumin increased, and LLT Blood glycoalbumin normal will be moved from PT Fructosamine normal to new PT Glycated albumin normal for better alignment.

**CR Number: 2019079017** **Implementation Date:** 20-Mar-19 Related CR: 2019073013

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Glycated albumin increased* | Approved as Requested | Proposed PT | |
| HLT primary | *Carbohydrate tolerance analyses (incl diabetes)* | | *Glycated albumin increased* | 10082836 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Carbohydrate tolerance analyses (incl diabetes)* | 10007217 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019079018** **Implementation Date:** 20-Mar-19 Related CR: 2019073013

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Glycated albumin normal* | Approved as Requested | Proposed PT | |
| HLT primary | *Carbohydrate tolerance analyses (incl diabetes)* | | *Glycated albumin normal* | 10082834 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Carbohydrate tolerance analyses (incl diabetes)* | 10007217 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment:

**CR Number: 2019079019** **Implementation Date:** 20-Mar-19 Related CR: 2019073013

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Glycated albumin* | Approved as Requested | Proposed PT | |
| HLT primary | *Carbohydrate tolerance analyses (incl diabetes)* | | *Glycated albumin* | 10082835 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Carbohydrate tolerance analyses (incl diabetes)* | 10007217 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019079020** **Implementation Date:** 20-Mar-19 Related CR: 2019073013

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Blood glycoalbumin* | Approved as Requested | Proposed LLT | |
| From PT | *Fructosamine* | | *Blood glycoalbumin* | 10062709 Current |
| To PT | *Glycated albumin* | | From PT | |
| | | | *Fructosamine* | 10017393 |
| | | | To PT | |
| | | | *Glycated albumin* | 10082835 |

MSSO Comment:

**CR Number: 2019079021** **Implementation Date:** 20-Mar-19 Related CR: 2019073013

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Blood glycoalbumin increased* | Approved as Requested | Proposed LLT | |
| From PT | *Fructosamine increased* | | *Blood glycoalbumin increased* | 10062710 Current |
| To PT | *Glycated albumin increased* | | From PT | |
| | | | *Fructosamine increased* | 10017395 |
| | | | To PT | |
| | | | *Glycated albumin increased* | 10082836 |

MSSO Comment:

**CR Number: 2019079022** **Implementation Date:** 20-Mar-19 Related CR: 2019073013

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Blood glycoalbumin normal* | Approved as Requested | Proposed LLT | |
| From PT | *Fructosamine normal* | | *Blood glycoalbumin normal* | 10062712 Current |
| To PT | *Glycated albumin normal* | | From PT | |
| | | | *Fructosamine normal* | 10017396 |
| | | | To PT | |
| | | | *Glycated albumin normal* | 10082834 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019079023** **Implementation Date:** 20-Mar-19 Related CR: 2019073013

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Blood glycoalbumin decreased* | Approved as Requested | Proposed LLT | |
| From PT | *Fructosamine decreased* | | *Blood glycoalbumin decreased* | 10062711 Current |
| To PT | *Glycated albumin decreased* | | From PT | |
| | | | *Fructosamine decreased* | 10017394 |
| | | | To PT | |
| | | | *Glycated albumin decreased* | 10082837 |

MSSO Comment:

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**CR Number: 2019074001** **Implementation Date:** 19-Mar-19 Related CR: 2019074001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Providencia urinary tract infection* | Approved as Requested | Proposed PT | |
| | | | *Providencia urinary tract infection* | 10082818 |
| | | | HLT primary | |
| | | | *Bacterial infections NEC* | 10004047 |
| | | | SOC primary | |
| | | | *Infections and infestations* | 10021881 |
| | | | HLT secondary | |
| | | | *Genitourinary tract infections and inflammations NEC* | 10018191 |
| | | | SOC secondary | |
| | | | *Renal and urinary disorders* | 10038359 |

MSSO Comment: The proposal to add a new term Providencia urinary tract infection is approved as requested. Providencia stuartii, and (less frequently) Providencia rettgeri are the members of the Providentia genus that cause human infections, and is primarily urinary tract pathogens, causing UTIs that are most often associated with long-term (>30-day) catheterization. Providencia occurs more commonly among long-term-care facility residents than among hospitalized patients, largely resulting from chronic urinary-catheter use and may be extensively resistant to antibiotics. Providencia urinary tract infection will be added as a PT to primary HLT Bacterial infections NEC and secondary HLT Genitourinary tract infections and inflammations NEC. In a related change, the broad PT Providencia infection, will also be added and linked to HLT Bacterial infections NEC.

# Supplemental Update Report

**CR Number: 2019078002** **Implementation Date:** 19-Mar-19 Related CR: 2019074001

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Providencia infection* | Approved as Requested | Proposed PT | |
| HLT primary | *Bacterial infections NEC* | | *Providencia infection* | 10082819 |
| SOC primary | *Infections and infestations* | | HLT primary | |
| | | | *Bacterial infections NEC* | 10004047 |
| | | | SOC primary | |
| | | | *Infections and infestations* | 10021881 |

MSSO Comment:

**CR Number: 2019074002** **Implementation Date:** 19-Mar-19 Related CR: 2019074002

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Minor cognitive motor disorder* | Approved as Requested | Proposed LLT | |
| From PT | *HIV-associated neurocognitive disorder* | | *Minor cognitive motor disorder* | 10069149 Current |
| To PT | *Cognitive disorder* | | From PT | |
| | | | *HIV-associated neurocognitive disorder* | 10078164 |
| | | | To PT | |
| | | | *Cognitive disorder* | 10057668 |

MSSO Comment: The proposal to move the LLT Minor cognitive motor disorder from PT HIV-associated neurocognitive disorder to PT Cognitive disorder is approved as requested. With changes in terminology in relation with neurocognitive conditions associated with HIV infection, “minor cognitive-motor disorder” has fallen out of use as an specific term for HIV infected patients. The proposed move will put it in alignment with other general meaning existing terms such as LLT Mild neurocognitive disorder. In a related change, a new HIV-associated mild neurocognitive disorder will be added as a sub-concept LLT under PT HIV-associated neurocognitive disorder, to refer to the early stages of HIV-associated neurocognitive disorder.

**CR Number: 2019078003** **Implementation Date:** 19-Mar-19 Related CR: 2019074002

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *HIV-associated mild neurocognitive disorder* | Approved as Requested | Proposed LLT | |
| To PT | *HIV-associated neurocognitive disorder* | | *HIV-associated mild neurocognitive disorder* | 10082820 Current |
| | | | To PT | |
| | | | *HIV-associated neurocognitive disorder* | 10078164 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019074003** **Implementation Date:** 19-Mar-19 Related CR: 2019074003

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Minor cognitive motor disorder* | Rejected | | |
| From PT | *HIV-associated neurocognitive disorder* | | | |
| To PT | *Cognitive disorder* | | | |

MSSO Comment: The proposal to move the LLT Minor cognitive motor disorder from PT HIV-associated neurocognitive disorder to PT Cognitive disorder is not approved. The proposed move was submitted and approved in change request 2019074002.

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**CR Number: 2019074004** **Implementation Date:** 19-Mar-19 Related CR: 2019074004

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Minor cognitive motor disorder* | Rejected | | |
| From PT | *HIV-associated neurocognitive disorder* | | | |
| To PT | *Cognitive disorder* | | | |

MSSO Comment: The proposal to move the LLT Minor cognitive motor disorder from PT HIV-associated neurocognitive disorder to PT Cognitive disorder is not approved. The proposed move was submitted and approved in change request 2019074002.

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**CR Number: 2019077001** **Implementation Date:** 19-Mar-19 Related CR: 2019077001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *End plate inflammation* | Approved Not as Requested | Proposed PT | |
| | | | *Vertebral end plate inflammation* | 10082831 |
| | | | HLT primary | |
| | | | *Bone disorders NEC* | 10027658 |
| | | | SOC primary | |
| | | | *Musculoskeletal and connective tissue disorders* | 10028395 |

MSSO Comment: The proposal to add a new term End plate inflammation is approved but not as requested. The vertebral end plate is composed of a layer of thickened cancellous bone. Force imposed on the endplate from major load bearing or a herniated disc can cause end-plate abnormalities and dysfunction, which may result in inflammation, degenerative disc disease, and chronic low back pain. The proposed term End plate inflammation will be rephrased as Vertebral end plate inflammation to represent the concept more specifically, and added as a new PT to HLT Bone disorders NEC.

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# Supplemental Update Report

**CR Number: 2019077002** **Implementation Date:** 19-Mar-19 Related CR: 2019077002

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *AST/ALT ratio abnormal* | Approved as Requested | Proposed PT<br>*AST/ALT ratio abnormal* | 10082832 |
| | | | HLT primary<br>*Liver function analyses* | 10024689 |
| | | | SOC primary<br>*Investigations* | 10022891 |

MSSO Comment: The proposal to add a new term AST/ALT ratio abnormal is approved as requested. The AST/ALT ratio is the ratio between the concentrations of the enzymes aspartate transaminase (AST) and alanine transaminase, also known as alanine aminotransferase (ALT) in the blood. Different proportions of this ratio may help to differentiate between different hepathopaties, as well as hepatic from inflammatory muscle conditions. AST/ALT ratio abnormal will be added as a new PT to HLT Liver function analyses. In a related change, synonym LLT De Ritis ratio abnormal will be added to new PT AST/ALT ratio abnormal.

**CR Number: 2019078008** **Implementation Date:** 19-Mar-19 Related CR: 2019077002

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *De Ritis ratio abnormal* | Approved as Requested | Proposed LLT<br>*De Ritis ratio abnormal* | 10082833 Current |
| To PT | *AST/ALT ratio abnormal* | | To PT<br>*AST/ALT ratio abnormal* | 10082832 |

MSSO Comment:

**CR Number: 2019078001** **Implementation Date:** 20-Mar-19 Related CR: 2019078001

| Change Requested | Rename PT/LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Term to modify | *Inner segment ellipsoid band dysruption* | Approved as Requested | Term to modify<br>*Inner segment ellipsoid band dysruption* | |
| Replacement term | *Inner segment ellipsoid band disruption* | | Replacement term<br>*Inner segment ellipsoid band disruption* | 10082803 Current |

MSSO Comment: The proposal to rename PT/LLT Inner segment ellipsoid band dysruption to Inner segment ellipsoid band disruption is approved as requested. PT Inner segment ellipsoid band dysruption, recently added in change request 2019073002, is misspelled and will thus be replaced by PT Inner segment ellipsoid band disruption.

# Supplemental Update Report

**CR Number: 2019079001** **Implementation Date:** 26-Mar-19 Related CR: 2019079001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Apronectomy* | Approved as Requested | Proposed LLT<br>*Apronectomy* | 10082842 Current |
| | | | To PT<br>*Abdominoplasty* | 10053774 |

MSSO Comment: The proposal to add a new term Apronectomy is approved as requested. Apronectomy, a synonym of LLT Tummy tuck will be added as LLT to PT Abdominoplasty.

**CR Number: 2019079002** **Implementation Date:** 26-Mar-19 Related CR: 2019079002

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Transhiatal bilateral splanchnicectomy* | Approved as Requested | Proposed LLT<br>*Transhiatal bilateral splanchnicectomy* | 10082841 Current |
| | | | To PT<br>*Splanchnicectomy* | 10082839 |

MSSO Comment: The proposal to add a new term Transhiatal bilateral splanchnicectomy is approved as requested. Splanchnicectomy by retroperitoneal, intraperitoneal, and transhiatal approaches, transthoracic left splanchnicectomy combined with truncal vagotomy, and percutaneous celiac block is a technique to treat neuropathic pain originating from the abdominal region by impeding, or blocking, the transmission of pain information from the area to the spinal cord and brain. Transhiatal bilateral splanchnicectomy will be added as sub-concept LLT to the broad new PT Splanchnicectomy. In a related change, Splanchnicectomy will be added to HLT Autonomic nerve therapeutic procedures.

**CR Number: 2019085004** **Implementation Date:** 26-Mar-19 Related CR: 2019079002

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Splanchnicectomy* | Approved as Requested | Proposed PT<br>*Splanchnicectomy* | 10082839 |
| HLT primary | *Autonomic nerve therapeutic procedures* | | HLT primary<br>*Autonomic nerve therapeutic procedures* | 10003838 |
| SOC primary | *Surgical and medical procedures* | | SOC primary<br>*Surgical and medical procedures* | 10042613 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019079003** **Implementation Date:** 26-Mar-19 Related CR: 2019079003

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Virtual gastroscopy* | Approved as Requested | Proposed LLT | |
| | | | *Virtual gastroscopy* | 10082843 Current |
| | | | To PT | |
| | | | *Computed tomographic gastrography* | 10082840 |

MSSO Comment: The proposal to add a new LLT Virtual gastroscopy is approved as requested. Virtual gastroscopy, also called computed tomographic gastrography, is a noninvasive procedure for the detection of gastric abnormalities. Multiple X-rays are used to create a 3-dimensional image of the organ, allowing examine abnormalities such as hiatal hernia, polyps, ulcers, or early detection of gastric carcinoma. Virtual gastroscopy will be placed as LLT to a new PT Computed tomographic gastrography which will be added in change request 2019079004.

**CR Number: 2019079004** **Implementation Date:** 26-Mar-19 Related CR: 2019079004

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Computed tomographic gastrography* | Approved as Requested | Proposed PT | |
| | | | *Computed tomographic gastrography* | 10082840 |
| | | | HLT primary | |
| | | | *Gastrointestinal and abdominal imaging procedures* | 10017963 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new term Computed tomographic gastrography is approved as requested. Virtual gastroscopy, also called computed tomographic gastrography, is a noninvasive procedure for the detection of gastric abnormalities. Multiple X-rays are used to create a 3-dimensional image of the organ, allowing examine abnormalities such as hiatal hernia, polyps, ulcers, or early detection of gastric carcinoma. Computed tomographic gastrography will be added as a PT to HLT Gastrointestinal and abdominal imaging procedures.

**CR Number: 2019079005** **Implementation Date:** 26-Mar-19 Related CR: 2019079005

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Arteriovenous fistula site erosion* | Approved as Requested | Proposed LLT | |
| | | | *Arteriovenous fistula site erosion* | 10082844 Current |
| | | | To PT | |
| | | | *Arteriovenous fistula site complication* | 10055122 |

MSSO Comment: The proposal to add a new LLT Arteriovenous fistula site erosion is approved as requested. Arteriovenous fistula site erosion, a complication of arteriovenous hemodialysis access, will be added as an LLT to PT Arteriovenous fistula site complication.

# Supplemental Update Report

**CR Number: 2019079006** **Implementation Date:** 26-Mar-19 Related CR: 2019079006

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Radiation contamination survey* | Approved as Requested | Proposed PT | |
| HLT primary | *Investigations NEC* | | *Radiation contamination survey* | 10082846 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Investigations NEC* | 10022892 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Radiation contamination survey to primary HLT Investigations NEC in SOC Investigations is approved as requested. Radiation contamination surveys provide a direct measure of radioactive material and can indicate the radiation exposure hazard in areas where radioactive materials are used, including storage and waste facilities, to detect contamination and control exposure to radioactive material. Routine surveys are an important to prevent radiation hazard.

**CR Number: 2019079007** **Implementation Date:** 26-Mar-19 Related CR: 2019079007

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Subcapsular haematoma* | Rejected | | |
| HLT primary | *Haemorrhages NEC* | | | |
| SOC primary | *Vascular disorders* | | | |

MSSO Comment: The proposal to add a new PT Subcapsular haematoma to primary HLT Haemorrhages NEC in SOC Vascular disorders is not approved. A subcapsular haematoma is perhaps most commonly described in the liver, spleen, and kidney, frequently associated with trauma. In addition, joint subcapsular haematoma is occasionally used in the clinical context of severe ligament or capsular joint injuries associated with haemarthrosis. Subcapsular haematoma without a qualification as to the organ or anatomical site of manifestation is an excessively imprecise term concept for representation in MedDRA. Should you have a coding need for a subcapsular haemorrhage of a particular organ, please feel welcome to submit a change request to the MSSO for a new term proposal of a more specific nature.

**CR Number: 2019079008** **Implementation Date:** 26-Mar-19 Related CR: 2019079008

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Fractional uric acid excretion* | Approved as Requested | Proposed PT | |
| HLT primary | *Renal function analyses* | | *Fractional uric acid excretion* | 10082845 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Renal function analyses* | 10038454 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Fractional uric acid excretion to primary HLT Renal function analyses in SOC Investigations is approved as requested. Fractional uric acid excretion is defined as the percentage of urate filtered by glomeruli that is excreted in urine. An elevated fractional uric acid excretion level is often associated with the syndrome of inappropriate antidiuretic hormone secretion.

# Supplemental Update Report

**CR Number: 2019079009** **Implementation Date:** 26-Mar-19 Related CR: 2019079009

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Fractional excretion of bicarbonate* | Approved as Requested | Proposed PT | |
| HLT primary | *Renal function analyses* | | *Fractional excretion of bicarbonate* | 10082847 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Renal function analyses* | 10038454 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Fractional excretion of bicarbonate to primary HLT Renal function analyses in SOC Investigations is approved as requested. Fractional excretion of bicarbonate is calculated using the following quantitative assays: urine bicarbonate, serum bicarbonate, urine creatinine and serum creatinine. Normally urinary bicarbonate is barely detectable and fractional excretion is <5% of the glomerular filtered load, but in proximal renal tubular acidosis, it is usually around 15%. In distal renal tubular acidosis, urine pH will be high, but plasma bicarbonate concentration can be low or normal. Fractional excretion of bicarbonate assessment is thus helpful to distinguish proximal renal tubular acidosis from distal renal tubular acidosis.

**CR Number: 2019079010** **Implementation Date:** 26-Mar-19 Related CR: 2019079010

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Aphonia (excl. psychogenic and nervous disorder origin)* | Rejected | | |

MSSO Comment: The proposal to add a new term Aphonia (excl. psychogenic and nervous disorder origin) is not approved. Unless a clinically significant etiologic factor is intrinsic to the name of a disorder or disease concept, MedDRA Preferred Term/Lowest Level Term naming conventions generally do not include exclusion of specific potential etiologies in the wording of the term. In a related change, the primary SOC for PT Aphonia will be re-assigned from SOC Nervous system disorders to SOC Respiratory, thoracic and mediastinal disorders to reflect site of manifestation as the primary SOC following MedDRA rules.

# Supplemental Update Report

**CR Number: 2019085005** **Implementation Date:** 26-Mar-19 Related CR: 2019079010

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Aphonia* | Approved as Requested | Proposed PT | |
| Old Primary SOC | *Nervous system disorders* | | *Aphonia* | 10002953 |
| New Primary SOC | *Respiratory, thoracic and mediastinal disorders* | | Old Primary SOC | |
| | | | *Nervous system disorders* | 10029205 |
| | | | New Primary SOC | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |

MSSO Comment:

**CR Number: 2019079011** **Implementation Date:** 26-Mar-19 Related CR: 2019079011

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Chronic active Epstein-Barr infection* | Approved Not as Requested | Proposed PT | |
| | | | *Chronic active Epstein-Barr virus infection* | 10082848 |
| | | | HLT primary | |
| | | | *Epstein-Barr viral infections* | 10015107 |
| | | | SOC primary | |
| | | | *Infections and infestations* | 10021881 |

MSSO Comment: The proposal to add a new term Chronic active Epstein-Barr infection is approved but not as requested. The disease is progressive with markedly elevated levels of EBV DNA in the blood and infiltration of organs by EBV-positive lymphocytes. Patients often present with fever, lymphadenopathy, splenomegaly, EBV hepatitis, or pancytopenia. Over time, these patients develop progressive immunodeficiency and if not treated, succumb to opportunistic infections, hemophagocytosis, multiorgan failure, or EBV-positive lymphomas. Chronic active Epstein-Barr infection will be modified to Chronic active Epstein-Barr virus infection and added as a new PT to HLT Epstein-Barr viral infections.

**CR Number: 2019079012** **Implementation Date:** 26-Mar-19 Related CR: 2019079012

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Glycogenic hepatopahty* | Approved Not as Requested | Proposed LLT | |
| To PT | *Diabetic hepatopathy* | | *Glycogenic hepatopathy* | 10082849 Current |
| | | | To PT | |
| | | | *Diabetic hepatopathy* | 10071265 |

MSSO Comment: The proposal to add a new LLT Glycogenic hepatopahty to PT Diabetic hepatopathy is approved but not as requested. The proposed term will be amended to the correctly spelled, Glycogenic hepatopathy. Glycogenic hepatopathy, a synonym of Diabetic hepatopathy, is a rare complication of poorly controlled diabetes mellitus characterized by transient liver dysfunction with elevated liver enzymes and associated hepatomegaly caused by the reversible accumulation of excess glycogen in the hepatocytes. It is predominantly seen in patients with longstanding type 1 diabetes mellitus and rarely reported in association with type 2 diabetes mellitus. Glycogenic hepatopathy will be added as an LLT to PT Diabetic hepatopathy.

# Supplemental Update Report

**CR Number: 2019080001** **Implementation Date:** 26-Mar-19 Related CR: 2019080001

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Mental impairment* | Rejected | | |
| Old Primary SOC | *Nervous system disorders* | | | |
| New Primary SOC | *Psychiatric disorders* | | | |

MSSO Comment: The proposal to reassign the primary SOC of PT Mental impairment from current SOC Nervous system disorders to SOC Psychiatric disorders is not approved. According to the American Psychiatric Association's (APA) Diagnostic and Statistical Manual of Mental Disorders - Fifth Edition (DSM-5) cognitive disorders are now listed as neurocognitive disorders (NCDs) to indicate that there is some type of involvement of the brain. Some of the major causes of cognitive disorders include genetic disorders, head injuries, brain diseases such as Parkinson's and Alzheimer's, brain infections such as meningitis, brain tumors, exposure to toxic substances, and malnutrition. Cognitive disorders used to be called "organic mental/ brain syndromes" or "organic mental disorders" to indicate that these disorders had a brain or biological basis. However, the term "organic" is no longer used because it implies that all other mental disorders (not categorized as organic) do not have a biological basis. Most mental health professionals now believe that the majority of mental disorders are caused or influenced by brain chemistry or another medical issue that affects how the brain functions. In addition, since MedDRA Version 6.1 PT Mental impairment has continued unchanged with its primary [SOC Nervous system disorders] and secondary [SOC Psychiatric disorders] SOC hierarchies. Furthermore, LLT Cognitive impairment/ PT Cognitive disorder comprises of similar primary and secondary SOC hierarchies and has existed unchanged since MedDRA Version 5.0.

**CR Number: 2019081001** **Implementation Date:** 29-Mar-19 Related CR: 2019081001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *CFC syndrome* | Approved as Requested | Proposed LLT | |
| To PT | *Cardiofaciocutaneous syndrome* | | *CFC syndrome* | 10082855 Current |
| | | | To PT | |
| | | | *Cardiofaciocutaneous syndrome* | 10082805 |

MSSO Comment: The proposal to add a new LLT CFC syndrome to PT Cardiofaciocutaneous syndrome is approved as requested. CFC syndrome is a recognized acronym for Cardiofaciocutaneous syndrome.

**CR Number: 2019081002** **Implementation Date:** 29-Mar-19 Related CR: 2019081002

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Common femoral vein thrombus extension* | Approved Not as Requested | Proposed LLT | |
| HLT primary | *Peripheral embolism and thrombosis* | | *Common femoral vein thrombus extension* | 10082854 Current |
| SOC primary | *Vascular disorders* | | To PT | |
| | | | *Peripheral vein thrombus extension* | 10082853 |

MSSO Comment: The proposal to add a new PT Common femoral vein thrombus extension to primary HLT Peripheral embolism and thrombosis in SOC Vascular disorders is approved but not as requested. A venous thrombus extension is often defined as a downstream (proximal) progression of an initial thrombus. A vein thrombus extension may be potentially be associated with embolic complications. Common femoral vein thrombus extension will be added as an LLT to a new broader PT Peripheral vein thrombus extension. In a related change, Peripheral vein thrombus extension will be added as a PT to HLT Peripheral embolism and thrombosis.

# Supplemental Update Report

**CR Number: 2019088005** **Implementation Date:** 29-Mar-19 Related CR: 2019081002

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Peripheral vein thrombus extension* | Approved as Requested | Proposed PT | |
| HLT primary | *Peripheral embolism and thrombosis* | | *Peripheral vein thrombus extension* | 10082853 |
| SOC primary | *Vascular disorders* | | HLT primary | |
| | | | *Peripheral embolism and thrombosis* | 10034572 |
| | | | SOC primary | |
| | | | *Vascular disorders* | 10047065 |

MSSO Comment:

**CR Number: 2019081003** **Implementation Date:** 26-Mar-19 Related CR: 2019081003

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Ectopic pregnancy termination* | Approved as Requested | Proposed PT | |
| From HLT | *Fallopian tube therapeutic procedures* | | *Ectopic pregnancy termination* | 10014168 |
| To HLT | *Obstetric therapeutic procedures* | | From HLT | |
| | | | *Fallopian tube therapeutic procedures* | 10016189 |
| | | | To HLT | |
| | | | *Obstetric therapeutic procedures* | 10029906 |

MSSO Comment: The proposal to move the PT Ectopic pregnancy termination from HLT Fallopian tube therapeutic procedures to HLT Obstetric therapeutic procedures is approved as requested. An ectopic pregnancy occurs in the fallopian tube in the majority of cases, but not exclusively as it may also arise in the pelvis, in ovaries or in abdomen.

# Supplemental Update Report

**CR Number: 2019081004** **Implementation Date:** 29-Mar-19 Related CR: 2019081004

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Papillon–Lefèvre syndrome* | Approved Not as Requested | Proposed PT | |
| | | | *Papillon-Lefevre syndrome* | 10082856 |
| | | | HLT primary | |
| | | | *Skin and subcutaneous tissue disorders congenital NEC* | 10040834 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary | |
| | | | *Hyperkeratoses* | 10020648 |
| | | | SOC secondary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment: The proposal to add a new term Papillon–Lefèvre syndrome is approved but not as requested. Papillon–Lefèvre syndrome, a very rare autosomal recessive trait characterized by palmoplantar hyperkeratosis and severe generalized early-onset periodontitis, will be added as PT Papillon–Lefevre syndrome without the accent following MedDRA conventions in respect of diacritical marks to primary HLT Skin and subcutaneous tissue disorders congenital NEC, secondary HLT Hyperkeratoses, secondary HLT Dental and oral soft tissue infections and secondary HLT Dental and periodontal infections and inflammations. In a related change, synonym LLT Keratosis palmoplantaris with periodontopathy will be added to new PT Papillon–Lefevre syndrome.

**CR Number: 2019088006** **Implementation Date:** 29-Mar-19 Related CR: 2019081004

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Keratosis palmoplantaris with periodontopathy* | Approved as Requested | Proposed LLT | |
| To PT | *Papillon-Lefevre syndrome* | | *Keratosis palmoplantaris with periodontopathy* | 10082857 Current |
| | | | To PT | |
| | | | *Papillon-Lefevre syndrome* | 10082856 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019088007** **Implementation Date:** 29-Mar-19 Related CR: 2019081004

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Papillon-Lefevre syndrome* | Approved as Requested | Proposed PT | |
| To HLT | *Dental and oral soft tissue infections* | | *Papillon-Lefevre syndrome* | 10082856 |
| | | | To HLT | |
| | | | *Dental and oral soft tissue infections* | 10012326 |

MSSO Comment:

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**CR Number: 2019088008** **Implementation Date:** 29-Mar-19 Related CR: 2019081004

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Papillon-Lefevre syndrome* | Approved as Requested | Proposed PT | |
| To HLT | *Dental and periodontal infections and inflammations* | | *Papillon-Lefevre syndrome* | 10082856 |
| | | | To HLT | |
| | | | *Dental and periodontal infections and inflammations* | 10012325 |

MSSO Comment:

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**CR Number: 2019081005** **Implementation Date:** 26-Mar-19 Related CR: 2019081005

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Radiotherapy to Tongue* | Approved Not as Requested | Proposed PT | |
| | | | *Radiotherapy to tongue* | 10082850 |
| | | | HLT primary | |
| | | | *Tongue therapeutic procedures* | 10043968 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment: The proposal to add a new LLT Radiotherapy to Tongue is approved but not as requested. The main treatments for tongue cancer are surgery, radiotherapy and chemotherapy, either combined or on their own. Treatment depends on how far the cancer has grown and whether it has spread. It also depends on which part of the tongue is affected. The requested term will be modified to comply with MedDRA capitalization conventions and added as a PT Radiotherapy to tongue to HLT Tongue therapeutic procedures.

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# Supplemental Update Report

**CR Number: 2019084001** **Implementation Date:** 26-Mar-19 Related CR: 2019084001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Laron-type dwarfism* | Approved as Requested | Proposed LLT | |
| To PT | *Laron syndrome* | | *Laron-type dwarfism* | 10082851 Current |
| | | | To PT | |
| | | | *Laron syndrome* | 10075492 |

MSSO Comment: The proposal to add a new LLT Laron-type dwarfism to PT Laron syndrome is approved as requested. Laron-type dwarfism, an autosomal recessive disorder characterized by an insensitivity to growth hormone, is a synonym of Laron syndrome.

**CR Number: 2019084002** **Implementation Date:** 26-Mar-19 Related CR: 2019084002

| Change Requested | Rename PT/LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Term to modify | *Asthma bronchial* | Approved Not as Requested | Proposed LLT | |
| Replacement term | *Bronchial asthma* | | *Bronchial asthma* | 10082852 Current |
| | | | To PT | |
| | | | *Asthma* | 10003553 |

MSSO Comment: The proposal to rename PT/LLT Asthma bronchial to Bronchial asthma is approved but not as requested. Asthma bronchial is LLT under PT Asthma since MedDRA Version 2.1 and modifying may have impact on legacy data. To enhance autoencoding, the LLT Bronchial asthma in the natural word order will be added to PT Asthma.

**CR Number: 2019084003** **Implementation Date:** 29-Mar-19 Related CR: 2019084003

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Sweat electrolytes test* | Approved as Requested | Proposed LLT | |
| To PT | *Sweat test* | | *Sweat electrolytes test* | 10082871 Current |
| | | | To PT | |
| | | | *Sweat test* | 10068025 |

MSSO Comment: The proposal to add a new LLT Sweat electrolytes test to PT Sweat test is approved as requested. This change request is part of a mapping project for a cystic fibrosis registry. The sweat test, a quantitative analysis of electrolytes including sodium and chloride in sweat, is the most valuable and widely used laboratory test for the diagnosis of cystic fibrosis. Sweat electrolytes test will be added as sub-concept LLT to PT Sweat test in line with existing LLT Sweat chloride test and LLT Sweat sodium test.

# Supplemental Update Report

**CR Number: 2019084004** **Implementation Date:** 29-Mar-19 Related CR: 2019084004

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Nasal potential difference test* | Approved as Requested | Proposed PT | |
| | | | *Nasal potential difference test* | 10082865 |
| HLT primary | *Mineral and electrolyte analyses* | | HLT primary | |
| | | | *Mineral and electrolyte analyses* | 10027637 |
| SOC primary | *Investigations* | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Nasal potential difference test to primary HLT Mineral and electrolyte analyses in SOC Investigations is approved as requested. This change request is part of a mapping project for a cystic fibrosis registry. The nasal potential difference test measures how well salts (sodium and chloride) flow across the mucous membranes in the nose. This type of test can be helpful when the results of a sweat test or a genetic test are not clear in the diagnosis of cystic fibrosis.

**CR Number: 2019084005** **Implementation Date:** 29-Mar-19 Related CR: 2019084005

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Intestinal current measurement test* | Approved Not as Requested | Proposed PT | |
| | | | *Intestinal current measurement test* | 10082868 |
| HLT primary | *Gastrointestinal histopathology procedures* | | HLT primary | |
| | | | *Mineral and electrolyte analyses* | 10027637 |
| SOC primary | *Investigations* | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Intestinal current measurement test to primary HLT Gastrointestinal histopathology procedures in SOC Investigations is approved but not as requested. This change request is part of a mapping project for a cystic fibrosis registry. Intestinal current measurement test is an electrophysiological technique for the diagnosis of cystic fibrosis using electrical current measurement on rectal biopsies. Intestinal current measurement test will be added to more appropriate HLT Mineral and electrolyte analyses.

# Supplemental Update Report

**CR Number: 2019084006** **Implementation Date:** 29-Mar-19 Related CR: 2019084006

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Lung clearance index* | Approved as Requested | Proposed PT | |
| HLT primary | *Respiratory and pulmonary function diagnostic procedures* | | *Lung clearance index* | 10082863 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Respiratory and pulmonary function diagnostic procedures* | 10037385 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Lung clearance index to primary HLT Respiratory and pulmonary function diagnostic procedures in SOC Investigations is approved as requested. This change request is part of a mapping project for a cystic fibrosis registry. Lung clearance index is a measure of abnormal ventilation distribution in obstructive airway diseases such as cystic fibrosis and is derived from the multiple breath inert gas washout technique. It is a description of how much ventilation is required to completely clear the Functional Residual Capacity.

**CR Number: 2019084007** **Implementation Date:** 29-Mar-19 Related CR: 2019084007

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *CFTR gene mutation* | Approved as Requested | Proposed PT | |
| HLT primary | *Chromosomal abnormalities NEC* | | *CFTR gene mutation* | 10082864 |
| SOC primary | *Congenital, familial and genetic disorders* | | HLT primary | |
| | | | *Chromosomal abnormalities NEC* | 10008805 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |

MSSO Comment: The proposal to add a new PT CFTR gene mutation to primary HLT Chromosomal abnormalities NEC in SOC Congenital, familial and genetic disorders is approved as requested. This change request is part of a mapping project for a cystic fibrosis registry. The CFTR gene provides instructions for making a protein called the cystic fibrosis transmembrane conductance regulator which functions as a channel across the membrane of cells that produce mucus, sweat, saliva, tears, and digestive enzymes. Conditions such as cystic fibrosis, congenital bilateral absence of the vas deferens, and hereditary pancreatitis are caused by mutations, or errors, in the CFTR gene, which result in either no CFTR protein being made or a malformed CFTR protein that cannot perform its key function in the cell. In related a change, the non-abbreviated LLT Cystic fibrosis transmembrane conductance regulator gene mutation will be added to the new PT CFTR gene mutation.

# Supplemental Update Report

**CR Number: 2019088013** **Implementation Date:** 29-Mar-19 Related CR: 2019084007

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Cystic fibrosis transmembrane conductance regulator gene mutation* | Approved as Requested | Proposed LLT | |
| To PT | *CFTR gene mutation* | | *Cystic fibrosis transmembrane conductance regulator gene mutation* | 10082876 Current |
| | | | To PT | |
| | | | *CFTR gene mutation* | 10082864 |

MSSO Comment:

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**CR Number: 2019084008** **Implementation Date:** 29-Mar-19 Related CR: 2019084008

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *ΔF508-mutation* | Approved Not as Requested | Proposed LLT | |
| To PT | *CFTR gene mutation* | | *CFTR delta F508* | 10082872 Current |
| | | | To PT | |
| | | | *CFTR gene mutation* | 10082864 |

MSSO Comment: The proposal to add a new LLT ΔF508-mutation to PT CFTR gene mutation is approved but not as requested. This change request is part of a mapping project for a cystic fibrosis registry. Delta F508 mutation accounts for 70% of the mutant CFTR genes in the world; it corresponds to the deletion of phenylalanine at position 508 of the CFTR protein. The requested term will be added with spelled out delta as LLT CFTR delta F508 to PT CFTR gene mutation.

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**CR Number: 2019084009** **Implementation Date:** 29-Mar-19 Related CR: 2019084009

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Achromobacter infection* | Approved Not as Requested | Proposed PT | |
| HLT primary | *Burkholderia infections* | | *Achromobacter infection* | 10082866 |
| SOC primary | *Infections and infestations* | | HLT primary | |
| | | | *Bacterial infections NEC* | 10004047 |
| | | | SOC primary | |
| | | | *Infections and infestations* | 10021881 |

MSSO Comment: The proposal to add a new PT Achromobacter infection to primary HLT Burkholderia infections in SOC Infections and infestations is approved but not as requested. This change request is part of a mapping project for a cystic fibrosis registry. Achromobacteria are ubiquitous environmental organisms that may also become opportunistic pathogens in certain conditions, such as cystic fibrosis, hematologic and solid organ malignancies, renal failure, and certain immune deficiencies. Achromobacter infection will be added as a PT to the more appropriate HLT Bacterial infections NEC. In a related change, LLT Achromobacter xylosoxidans infection will be added to new PT Achromobacter infection.

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# Supplemental Update Report

**CR Number: 2019088014** **Implementation Date:** 29-Mar-19 Related CR: 2019084009

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Achromobacter xylosoxidans infection* | Approved as Requested | Proposed LLT | |
| To PT | *Achromobacter infection* | | *Achromobacter xylosoxidans infection* | 10082877 Current |
| | | | To PT | |
| | | | *Achromobacter infection* | 10082866 |

MSSO Comment:

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**CR Number: 2019084010** **Implementation Date:** 29-Mar-19 Related CR: 2019084010

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Chronic Pseudomonas aeruginosa* | Approved Not as Requested | Proposed LLT | |
| To PT | *Pseudomonas infection* | | *Chronic Pseudomonas aeruginosa infection* | 10082869 Current |
| | | | To PT | |
| | | | *Pseudomonas infection* | 10061471 |

MSSO Comment: The proposal to add a new LLT Chronic Pseudomonas aeruginosa to PT Pseudomonas infection is approved but not as requested. This change request is part of a mapping project for a cystic fibrosis registry. It has been recognized that chronic P. aeruginosa infection is associated with more rapid lung function decline and earlier death in individuals with cystic fibrosis. Defining chronic P. aeruginosa infection is, therefore, an important step in identifying cystic fibrosis patients most at risk of lung disease progression. Chronic Pseudomonas aeruginosa infection will be added as an LLT to PT Pseudomonas infection to more specifically represent the concept.

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**CR Number: 2019084011** **Implementation Date:** 29-Mar-19 Related CR: 2019084011

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Faecal elastase test* | Approved as Requested | Proposed PT | |
| HLT primary | *Digestive enzymes* | | *Faecal elastase test* | 10082867 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Digestive enzymes* | 10012981 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Faecal elastase test to primary HLT Digestive enzymes in SOC Investigations is approved as requested. This change request is part of a mapping project for a cystic fibrosis registry. Elastase is an enzyme produced by exocrine tissue in the pancreas. This test measures the amount of elastase in stool (feces) to help evaluate whether a person's pancreas is functioning properly. It is used to test for conditions such as chronic pancreatitis and sometimes pancreatic cancer. In children, it is used to test for cystic fibrosis or Shwachman-Diamond syndrome. In a related change, American English counterpart LLT Fecal elastase test will be added to this new PT Faecal elastase test.

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# Supplemental Update Report

**CR Number: 2019088011** **Implementation Date:** 29-Mar-19 Related CR: 2019084011

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Fecal elastase test* | Approved as Requested | Proposed LLT | |
| To PT | *Faecal elastase test* | | *Fecal elastase test* | 10082878 Current |
| | | | To PT | |
| | | | *Faecal elastase test* | 10082867 |

MSSO Comment:

**CR Number: 2019084012** **Implementation Date:** 29-Mar-19 Related CR: 2019084012

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Chronic Haemophilus influenza infection* | Approved Not as Requested | Proposed LLT | |
| To PT | *Haemophilus infection* | | *Chronic Haemophilus influenzae infection* | 10082874 Current |
| | | | To PT | |
| | | | *Haemophilus infection* | 10061190 |

MSSO Comment: The proposal to add a new LLT Chronic Haemophilus influenza infection to PT Haemophilus infection is approved but not as requested. This change request is part of a mapping project for a cystic fibrosis registry. It has been recognized that chronic infection is associated with more rapid lung function decline and earlier death in individuals with cystic fibrosis. The term will be reworded to Chronic Haemophilus influenzae infection to correct spelling. In a related change, American English counterpart LLT Chronic Hemophilus influenzae infection will also be added as LLT to PT Haemophilus infection.

**CR Number: 2019088012** **Implementation Date:** 29-Mar-19 Related CR: 2019084012

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Chronic Hemophilus influenzae infection* | Approved as Requested | Proposed LLT | |
| To PT | *Haemophilus infection* | | *Chronic Hemophilus influenzae infection* | 10082875 Current |
| | | | To PT | |
| | | | *Haemophilus infection* | 10061190 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019084013** **Implementation Date:** 29-Mar-19 Related CR: 2019084013

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Chronic Burkholderia cepacia complex infection* | Approved as Requested | Proposed LLT | | |
| To PT | *Burkholderia cepacia complex infection* | | *Chronic Burkholderia cepacia complex infection* | 10082870 | Current |
| | | | To PT | | |
| | | | *Burkholderia cepacia complex infection* | 10069657 | |

MSSO Comment: The proposal to add a new LLT Chronic Burkholderia cepacia complex infection to PT Burkholderia cepacia complex infection is approved as requested. This change request is part of a mapping project for a cystic fibrosis registry. The primary cause of premature death in cystic fibrosis is progressive airway disease caused by recurring infections.

**CR Number: 2019084014** **Implementation Date:** 29-Mar-19 Related CR: 2019084014

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Chornic Staphylococcal infection* | Approved Not as Requested | Proposed LLT | | |
| To PT | *Staphylococcal infection* | | *Chronic staphylococcal infection* | 10082873 | Current |
| | | | To PT | | |
| | | | *Staphylococcal infection* | 10058080 | |

MSSO Comment: The proposal to add a new LLT Chornic Staphylococcal infection to PT Staphylococcal infection is approved but not as requested. The term will be updated to Chronic staphylococcal infection, to correct misspelling and comply with MedDRA capitalization conventions. This change request is part of a mapping project for a cystic fibrosis registry. The primary cause of premature death in cystic fibrosis is progressive airway disease caused by recurring infections. The most common bacteria involved are Pseudomonas aeruginosa and Staphylococcus aureus. Chronic staphylococcal infection will be added as an LLT to PT Staphylococcal infection.

**CR Number: 2019084015** **Implementation Date:** 29-Mar-19 Related CR: 2019084015

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed Term | *Subcutaneous sarcoidosis* | Approved as Requested | Proposed LLT | | |
| | | | *Subcutaneous sarcoidosis* | 10082858 | Current |
| | | | To PT | | |
| | | | *Cutaneous sarcoidosis* | 10011674 | |

MSSO Comment: The proposal to add a new term Subcutaneous sarcoidosis is approved as requested. Subcutaneous sarcoidosis is a specific form of cutaneous sarcoidosis, which has been reported to occur in 1.4% to 6% of patients with systemic sarcoidosis. Most reported cases are in women, most often in their fifth and sixth decades, and appear as multiple, asymptomatic, hardly indurated subcutaneous nodules without changes in the overlying epidermis. The lesions are characteristically located in the upper extremities, mainly in the forearms, and usually are bilateral and asymmetric. Subcutaneous sarcoidosis will be added as a sub-element LLT of PT Cutaneous sarcoidosis.

# Supplemental Update Report

**CR Number: 2019084016** **Implementation Date:** 29-Mar-19 Related CR: 2019084016

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Radiotherapy to nasopharynx* | Approved as Requested | Proposed LLT | |
| | | | *Radiotherapy to nasopharynx* | 10082860 Current |
| | | | To PT | |
| | | | *Radiotherapy to pharynx* | 10082859 |

MSSO Comment: The proposal to add a new term Radiotherapy to nasopharynx is approved as requested. Radiotherapy to nasopharynx will be added as a sub-concept LLT to a broader new PT Radiotherapy to pharynx. In a related change, Radiotherapy to pharynx will be added as a PT to HLT Ear, nose and throat radiotherapies. In addition, PT Radiotherapy to throat will be demoted under new PT Radiotherapy to pharynx as a sub-concept LLT.

**CR Number: 2019088009** **Implementation Date:** 29-Mar-19 Related CR: 2019084016

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Radiotherapy to pharynx* | Approved as Requested | Proposed PT | |
| HLT primary | *Ear, nose and throat radiotherapies* | | *Radiotherapy to pharynx* | 10082859 |
| SOC primary | *Surgical and medical procedures* | | HLT primary | |
| | | | *Ear, nose and throat radiotherapies* | 10037797 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment:

**CR Number: 2019088010** **Implementation Date:** 29-Mar-19 Related CR: 2019084016

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Radiotherapy to throat* | Approved as Requested | PT to merge | |
| To PT | *Radiotherapy to pharynx* | | *Radiotherapy to throat* | 10062097 Current |
| | | | To PT | |
| | | | *Radiotherapy to pharynx* | 10082859 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019085001** **Implementation Date:** 01-Apr-19 Related CR: 2019085001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *RPE65 gene mutation* | Approved as Requested | Proposed PT | |
| | | | *RPE65 gene mutation* | 10082888 |
| | | | HLT primary | |
| | | | *Chromosomal abnormalities NEC* | 10008805 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary | |
| | | | *Retinal structural change, deposit and degeneration* | 10038896 |
| | | | SOC secondary | |
| | | | *Eye disorders* | 10015919 |

MSSO Comment: The proposal to add a new term RPE65 gene mutation is approved as requested. The RPE65 gene provides instructions for making a protein (synthesized in the retinal pigment epithelium) that is essential for normal vision. The RPE65 protein is involved in a multi-step process called the visual cycle, which converts light entering the eye into electrical signals that are transmitted to the brain. Mutations of the RPE65 gene may lead to partial or complete lack of a functional RPE65 protein, which blocks the visual cycle, and leads to severe visual impairment beginning very early in life. RPE65 gene mutation will be added as a PT with a primary link to HLT Chromosomal abnormalities NEC and a secondary link to HLT Retinal structural change, deposit and degeneration.

**CR Number: 2019085002** **Implementation Date:** 29-Mar-19 Related CR: 2019085002

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Glottal incompetence* | Approved as Requested | Proposed PT | |
| | | | *Glottal incompetence* | 10082861 |
| | | | HLT primary | |
| | | | *Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms)* | 10023819 |
| | | | SOC primary | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |

MSSO Comment: The proposal to add a new term Glottal incompetence is approved as requested. Glottal incompetence is a condition of weakened voice production. The incompetence derives from loss of air through the vocal folds during phonation. Causes include neurologic disorders, aging, deconditioning, scar formation, and iatrogenic effects of procedures. Affected patients often report a weak breathy voice, decreased loudness, vocal fatigue, inability to produce an adequate cough, and shortness of breath while talking. Glottal incompetence will be added as a PT to HLT Laryngeal and adjacent sites disorders NEC (excl infections and neoplasms).

# Supplemental Update Report

**CR Number: 2019085003** **Implementation Date:** 29-Mar-19 Related CR: 2019085003

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Respiratory compromise* | Approved as Requested | Proposed LLT | |
| | | | *Respiratory compromise* | 10082862 Current |
| | | | To PT | |
| | | | *Respiratory disorder* | 10038683 |

MSSO Comment: The proposal to add a new term Respiratory compromise is approved as requested. Respiratory compromise, is a nonspecific concept that does not appear to have universally recognized meaning, as it could be used to describe a compromised airway, and a variety of other acute and chronic respiratory conditions and disorders. Respiratory compromise will be added as an LLT to PT Respiratory disorder.

**CR Number: 2019085006** **Implementation Date:** 01-Apr-19 Related CR: 2019085006

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Upper lip bite test* | Approved Not as Requested | Proposed PT | |
| | | | *Upper lip bite test* | 10082889 |
| | | | HLT primary | |
| | | | *Physical examination procedures and organ system status* | 10071941 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new LLT Upper lip bite test is approved but not as requested. Upper lip bite test is one of the various bedside tests used for prediction of difficult laryngoscopic intubation. It is based on the assumption that a patient's ability to eclipse the entire upper lip with the lower incisors correlates inversely with difficult intubation. Upper lip bite test is a well defined physical examination which warrants representation as its own PT, and therefore will be added as a PT under HLT Physical examination procedures and organ system status, in parallel with its related existing PT Mallampati score.

**CR Number: 2019086001** **Implementation Date:** 01-Apr-19 Related CR: 2019086001

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Anal eczema* | Rejected | | |
| From PT | *Eczema* | | | |
| HLT primary | *Anal and rectal signs and symptoms* | | | |

MSSO Comment: The proposal to promote the LLT Anal eczema from PT Eczema to primary HLT Anal and rectal signs and symptoms in SOC Gastrointestinal disorders and secondary HLT Dermatitis and eczema in SOC Skin and subcutaneous tissue disorders is not approved. Because eczema is the principal conceptual element of LLT Anal eczema, this LLT is appropriately placed as a sub-concept of PT Eczema, with other LLTs representing specific anatomical sites of eczema.

# Supplemental Update Report

**CR Number:** **2019086002** **Implementation Date:** 01-Apr-19 Related CR: 2019086002

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Vulval eczema* | Rejected | | |
| From PT | *Eczema* | | | |
| HLT primary | *Vulvovaginal signs and symptoms* | | | |

MSSO Comment: The proposal to promote the LLT Vulval eczema from PT Eczema to primary HLT Vulvovaginal signs and symptoms in SOC Reproductive system and breast disorders and secondary HLT Dermatitis and eczema in SOC Skin and subcutaneous tissue disorders is not approved. Because eczema is the principal conceptual element of LLT Vulval eczema, this LLT is appropriately placed as a sub-concept of PT Eczema, with other LLTs representing specific anatomical sites of eczema.

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**CR Number:** **2019086003** **Implementation Date:** 01-Apr-19 Related CR: 2019086003

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Penile discomfort* | Approved as Requested | Proposed LLT | |
| | | | *Penile discomfort* | 10082880 Current |
| | | | To PT | |
| | | | *Genital discomfort* | 10066887 |

MSSO Comment: The proposal to add a new term Penile discomfort is approved as requested. Discomfort is a non-specific term that may be used to describe soreness, tenderness, irritation, ache, etc. Penile discomfort will be added as an LLT to PT Genital discomfort.

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**CR Number:** **2019086004** **Implementation Date:** 01-Apr-19 Related CR: 2019086004

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Eyelid discomfort* | Approved Not as Requested | Proposed LLT | |
| HLT primary | *Ocular disorders NEC* | | *Eyelid discomfort* | 10082883 Current |
| SOC primary | *Eye disorders* | | To PT | |
| | | | *Eyelid irritation* | 10057385 |

MSSO Comment: The proposal to add a new PT Eyelid discomfort to primary HLT Ocular disorders NEC in SOC Eye disorders and secondary HLT Dermal and epidermal conditions NEC in SOC Skin and subcutaneous tissue disorders is approved but not as requested. Eyelid discomfort is a non-specific term that may be used to describe soreness, tenderness, irritation, ache, etc., of the eyelid. Eyelid discomfort will be placed as a sub-concept LLT to PT Eyelid irritation.

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# Supplemental Update Report

**CR Number: 2019086005** **Implementation Date:** 01-Apr-19 Related CR: 2019086005

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Product contamination animal* | Approved Not as Requested | Proposed LLT | |
| To PT | *Product contamination physical* | | *Product contamination animal matter* | 10082881 Current |
| | | | To PT | |
| | | | *Product contamination physical* | 10069176 |

MSSO Comment: The proposal to add a new LLT Product contamination animal to PT Product contamination physical is approved but not as requested. A product may potentially be physically contaminated with animal matter. The requested concept will be modified and added as LLT Product contamination animal matter to PT Product contamination physical.

**CR Number: 2019086006** **Implementation Date:** 01-Apr-19 Related CR: 2019086006

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Product contamination plant matter* | Approved as Requested | Proposed LLT | |
| To PT | *Product contamination physical* | | *Product contamination plant matter* | 10082885 Current |
| | | | To PT | |
| | | | *Product contamination physical* | 10069176 |

MSSO Comment: The proposal to add a new LLT Product contamination plant matter to PT Product contamination physical is approved as requested. A product may potentially be physically contaminated with plant matter.

**CR Number: 2019086007** **Implementation Date:** 01-Apr-19 Related CR: 2019086007

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Product contamination inorganic matter* | Approved as Requested | Proposed LLT | |
| To PT | *Product contamination physical* | | *Product contamination inorganic matter* | 10082886 Current |
| | | | To PT | |
| | | | *Product contamination physical* | 10069176 |

MSSO Comment: The proposal to add a new LLT Product contamination inorganic matter to PT Product contamination physical is approved as requested. A product may potentially be physically contaminated with inorganic matter.

# Supplemental Update Report

**CR Number: 2019086008** **Implementation Date:** 01-Apr-19 Related CR: 2019086008

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Mouth pustule* | Approved as Requested | Proposed LLT | |
| To PT | *Oral pustule* | | *Mouth pustule* | 10082882 Current |
| | | | To PT | |
| | | | *Oral pustule* | 10056674 |

MSSO Comment: The proposal to add a new LLT Mouth pustule to PT Oral pustule is approved as requested. Mouth pustule is a frequently used synonym of PT Oral pustule.

**CR Number: 2019086009** **Implementation Date:** 01-Apr-19 Related CR: 2019086009

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Lip pustule* | Approved as Requested | Proposed LLT | |
| | | | *Lip pustule* | 10082884 Current |
| | | | To PT | |
| | | | *Oral pustule* | 10056674 |

MSSO Comment: The proposal to add a new term Lip pustule is approved as requested. Lip pustule represents a visible collection of pus within or beneath the epidermal or mucous layers or the lip. Lip pustule will be added as an LLT under PT Oral pustule.

**CR Number: 2019086010** **Implementation Date:** 01-Apr-19 Related CR: 2019086010

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Gingival pustule* | Approved Not as Requested | Proposed LLT | |
| | | | *Gingival pustule* | 10082887 Current |
| | | | To PT | |
| | | | *Gingival abscess* | 10052359 |

MSSO Comment: The proposal to add a new PT Gingival pustule is approved but not as requested. Gingival pustule represents a visible collection of pus within or beneath the gingival mucosa. Gingival pustule will be added as a sub-concept LLT to PT Gingival abscess.

# Supplemental Update Report

**CR Number:** **2019086011** **Implementation Date:** 01-Apr-19 Related CR: 2019086011

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Tongue pustule* | Rejected | | |

MSSO Comment: The proposal to add a new PT Tongue pustule is not approved. The MSSO has conducted a literature search and was unable to identify clinical descriptions of "tongue pustule". Furthermore, the submitter's request for this new term did not describe a particular coding need for one or more reports of this nature. Please consider the existing terms LLT Oral pustule or LLT Tongue abscess.

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**CR Number:** **2019086012** **Implementation Date:** 01-Apr-19 Related CR: 2019086012

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Genital acne* | Rejected | | |
| HLT primary | *Reproductive tract signs and symptoms NEC* | | | |
| SOC primary | *Reproductive system and breast disorders* | | | |

MSSO Comment: The proposal to add a new PT Genital acne to primary HLT Reproductive tract signs and symptoms NEC in SOC Reproductive system and breast disorders and secondary HLT Acnes in SOC Skin and subcutaneous tissue disorders is not approved. The proposed term could be misleading since it may represent the presence or acne vulgaris in the genital region (uncommon) or a disorder of the apocrine sweat glands called acne inversa (hidradenitis suppurativa) which is a frequent, chronic and recurrent disorder, usually developing after puberty and most commonly involving the genitofemoral area or axillae. Should the term be considered for further requests, please clarify the need and context of it.

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**CR Number:** **2019086013** **Implementation Date:** 01-Apr-19 Related CR: 2019086013

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Genital pimples* | Rejected | | |
| To PT | *Genital acne* | | | |

MSSO Comment: The proposal to add a new LLT Genital pimples to PT Genital acne is not approved. Due to the previous rejection of Genital acne in change request 2019086012. The reported event can be coded by split coding with LLT Pimple and LLT Genital disorder male/LLT Genital disorder female.

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# Supplemental Update Report

**CR Number: 2019086014** **Implementation Date:** 01-Apr-19 Related CR: 2019086014

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Genital urticaria* | Rejected | | |
| HLT primary | *Reproductive tract signs and symptoms NEC* | | | |
| SOC primary | *Reproductive system and breast disorders* | | | |

MSSO Comment: The proposal to add a new PT Genital urticaria to primary HLT Reproductive tract signs and symptoms NEC in SOC Reproductive system and breast disorders and secondary HLT Urticarias in SOC Immune system disorders is not approved. MedDRA does provide terms for types of urticaria such cold, solar, contact but not for all possible anatomical sites. Please consider LLT Urticaria localised for your coding needs.

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**CR Number: 2019086015** **Implementation Date:** 01-Apr-19 Related CR: 2019086015

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Discomfort around orbit* | Approved Not as Requested | Proposed LLT | |
| From PT | *Ocular discomfort* | | *Discomfort around orbit* | 10013085 Current |
| HLT primary | *Ocular disorders NEC* | | From PT | |
| | | | *Ocular discomfort* | 10052143 |
| | | | To PT | |
| | | | *Periorbital discomfort* | 10082879 |

MSSO Comment: The proposal to promote the LLT Discomfort around orbit from PT Ocular discomfort to primary HLT Ocular disorders NEC in SOC Eye disorders is approved but not as requested. After reconsideration, the MSSO will add new PT Periorbital discomfort which has been recently rejected in change request 2019051022 and move LLT Discomfort around orbit from PT Ocular discomfort to the new PT Periorbital discomfort. In a related change, PT Periorbital discomfort will be added to HLT Ocular disorders NEC.

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**CR Number: 2019091005** **Implementation Date:** 01-Apr-19 Related CR: 2019086015

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Periorbital discomfort* | Approved as Requested | Proposed PT | |
| HLT primary | *Ocular disorders NEC* | | *Periorbital discomfort* | 10082879 |
| SOC primary | *Eye disorders* | | HLT primary | |
| | | | *Ocular disorders NEC* | 10030032 |
| | | | SOC primary | |
| | | | *Eye disorders* | 10015919 |

MSSO Comment:

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# Supplemental Update Report

**CR Number:** **2019086016** **Implementation Date:** 04-Apr-19 Related CR: 2019086016

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pregnancy loss <20 weeks gestation* | Approved Not as Requested | Proposed LLT | |
| | | | *Pregnancy loss <20 weeks gestation* | 10082892 Current |
| | | | To PT | |
| | | | *Abortion spontaneous* | 10000234 |

MSSO Comment: The proposal to add a new PT Pregnancy loss <20 weeks gestation is approved but not as requested. An early miscarriage is the loss of a pregnancy in the first 13 weeks. A late miscarriage occurs after 13 weeks and before 20-24 weeks of pregnancy. Pregnancy loss <20 weeks gestation will be added as a sub-concept LLT to PT Abortion spontaneous. In a related change, LLT Pregnancy loss will be moved from PT Foetal death to PT Abortion spontaneous for better alignment.

**CR Number:** **2019094001** **Implementation Date:** 04-Apr-19 Related CR: 2019086016

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Pregnancy loss* | Approved as Requested | Proposed LLT | |
| From PT | *Foetal death* | | *Pregnancy loss* | 10072314 Current |
| To PT | *Abortion spontaneous* | | From PT | |
| | | | *Foetal death* | 10055690 |
| | | | To PT | |
| | | | *Abortion spontaneous* | 10000234 |

MSSO Comment:

**CR Number:** **2019087001** **Implementation Date:** 04-Apr-19 Related CR: 2019087001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Bent Spine Syndrome* | Approved Not as Requested | Proposed LLT | |
| To PT | *Camptocormia* | | *Bent spine syndrome* | 10082896 Current |
| | | | To PT | |
| | | | *Camptocormia* | 10069646 |

MSSO Comment: The proposal to add a new LLT Bent Spine Syndrome to PT Camptocormia is approved but not as requested. Camptocormia, also referred to as bent spine syndrome (BSS) is defined as an abnormal flexion of the trunk, appearing in standing position, increasing during walking and abating in supine position. Bent spine syndrome, modified in accordance with MedDRA capitalisation conventions will be added as a synonym LLT to PT Camptocormia.

# Supplemental Update Report

**CR Number: 2019087002** **Implementation Date:** 04-Apr-19 Related CR: 2019087002

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Necrotising fasciitis perineum* | Rejected | | |
| To PT | *Fournier's gangrene* | | | |

MSSO Comment: The proposal to add a new LLT Necrotising fasciitis perineum to PT Fournier's gangrene is not approved. Necrotising fasciitis perineum is conceptually equivalent to Necrotising fasciitis perineal which will be added in change request 2019087003.

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**CR Number: 2019087003** **Implementation Date:** 04-Apr-19 Related CR: 2019087003

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Necrotising fasciitis perineal* | Approved as Requested | Proposed LLT | | |
| To PT | *Fournier's gangrene* | | *Necrotising fasciitis perineal* | 10082895 | Current |
| | | | To PT | | |
| | | | *Fournier's gangrene* | 10017068 | |

MSSO Comment: The proposal to add a new LLT Necrotising fasciitis perineal to PT Fournier's gangrene is approved as requested. Fournier's gangrene is a fulminant form of infective necrotizing fasciitis of the perineal, genital, or perianal regions, which commonly affects men, but can also occur in women and children. Necrotising fasciitis perineal will therefore be added as a sub-concept LLT to PT Fournier's gangrene. In a related change, the American English counterpart LLT Necrotizing fasciitis perineal will also be added as an LLT to PT Fournier's gangrene.

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**CR Number: 2019094012** **Implementation Date:** 04-Apr-19 Related CR: 2019087003

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Necrotizing fasciitis perineal* | Approved as Requested | Proposed LLT | | |
| To PT | *Fournier's gangrene* | | *Necrotizing fasciitis perineal* | 10082898 | Current |
| | | | To PT | | |
| | | | *Fournier's gangrene* | 10017068 | |

MSSO Comment:

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# Supplemental Update Report

**CR Number: 2019087004** **Implementation Date:** 04-Apr-19 Related CR: 2019087004

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Necrotising fasciitis genital* | Approved as Requested | Proposed LLT | |
| To PT | *Fournier's gangrene* | | *Necrotising fasciitis genital* | 10082893 Current |
| | | | To PT | |
| | | | *Fournier's gangrene* | 10017068 |

MSSO Comment: The proposal to add a new LLT Necrotising fasciitis genital to PT Fournier's gangrene is approved as requested. Fournier's gangrene is a fulminant form of infective necrotizing fasciitis of the perineal, genital, or perianal regions, which commonly affects men, but can also occur in women and children. Necrotising fasciitis genital will therefore be added as a sub-concept LLT to PT Fournier's gangrene. In a related change, the American English counterpart LLT Necrotizing fasciitis genital will also be added as an LLT to PT Fournier's gangrene.

**CR Number: 2019094013** **Implementation Date:** 04-Apr-19 Related CR: 2019087004

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Necrotizing fasciitis genital* | Approved as Requested | Proposed LLT | |
| To PT | *Fournier's gangrene* | | *Necrotizing fasciitis genital* | 10082897 Current |
| | | | To PT | |
| | | | *Fournier's gangrene* | 10017068 |

MSSO Comment:

**CR Number: 2019087005** **Implementation Date:** 04-Apr-19 Related CR: 2019087005

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Necrotising fasciitis perianal* | Approved as Requested | Proposed LLT | |
| To PT | *Fournier's gangrene* | | *Necrotising fasciitis perianal* | 10082894 Current |
| | | | To PT | |
| | | | *Fournier's gangrene* | 10017068 |

MSSO Comment: The proposal to add a new LLT Necrotising fasciitis perianal to PT Fournier's gangrene is approved as requested. Fournier's gangrene is a fulminant form of infective necrotizing fasciitis of the perineal, genital, or perianal regions, which commonly affects men, but can also occur in women and children. Necrotising fasciitis perianal will therefore be added as a sub-concept LLT to PT Fournier's gangrene. In a related change, the American English counterpart LLT Necrotizing fasciitis perianal will also be added as an LLT to PT Fournier's gangrene.

# Supplemental Update Report

**CR Number: 2019094014** **Implementation Date:** 04-Apr-19 Related CR: 2019087005

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Necrotizing fasciitis perianal* | Approved as Requested | Proposed LLT | |
| To PT | *Fournier's gangrene* | | *Necrotizing fasciitis perianal* | 10082899 Current |
| | | | To PT | |
| | | | *Fournier's gangrene* | 10017068 |

MSSO Comment:

**CR Number: 2019087006** **Implementation Date:** 01-Apr-19 Related CR: 2019087006

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Montreal cognitive assessment* | Approved as Requested | Proposed PT | |
| | | | *Montreal cognitive assessment* | 10082890 |
| | | | HLT primary | |
| | | | *Neurologic diagnostic procedures* | 10029285 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new term Montreal cognitive assessment is approved as requested. The Montreal Cognitive Assessment (MoCA) is a widely used screening assessment for detecting cognitive impairment. Since the MoCA assesses multiple cognitive domains, it may be a useful cognitive screening tool for several neurological diseases that affect younger populations, such as Parkinson's disease, vascular cognitive impairment, Huntington's disease, brain metastasis, sleep behaviour disorder, primary brain tumors, multiple sclerosis and other conditions such as traumatic brain injury, depression, schizophrenia and heart failure. Montreal cognitive assessment will be added as a new PT to HLT Neurologic diagnostic procedures.

**CR Number: 2019087007** **Implementation Date:** 01-Apr-19 Related CR: 2019087007

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Venous blood pH* | Approved as Requested | Proposed LLT | |
| | | | *Venous blood pH* | 10082891 Current |
| | | | To PT | |
| | | | *Blood pH* | 10061724 |

MSSO Comment: The proposal to add a new term Venous blood pH is approved as requested. Venous blood pH, quantitative measurement of acidity or alkalinity of venous blood, will be added as a sub-concept LLT to PT Blood pH in line with LLT Arterial blood pH.

# Supplemental Update Report

**CR Number:** **2019088001** **Implementation Date:** 04-Apr-19 Related CR: 2019088001

| Change Requested | Change Status of LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| LLT to change | *LUMBAR syndrome* | Rejected | | |
| Status | *non-current* | | | |

MSSO Comment: The proposal to change status of LLT LUMBAR syndrome to non-current is not approved. In MedDRA, capitalization conventions for full words only pertain to the capitalization of first letter of a word. An entire word is not capitalized, unless it is an abbreviation or an acronym. Accordingly, regarding PT/LLT LUMBAR syndrome, the all upper case letter expression "LUMBAR" is a recognized acronym for: lower body infantile hemangioma, urogential anomalies, ulceration, myelopathy, bony deformities, anorectal malformations, arterial anomalies, and renal anomalies.

**CR Number:** **2019088002** **Implementation Date:** 04-Apr-19 Related CR: 2019088002

| Change Requested | Change Status of LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| LLT to change | *PELVIS syndrome* | Rejected | | |
| Status | *non-current* | | | |

MSSO Comment: The proposal to change status of LLT PELVIS syndrome to non-current is not approved. In MedDRA, capitalization conventions for full words only pertain to the capitalization of first letter of a word. An entire word is not capitalized, unless it is an abbreviation or an acronym. Accordingly, regarding LLT PELVIS syndrome, the all upper case letter expression "PELVIS" is a recognized acronym for: perineal hemangioma, external genitalia malformations, lipomyelomeningocele, vesicorenal abnormalities, imperforate anus, and skin tag. LLT PELVIS syndrome and LLT LUMBAR syndrome are synonyms.

**CR Number:** **2019088003** **Implementation Date:** 04-Apr-19 Related CR: 2019088003

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Talipes calcaneus* | Approved as Requested | Proposed LLT | |
| To PT | *Talipes* | | *Talipes calcaneus* | 10082900 Current |
| | | | To PT | |
| | | | *Talipes* | 10043101 |

MSSO Comment: The proposal to add a new LLT Talipes calcaneus to PT Talipes is approved as requested. Talipes calcaneus (a type of talipes, or clubfoot) is characterized by upward pointing toes, and the foot resting on the heel.

# Supplemental Update Report

**CR Number: 2019088004** **Implementation Date:** 04-Apr-19 Related CR: 2019088004

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Symbrachydactyly* | Approved as Requested | Proposed LLT | |
| | | | *Symbrachydactyly* | 10082901 Current |
| | | | To PT | |
| | | | *Syndactyly* | 10042778 |

MSSO Comment: The proposal to add a new term Symbrachydactyly is approved as requested. Symbrachydactyly is a unilateral hand malformation characterized by failure of formation of fingers and presence of rudimentary nubbins that include elements of nail plate, bone, and cartilage. Symbrachydactyly will be added as a sub-concept LLT to PT Syndactyly.

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**CR Number: 2019088015** **Implementation Date:** 04-Apr-19 Related CR: 2019088015

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Red light therapy* | Approved as Requested | Proposed PT | |
| | | | *Red light therapy* | 10082902 |
| | | | HLT primary | |
| | | | *Phototherapies* | 10034976 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment: The proposal to add a new term Red light therapy is approved as requested. Red light therapy, a therapeutic technique that uses red low-level wavelengths of light to treat skin issues, such as wrinkles, scars, and persistent wounds, among other conditions, will be added as a PT to HLT Phototherapies.

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**CR Number: 2019091001** **Implementation Date:** 04-Apr-19 Related CR: 2019091001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Fluid in inner ear* | Rejected | | |

MSSO Comment: The proposal to add a new term Fluid in inner ear is not approved. Fluid in the inner ear is not a well-recognized concept, because the semicircular canals that comprise the inner ear are normally filled with fluid. If your coding needs to represent an inner ear fluid abnormality, regarding quantity, composition, and/or pressure of the endolymph (the fluid within the endolymphatic sac, a compartment of the inner ear), please re-submit a more specific concept.

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# Supplemental Update Report

**CR Number: 2019091002** **Implementation Date:** 04-Apr-19 Related CR: 2019091002

| Change Requested | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|
| Add a New Term | | | |
| Proposed Term *Polyp eye* | Rejected | | |

MSSO Comment: The proposal to add a new term Polyp eye is not approved. Polyp eye is a vague and nonspecific term that can relate to a variety of polypoid lesions of the eye and its surrounding structures, such as, but not limited to: conjunctival polyps, periocular skin polyps, eyelid polyps, and polypoidal choroidal vasculopathy.

**CR Number: 2019091003** **Implementation Date:** 04-Apr-19 Related CR: 2019091003

| Change Requested | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|
| Add a New Term | | | |
| Proposed Term *Allergy induced anaphylaxis* | Rejected | | |

MSSO Comment: The proposal to add a new term Allergy induced anaphylaxis is not approved. Since a majority of anaphylactic reactions are an allergic or hypersensitivity reaction to food, chemicals, drugs, vaccines, venoms, etc., it is understood that most anaphylactic reactions are allergy-induced. If an anaphylactic reaction is documented to be precipitated by a known allergic agent, such an event may be split coded with LLT Anaphylaxis (or another appropriate LLT under PT Anaphylactic reaction), and an LLT representing the allergen.

**CR Number: 2019091004** **Implementation Date:** 04-Apr-19 Related CR: 2019091004

| Change Requested | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|
| Add a New Term | | | |
| Proposed Term *Darier-Roussy sarcoidosis* | Approved as Requested | Proposed LLT | |
| | | *Darier-Roussy sarcoidosis* | 10082903 Current |
| | | To PT | |
| | | *Cutaneous sarcoidosis* | 10011674 |

MSSO Comment: The proposal to add a new term Darier-Roussy sarcoidosis is approved as requested. Sarcoidosis is a multi-system disease characterized by granulomatous inflammation of unknown etiology commonly occurring in the lung and the skin, but any organ system can be affected. Subcutaneous sarcoidosis (also known as "Darier-Roussy sarcoid or sarcoidosis") is a cutaneous condition characterized by numerous, tender or painless, 0.5- to 0.3-cm deep-seated nodules on the trunk and extremities. Please note that LLT Subcutaneous sarcoidosis recently has been added as a subconcept LLT to PT Cutaneous sarcoidosis in change request 2019084015 for version 22.1. Darier-Roussy sarcoidosis will also be added as a subconcept LLT to PT Cutaneous sarcoidosis.

# Supplemental Update Report

**CR Number: 2019092001** **Implementation Date:** 04-Apr-19 Related CR: 2019092001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Nodular tenosynovitis* | Approved as Requested | Proposed LLT | |
| | | | *Nodular tenosynovitis* | 10082904 Current |
| | | | To PT | |
| | | | *Giant cell tumour of tendon sheath* | 10018255 |

MSSO Comment: The proposal to add a new term Nodular tenosynovitis is approved as requested. Nodular tenosynovitis will be added as a synonym LLT to existing PT Giant cell tumour of tendon sheath, which is a benign and proliferative process of monoclonal origin of the synovial membrane, with most frequent site of appearance in the hand. It is usually as a painless growth of soft tissues. Treatment is by complete excision and recurrence may occur with a variable incidence. In a related change, the HLT in the secondary SOC Musculoskeletal and connective tissue disorders for PT Giant cell tumour of tendon sheath will be changed from HLT Musculoskeletal and connective tissue neoplasms NEC to HLT Synovial disorders for more specific representation at the secondary link.

**CR Number: 2019094015** **Implementation Date:** 04-Apr-19 Related CR: 2019092001

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Giant cell tumour of tendon sheath* | Approved as Requested | Proposed PT | |
| | | | *Giant cell tumour of tendon sheath* | 10018255 |
| From HLT | *Musculoskeletal and connective tissue neoplasms NEC* | | From HLT | |
| | | | *Musculoskeletal and connective tissue neoplasms NEC* | 10028390 |
| To HLT | *Synovial disorders* | | To HLT | |
| | | | *Synovial disorders* | 10013360 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019093001** **Implementation Date:** 04-Apr-19 Related CR: 2019093001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Anastomotic erosion* | Approved as Requested | Proposed PT | |
| | | | *Anastomotic erosion* | 10082905 |
| | | | HLT primary | |
| | | | *Gastrointestinal and hepatobiliary procedural complications* | 10017927 |
| | | | SOC primary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |
| | | | HLT secondary | |
| | | | *Gastrointestinal ulcers and perforation, site unspecified* | 10018023 |
| | | | SOC secondary | |
| | | | *Gastrointestinal disorders* | 10017947 |

MSSO Comment: The proposal to add a new term Anastomotic erosion is approved as requested. Anastomotic erosion, a complication after gastrointestinal anastomosis procedure, will be placed as a PT to primary HLT Gastrointestinal and hepatobiliary procedural complications and secondary HLT Gastrointestinal ulcers and perforation, site unspecified.

**CR Number: 2019093002** **Implementation Date:** 11-Apr-19 Related CR: 2019093002

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Peripheral neurotoxicity* | Approved as Requested | Proposed LLT | |
| | | | *Peripheral neurotoxicity* | 10082906 Current |
| | | | To PT | |
| | | | *Neurotoxicity* | 10029350 |

MSSO Comment: The proposal to add a new term Peripheral neurotoxicity is approved as requested. Neurotoxicity is the quality of exerting a destructive or poisonous effect upon nerve tissue, while neuropathy is a functional disturbance or pathological change in the peripheral nervous system. Thus, Peripheral neurotoxicity will be placed as a sub-concept LLT to PT Neurotoxicity.

# Supplemental Update Report

**CR Number: 2019094002** **Implementation Date:** 11-Apr-19 Related CR: 2019094002

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Skin haemorrhage* | Rejected | | |
| From HLT | *Bruising, ecchymosis and purpura* | | | |
| To HLT | *Haemorrhages NEC* | | | |

MSSO Comment: The proposal to move the PT Skin haemorrhage from HLT Bruising, ecchymosis and purpura to HLT Haemorrhages NEC is not approved. Skin haemorrhage usually refers to bleeding within the skin and often appears as petechiae, or in larger, flat patches, such as purpura and ecchymosis. Therefore, PT Skin haemorrhage is best placed under HLT Bruising, ecchymosis and purpura.

**CR Number: 2019094003** **Implementation Date:** 11-Apr-19 Related CR: 2019094003

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Pharyngeal rash* | Approved as Requested | Proposed LLT | |
| To PT | *Pharyngeal enanthema* | | *Pharyngeal rash* | 10082908 Current |
| | | | To PT | |
| | | | *Pharyngeal enanthema* | 10073741 |

MSSO Comment: The proposal to add a new LLT Pharyngeal rash to PT Pharyngeal enanthema is approved as requested. Pharyngeal rash is a rarely used synonym of pharyngeal enanthema.

**CR Number: 2019094004** **Implementation Date:** 11-Apr-19 Related CR: 2019094004

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Nasal mucosal rash* | Rejected | | |

MSSO Comment: The proposal to add a new PT Nasal mucosal rash is not approved. Although a variety of descriptions pertaining to the nasal mucosa pertain to inflammatory, infective, traumatic, neoplastic, conditions, rash of the nasal mucosa does not appear to be commonly described in the medical literature. Please provide more details regarding the context of the verbatim terms to which you refer, in addition to any relevant references. Furthermore, MedDRA cannot provide a term for all possible sites of manifestation of "rash".

# Supplemental Update Report

**CR Number: 2019094005** **Implementation Date:** 11-Apr-19 Related CR: 2019094005

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Rash gum* | Rejected | | |
| From PT | *Gingival disorder* | | | |

MSSO Comment: The proposal to promote the LLT Rash gum from PT Gingival disorder is not approved. Although a number of descriptive lesions are described pertaining to the gingiva, gingival rash or rash gum, per se, does not appear to be commonly described in the medical literature.

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**CR Number: 2019094006** **Implementation Date:** 11-Apr-19 Related CR: 2019094006

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Taste perversion* | Rejected | | |
| From PT | *Dysgeusia* | | | |
| To PT | *Taste disorder* | | | |

MSSO Comment: The proposal to move the LLT Taste perversion from PT Dysgeusia to PT Taste disorder is not approved. The Dorland's Medical Dictionary definition of dysgeusia is: 1. perversion of the sense of taste. 2. a bad taste in the mouth. The MSSO communication referenced by the submitter was intended to convey that Dorland's first definition of dysgeusia does pertain to the meaning of PT Dysgeusia in MedDRA. Accordingly, LLT Taste perversion is appropriately placed as a sub-concept of PT Dysgeusia. For interoperability mapping needs between MedDRA and other terminologies, PT Taste disorder represents a problem or abnormality pertaining to taste that is not specifically reported as one of the term concepts under HLT Taste disorders, namely PT Dysgeusia, PT Ageusia, PT Hypergeusia, or PT Hypogeusia.

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**CR Number: 2019094007** **Implementation Date:** 11-Apr-19 Related CR: 2019094007

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Genital disorder* | Approved as Requested | Proposed PT | |
| | | | *Genital disorder* | 10082907 |
| HLT primary | *Reproductive tract disorders NEC (excl neoplasms)* | | HLT primary | |
| | | | *Reproductive tract disorders NEC (excl neoplasms)* | 10027696 |
| SOC primary | *Reproductive system and breast disorders* | | SOC primary | |
| | | | *Reproductive system and breast disorders* | 10038604 |

MSSO Comment: The proposal to add a new PT Genital disorder to primary HLT Reproductive tract disorders NEC (excl neoplasms) in SOC Reproductive system and breast disorders is approved as requested. To facilitate the coding of a genital disorder that is unqualified as male or female.

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# Supplemental Update Report

**CR Number:** **2019094008** **Implementation Date:** 11-Apr-19 Related CR: 2019094008

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Genital disorder female* | Rejected | | |
| To PT | *Genital disorder* | | | |

MSSO Comment: The proposal to demote the PT Genital disorder female under PT Genital disorder is not approved. PT Genital disorder female has been a MedDRA term since Version 6.1, and represents a genital condition or pathological concept which is gender-specific. The demotion of PT Genital disorder female to the less specific proposed new PT Genital disorder could potentially compromise pharmacovigilance signal detection.

**CR Number:** **2019094009** **Implementation Date:** 11-Apr-19 Related CR: 2019094009

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Genital disorder male* | Rejected | | |
| To PT | *Genital disorder* | | | |

MSSO Comment: The proposal to demote the PT Genital disorder male under PT Genital disorder is not approved. PT Genital disorder male has been a MedDRA term since Version 6.1, and represents a genital condition or pathological concept which is gender-specific. The demotion of PT Genital disorder male to the less specific proposed new PT Genital disorder could potentially compromise pharmacovigilance signal detection.

# Supplemental Update Report

**CR Number: 2019094010** **Implementation Date:** 11-Apr-19 Related CR: 2019094010

| Change Requested | Promote an LLT |
|---|---|
| Proposed LLT | *Anal eczema* |
| From PT | *Eczema* |
| HLT primary | *Anal and rectal signs and symptoms* |

Final Disposition: Approved as Requested

| Final Placement | MedDRA Code # |
|---|---|
| Proposed LLT *Anal eczema* | 10078682 |
| From PT *Eczema* | 10014184 |
| HLT primary *Anal and rectal signs and symptoms* | 10002118 |
| SOC primary *Gastrointestinal disorders* | 10017947 |
| HLT secondary *Dermatitis and eczema* | 10012435 |
| SOC secondary *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment: The proposal to promote the LLT Anal eczema from PT Eczema to primary HLT Anal and rectal signs and symptoms in SOC Gastrointestinal disorders and secondary HLT Dermatitis and eczema in SOC Skin and subcutaneous tissue disorders is approved as requested. Even though the principal conceptual element of this LLT is eczema, the site of manifestation takes precedence in MedDRA hierarchical primary SOC placement.

**CR Number: 2019094011** **Implementation Date:** 11-Apr-19 Related CR: 2019094011

| Change Requested | Promote an LLT |
|---|---|
| Proposed LLT | *Vulval eczema* |
| From PT | *Eczema* |
| HLT primary | *Vulvovaginal signs and symptoms* |

Final Disposition: Approved as Requested

| Final Placement | MedDRA Code # |
|---|---|
| Proposed LLT *Vulval eczema* | 10066273 |
| From PT *Eczema* | 10014184 |
| HLT primary *Vulvovaginal signs and symptoms* | 10047792 |
| SOC primary *Reproductive system and breast disorders* | 10038604 |
| HLT secondary *Dermatitis and eczema* | 10012435 |
| SOC secondary *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment: The proposal to promote the LLT Vulval eczema from PT Eczema to primary HLT Vulvovaginal signs and symptoms in SOC Reproductive system and breast disorders and secondary HLT Dermatitis and eczema in SOC Skin and subcutaneous tissue disorders is approved as requested. Even though the principal conceptual element of this LLT is eczema, the site of manifestation takes precedence in MedDRA hierarchical primary SOC placement.

# Supplemental Update Report

**CR Number: 2019095001** **Implementation Date:** 12-Apr-19 Related CR: 2019095001

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Allergic bronchopulmonary mycosis* | Approved as Requested | Proposed PT | |
| HLT primary | *Fungal infections NEC* | | *Allergic bronchopulmonary mycosis* | 10082909 |
| SOC primary | *Infections and infestations* | | HLT primary | |
| | | | *Fungal infections NEC* | 10017536 |
| | | | SOC primary | |
| | | | *Infections and infestations* | 10021881 |
| | | | HLT secondary | |
| | | | *Lower respiratory tract infections NEC* | 10024971 |
| | | | SOC secondary | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |

MSSO Comment: The proposal to add a new PT Allergic bronchopulmonary mycosis to primary HLT Fungal infections NEC in SOC Infections and infestations is approved as requested. Allergic bronchopulmonary mycosis is a clinical syndrome associated with immune sensitivity to various fungi that colonize the airways of asthmatics. Early diagnosis and treatment with systemic corticosteroids is the key in preventing the progression of the disease to irreversible lung fibrosis. Though Aspergillus spp., comprises the majority of cases, there are other fungi (such as candida albicans) associated with the development of allergic bronchopulmonary mycosis. Allergic bronchopulmonary mycosis will be added as a PT and linked to primary HLT Fungal infections NEC, secondary HLT Lower respiratory tract infections NEC, secondary HLT Allergic conditions NEC, and secondary HLT Eosinophilic disorders.

**CR Number: 2019102001** **Implementation Date:** 12-Apr-19 Related CR: 2019095001

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Allergic bronchopulmonary mycosis* | Approved as Requested | Proposed PT | |
| To HLT | *Allergic conditions NEC* | | *Allergic bronchopulmonary mycosis* | 10082909 |
| | | | To HLT | |
| | | | *Allergic conditions NEC* | 10027654 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019102002** **Implementation Date:** 12-Apr-19 Related CR: 2019095001

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Allergic bronchopulmonary mycosis* | Approved as Requested | Proposed PT | |
| To HLT | *Eosinophilic disorders* | | *Allergic bronchopulmonary mycosis* | 10082909 |
| | | | To HLT | |
| | | | *Eosinophilic disorders* | 10052828 |

MSSO Comment:

**CR Number: 2019095002** **Implementation Date:** 12-Apr-19 Related CR: 2019095002

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Tic cough* | Approved as Requested | Proposed LLT | |
| | | | *Tic cough* | 10082914 Current |
| | | | To PT | |
| | | | *Habit cough* | 10082913 |

MSSO Comment: The proposal to add a new LLT Tic cough is approved as requested. A habit cough is a repetitive cough that occurs in the absence of any underlying disease. Habit cough (also called psychogenic cough, somatic cough syndrome or tic cough) most frequently affects school age children, usually those in later primary school or early high school; boys and girls are equally affected. Tic cough will be added as an LLT under a new PT Habit cough. In a related change, PT Habit cough will be added and linked to primary HLT Coughing and associated symptoms and secondary HLT Somatic symptom disorders.

# Supplemental Update Report

**CR Number: 2019102003** **Implementation Date:** 12-Apr-19 Related CR: 2019095002

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Habit cough* | Approved as Requested | Proposed PT | |
| HLT primary | *Coughing and associated symptoms* | | *Habit cough* | 10082913 |
| SOC primary | *Respiratory, thoracic and mediastinal disorders* | | HLT primary | |
| | | | *Coughing and associated symptoms* | 10011233 |
| | | | SOC primary | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |
| | | | HLT secondary | |
| | | | *Somatic symptom disorders* | 10077547 |
| | | | SOC secondary | |
| | | | *Psychiatric disorders* | 10037175 |

MSSO Comment:

**CR Number: 2019095003** **Implementation Date:** 12-Apr-19 Related CR: 2019095003

| Change Requested | Change Status of LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| LLT to change | *Insomnia related to another mental condition* | Approved Not as Requested | PT to merge | | |
| Status | *non-current* | | *Insomnia related to another mental condition* | 10022443 | Non-Current |
| | | | To PT | | |
| | | | *Insomnia* | 10022437 | |

MSSO Comment: The proposal to change status of LLT Insomnia related to another mental condition to non-current is approved but not as requested. The first step to resolve this change request is to demote PT Insomnia related to another mental condition under the broad PT Insomnia. In the second step, the status of LLT Insomnia related to another mental condition will be changed to non-current because the concept “another mental condition” is vague. In a related change, and for a similar reason PT Hypersomnia related to another mental condition will be demoted under PT Hypersomnia. Then, LLT Hypersomnia related to another mental condition will have its status changed to non-current.

# Supplemental Update Report

**CR Number: 2019102004** **Implementation Date:** 12-Apr-19 Related CR: 2019095003

| Change Requested | Change Status of LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| LLT to change | *Insomnia related to another mental condition* | Approved as Requested | LLT to change | | |
| Status | *Non-current* | | *Insomnia related to another mental condition* | 10022443 | Non-Current |
| | | | Status | | |
| | | | *Non-current* | | |

MSSO Comment:

**CR Number: 2019102005** **Implementation Date:** 12-Apr-19 Related CR: 2019095003

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| PT to merge | *Hypersomnia related to another mental condition* | Approved as Requested | PT to merge | | |
| To PT | *Hypersomnia* | | *Hypersomnia related to another mental condition* | 10020767 | Non-Current |
| | | | To PT | | |
| | | | *Hypersomnia* | 10020765 | |

MSSO Comment:

**CR Number: 2019102006** **Implementation Date:** 12-Apr-19 Related CR: 2019095003

| Change Requested | Change Status of LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| LLT to change | *Hypersomnia related to another mental condition* | Approved as Requested | LLT to change | | |
| Status | *Non-current* | | *Hypersomnia related to another mental condition* | 10020767 | Non-Current |
| | | | Status | | |
| | | | *Non-current* | | |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019095004** **Implementation Date:** 12-Apr-19 Related CR: 2019095004

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Kohler's disease* | Approved Not as Requested | Proposed PT | |
| | | | *Kohler's disease* | 10082910 |
| | | | HLT primary | |
| | | | *Bone disorders NEC* | 10027658 |
| | | | SOC primary | |
| | | | *Musculoskeletal and connective tissue disorders* | 10028395 |
| | | | HLT secondary | |
| | | | *Musculoskeletal necrosis and vascular insufficiency* | 10065876 |
| | | | SOC secondary | |
| | | | *Vascular disorders* | 10047065 |

MSSO Comment: The proposal to add a new LLT Kohler's disease is approved but not as requested. Kohler's disease is a condition, where the navicular bone in the foot looses its blood supply temporarily evolving to an avascular necrosis. This most commonly happens in children, causing pain in the foot over the arch or inside aspect, tenderness in exploration and occasionally swelling. Kohler's disease will be added as a PT to primary HLT Bone disorders NEC, and a secondary HLT Musculoskeletal necrosis and vascular insufficiency.

**CR Number: 2019095005** **Implementation Date:** 12-Apr-19 Related CR: 2019095005

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Frontal sinusotomy* | Approved as Requested | Proposed LLT | |
| | | | *Frontal sinusotomy* | 10082912 Current |
| | | | To PT | |
| | | | *Frontal sinus operation* | 10017379 |

MSSO Comment: The proposal to add a new LLT Frontal sinusotomy is approved as requested. Endoscopic frontal sinusotomy is indicated for patients with severe forms of chronic frontal sinus disease that have failed after endoscopic frontal recess approach. This extended drainage procedure involves resection of the floor of the frontal sinus from the nasal septum medially, to the lamina papyracea laterally. Frontal sinusotomy will be added as a sub-concept LLT to PT Frontal sinus operation.

# Supplemental Update Report

**CR Number: 2019095006** **Implementation Date:** 12-Apr-19 Related CR: 2019095006

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Polypoid turbinate degeneration* | Approved as Requested | Proposed LLT<br>*Polypoid turbinate degeneration*<br>To PT<br>*Sinus polyp degeneration* | 10082911 Current<br>10040750 |

MSSO Comment: The proposal to add a new LLT Polypoid turbinate degeneration is approved as requested. The middle turbinate is part of the ethmoid bone. An enlarged middle turbinate with polypoid degeneration of the mucosa, is a common sinus pathology, usually related to chronic purulent rhinosinusitis. Polypoid turbinate degeneration will be added as a sub-element LLT to PT Sinus polyp degeneration.

**CR Number: 2019099001** **Implementation Date:** 11-Apr-19 Related CR: 2019099001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Otoneurological syndrome* | Rejected | | |

MSSO Comment: The proposal to add a new term Otoneurological syndrome is not approved. Otoneurological syndrome includes signs and symptoms that may refer to disorders such as positional vertigo, Meniere's disease, vestibular neuritis, migraine-associated dizziness, vestibular schwannoma, and other central nervous system or general medical causes of imbalance and dizziness. Therefore, the proposed term is rejected as it is vague and does not relate/point to a particular underlying medical condition. It is recommended to submit a change request with a more specific term. Please consider as well, whether existing PT Vestibular syndrome may represent the requested concept.

**CR Number: 2019100001** **Implementation Date:** 26-Apr-19 Related CR: 2019100001

| Change Requested | Change Status of LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| LLT to change | *Lumbar syndrome* | Approved After Suspension | LLT to change<br>*LUMBAR syndrome* | 10066910 Non-Current |
| Status | *non-current* | | Status<br>*Non-current* | |

MSSO Comment: The proposal to change status of LLT Lumbar syndrome to non-current is approved as requested after suspension. Lumbar syndrome and LUMBAR syndrome are two different concepts distinguished only by the capitalization. Because many data systems do not recognize nor differentiate upper case from lower case characters, changing the status of LUMBAR syndrome to non-current and the addition of two new clear concepts is needed. Please see change request 2019100002 for the addition of PT Congenital LUMBAR syndrome and LLT Lumbar pain syndrome.

# Supplemental Update Report

**CR Number: 2019100002** **Implementation Date:** 26-Apr-19 Related CR: 2019100002

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Lumbar syndrome* | Approved After Suspension | PT to merge | |
| To PT | *Back pain* | | *LUMBAR syndrome* | 10066910 Non-Current |
| | | | To PT | |
| | | | *Back pain* | 10003988 |

MSSO Comment: The proposal to demote the PT Lumbar syndrome under PT Back pain is approved as requested after suspension. Because many data systems do not recognize nor differentiate upper case from lower case characters, changing the status of LUMBAR syndrome to non-current (See change request 2019100001) and the addition of two new clear concepts is needed. In a related change, new PT Congenital LUMBAR syndrome will be to primary HLT Vascular anomalies congenital NEC and secondary HLT Cardiovascular neoplasms benign. Furthermore, new LLT Lumbar pain syndrome will be added as a sub-concept under PT Back pain. In addition, LLT PELVIS syndrome will be moved from PT Back pain to new PT Congenital LUMBAR syndrome.

**CR Number: 2019114005** **Implementation Date:** 26-Apr-19 Related CR: 2019100002

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Congenital LUMBAR syndrome* | Approved as Requested | Proposed PT | |
| HLT primary | *Vascular anomalies congenital NEC* | | *Congenital LUMBAR syndrome* | 10082949 |
| SOC primary | *Congenital, familial and genetic disorders* | | HLT primary | |
| | | | *Vascular anomalies congenital NEC* | 10047047 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary | |
| | | | *Cardiovascular neoplasms benign* | 10007656 |
| | | | SOC secondary | |
| | | | *Neoplasms benign, malignant and unspecified (incl cysts and polyps)* | 10029104 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019114006** **Implementation Date:** 26-Apr-19 Related CR: 2019100002

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Lumbar pain syndrome* | Approved as Requested | Proposed LLT | |
| To PT | *Back pain* | | *Lumbar pain syndrome* | 10082950 Current |
| | | | To PT | |
| | | | *Back pain* | 10003988 |

MSSO Comment:

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**CR Number: 2019114007** **Implementation Date:** 26-Apr-19 Related CR: 2019100002

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *PELVIS syndrome* | Approved as Requested | Proposed LLT | |
| From PT | *Back pain* | | *PELVIS syndrome* | 10082400 Current |
| To PT | *Congenital LUMBAR syndrome* | | From PT | |
| | | | *Back pain* | 10003988 |
| | | | To PT | |
| | | | *Congenital LUMBAR syndrome* | 10082949 |

MSSO Comment:

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**CR Number: 2019101001** **Implementation Date:** 17-Apr-19 Related CR: 2019101001

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Parainfluenzae viral laryngotracheobronchitis* | Approved as Requested | Proposed PT | |
| From HLT | *Viral upper respiratory tract infections* | | *Parainfluenzae viral laryngotracheobronchitis* | 10033797 |
| To HLT | *Viral lower respiratory tract infections* | | From HLT | |
| | | | *Viral upper respiratory tract infections* | 10047483 |
| | | | To HLT | |
| | | | *Viral lower respiratory tract infections* | 10047468 |

MSSO Comment: The proposal to move the PT Parainfluenzae viral laryngotracheobronchitis from HLT Viral upper respiratory tract infections to HLT Viral lower respiratory tract infections is approved as requested. In general, when a term concept represents both upper and lower anatomical sites of a respiratory infection, because of the clinical significance of lower respiratory infections, placement to HLTs pertaining to lower respiratory infections take precedence.

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# Supplemental Update Report

**CR Number: 2019101002** **Implementation Date:** 17-Apr-19 Related CR: 2019101002

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Tracheobronchitis mycoplasmal* | Approved as Requested | Proposed PT | |
| From HLT | *Upper respiratory tract infections NEC* | | *Tracheobronchitis mycoplasmal* | 10044315 |
| To HLT | *Lower respiratory tract infections NEC* | | From HLT | |
| | | | *Upper respiratory tract infections NEC* | 10045573 |
| | | | To HLT | |
| | | | *Lower respiratory tract infections NEC* | 10024971 |

MSSO Comment: The proposal to move the PT Tracheobronchitis mycoplasmal from HLT Upper respiratory tract infections NEC to HLT Lower respiratory tract infections NEC is approved as requested. In general, when a term concept represents both upper and lower anatomical sites of a respiratory infection, because of the clinical significance of lower respiratory infections, placement to HLTs pertaining to lower respiratory infections take precedence.

**CR Number: 2019101003** **Implementation Date:** 17-Apr-19 Related CR: 2019101003

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Tracheobronchitis viral* | Approved as Requested | Proposed PT | |
| From HLT | *Viral upper respiratory tract infections* | | *Tracheobronchitis viral* | 10061556 |
| To HLT | *Viral lower respiratory tract infections* | | From HLT | |
| | | | *Viral upper respiratory tract infections* | 10047483 |
| | | | To HLT | |
| | | | *Viral lower respiratory tract infections* | 10047468 |

MSSO Comment: The proposal to move the PT Tracheobronchitis viral from HLT Viral upper respiratory tract infections to HLT Viral lower respiratory tract infections is approved as requested. In general, when a term concept represents both upper and lower anatomical sites of a respiratory infection, because of the clinical significance of lower respiratory infections, placement to HLTs pertaining to lower respiratory infections take precedence.

**CR Number: 2019101004** **Implementation Date:** 17-Apr-19 Related CR: 2019101004

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Traumatic hepatic haematoma* | Rejected | | |

MSSO Comment: The proposal to add a new PT Traumatic hepatic haematoma is not approved. It is not feasible to add all possible hematoma concepts qualified with "traumatic". The requested concept can be represented by existing PTs - PT Hepatic haematoma, PT Liver contusion or PT Traumatic liver injury. Additionally, the PT Hepatic haematoma has a secondary link to SOC Injury, poisoning and procedural complications via HLT Abdominal injuries NEC for analysis purposes.

# Supplemental Update Report

**CR Number: 2019101005** **Implementation Date:** 17-Apr-19 Related CR: 2019101005

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Lumbar bruise* | Rejected | | |
| To PT | *Contusion* | | | |

MSSO Comment: The proposal to add a new LLT Lumbar bruise to PT Contusion is not approved. MedDRA cannot accommodate all possible anatomical site specificity for contusions or the synonym bruise. Please consider the broad LLT Contusion of back for your coding needs.

**CR Number: 2019102007** **Implementation Date:** 17-Apr-19 Related CR: 2019102007

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Neuroendocrine Carcinoma of the Prostate* | Approved Not as Requested | Proposed PT | |
| | | | *Neuroendocrine carcinoma of prostate* | 10082915 |
| | | | HLT primary | |
| | | | *Prostatic neoplasms malignant* | 10036908 |
| | | | SOC primary | |
| | | | *Neoplasms benign, malignant and unspecified (incl cysts and polyps)* | 10029104 |
| | | | HLT secondary | |
| | | | *Prostatic neoplasms and hypertrophy* | 10036966 |
| | | | SOC secondary | |
| | | | *Reproductive system and breast disorders* | 10038604 |

MSSO Comment: The proposal to add a new LLT Neuroendocrine Carcinoma of the Prostate is approved but not as requested. Neuroendocrine carcinoma of the prostate is an aggressive variant of prostate cancer that typically is diagnosed in the later stages of advanced disease. The proposed LLT Neuroendocrine Carcinoma of the Prostate will be rephrased and capitalized in accordance with MedDRA conventions as Neuroendocrine carcinoma of prostate, and added as a new PT to primary HLT Prostatic neoplasms malignant, and to secondary HLT Prostatic neoplasms and hypertrophy. Additionally, PT Neuroendocrine carcinoma of prostate will be secondarily linked to HLT Endocrine neoplasms NEC.

# Supplemental Update Report

**CR Number: 2019107010** **Implementation Date:** 17-Apr-19 Related CR: 2019102007

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Neuroendocrine carcinoma of prostate* | Approved as Requested | Proposed PT | |
| To HLT | *Endocrine neoplasms NEC* | | *Neuroendocrine carcinoma of prostate* | 10082915 |
| | | | To HLT | |
| | | | *Endocrine neoplasms NEC* | 10014714 |

MSSO Comment:

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**CR Number: 2019102008** **Implementation Date:** 17-Apr-19 Related CR: 2019102008

| Change Requested | Change Status of LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| LLT to change | *Hepatomegaly tenderness* | Approved as Requested | LLT to change | |
| Status | *non-current* | | *Hepatomegaly tenderness* | 10019843 Non-Current |
| | | | Status | |
| | | | *non-current* | |

MSSO Comment: The proposal to change status of LLT Hepatomegaly tenderness to non-current is approved as requested. Although LLT Hepatomegaly tenderness has been an LLT since Version 2.1, this combination concept term may compromise signal detection if the term is selected to represent both hepatomegaly and hepatic tenderness. LLT Hepatomegaly tenderness is best represented with individual terms, i.e., LLT Liver tenderness and LLT Hepatomegaly.

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**CR Number: 2019102009** **Implementation Date:** 17-Apr-19 Related CR: 2019102009

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Pelvic effusion* | Approved as Requested | Proposed LLT | |
| | | | *Pelvic effusion* | 10082916 Current |
| | | | To PT | |
| | | | *Pelvic fluid collection* | 10065388 |

MSSO Comment: The proposal to add a new term Pelvic effusion is approved as requested. Pelvic effusion will be added as a synonym LLT to existing PT Pelvic fluid collection.

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# Supplemental Update Report

**CR Number: 2019105001** **Implementation Date:** 17-Apr-19 Related CR: 2019105001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Bovine spongiform encephalopathy* | Rejected | | |
| To PT | *Creutzfeldt-Jakob disease* | | | |

MSSO Comment: The proposal to add a new LLT Bovine spongiform encephalopathy to PT Creutzfeldt-Jakob disease is not approved. Because Bovine spongiform encephalopathy is a disease of cattle, it is not within the scope of MedDRA. Strong epidemiologic and laboratory evidence exists for a causal association between a new human prion disease called variant Creutzfeldt-Jakob disease that was first reported from the United Kingdom in 1996 and the Bovine spongiform encephalopathy outbreak in cattle. Please consider existing terms, LLT Variant Creutzfeldt-Jakob disease, or LLT Transmissible spongiform encephalopathy, each under PT Variant Creutzfeldt-Jakob disease, for your coding needs.

**CR Number: 2019105002** **Implementation Date:** 17-Apr-19 Related CR: 2019105002

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Mad cow disease* | Rejected | | |
| To PT | *Creutzfeldt-Jakob disease* | | | |

MSSO Comment: The proposal to add a new LLT Mad cow disease to PT Creutzfeldt-Jakob disease is not approved. Because mad cow disease (Bovine spongiform encephalopathy) is a disease of cattle, it is not within the scope of MedDRA. Strong epidemiologic and laboratory evidence exists for a causal association between a new human prion disease called variant Creutzfeldt-Jakob disease that was first reported from the United Kingdom in 1996 and the Bovine spongiform encephalopathy outbreak in cattle. Please consider existing terms, LLT Variant Creutzfeldt-Jakob disease, or LLT Transmissible spongiform encephalopathy, each under PT Variant Creutzfeldt-Jakob disease, for your coding needs.

**CR Number: 2019106001** **Implementation Date:** 10-May-19 Related CR: 2019106001

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pneumoperitoneum* | Approved Not as Requested | Proposed PT<br>*Pneumoperitoneum* | 10048299 |
| To SMQ | *Gastrointestinal perforation (SMQ)* | | To SMQ<br>*Gastrointestinal perforation (SMQ)* | 20000107 |
| Term scope | *Broad* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Pneumoperitoneum to Gastrointestinal perforation (SMQ) as a broad term is approved but not as requested. PT Pneumoperitoneum will be added as a narrow scope term to Gastrointestinal perforation (SMQ) which comprises narrow scope terms only. Pneumoperitoneum is usually the result of a perforation in the gastrointestinal tract and warrants addition as a narrow scope term in this SMQ. In a related change, PT Pneumoretroperitoneum will also be added as a narrow scope term in Gastrointestinal perforation (SMQ).

# Supplemental Update Report

**CR Number: 2019127001** **Implementation Date:** 10-May-19 Related CR: 2019106001

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pneumoretroperitoneum* | Approved as Requested | Proposed PT<br>*Pneumoretroperitoneum* | 10068676 |
| To SMQ | *Gastrointestinal perforation (SMQ)* | | To SMQ<br>*Gastrointestinal perforation (SMQ)* | 20000107 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment:

**CR Number: 2019106002** **Implementation Date:** 26-Apr-19 Related CR: 2019106002

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Eyelid abrasion* | Approved as Requested | Proposed PT<br>*Eyelid abrasion* | 10081521 |
| From HLT | *Skin and subcutaneous tissue ulcerations* | | From HLT<br>*Skin and subcutaneous tissue ulcerations* | 10040796 |
| To HLT | *Skin injuries and mechanical dermatoses* | | To HLT<br>*Skin injuries and mechanical dermatoses* | 10040877 |

MSSO Comment: The proposal to move the PT Eyelid abrasion from HLT Skin and subcutaneous tissue ulcerations to HLT Skin injuries and mechanical dermatoses is approved as requested. Secondary HLT Skin and subcutaneous tissue ulcerations is not consistent with the pathophysiology and mechanism of eyelid abrasion. HLT Skin injuries and mechanical dermatoses is a more appropriate placement as eyelid abrasion is not an ulcerative condition. This request was initiated based on a review of an external clinical audit of MSSO actions.

# Supplemental Update Report

**CR Number: 2019106003** **Implementation Date:** 26-Apr-19 Related CR: 2019106003

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Arachnophobia* | Approved as Requested | PT to merge | |
| To PT | *Animal phobia* | | *Arachnophobia* | 10051408 Current |
| | | | To PT | |
| | | | *Animal phobia* | 10002518 |

MSSO Comment: The proposal to demote the PT Arachnophobia under PT Animal phobia is approved as requested. This change request is intended to reduce granularity and overrepresentation at PT Level for specific animal phobias. Arachnophobia can be considered as sub-concept of PT Animal phobia.

**CR Number: 2019106004** **Implementation Date:** 26-Apr-19 Related CR: 2019106004

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Herpetophobia* | Approved as Requested | PT to merge | |
| To PT | *Animal phobia* | | *Herpetophobia* | 10081809 Current |
| | | | To PT | |
| | | | *Animal phobia* | 10002518 |

MSSO Comment: The proposal to demote the PT Herpetophobia under PT Animal phobia is approved as requested. This change request is intended to reduce granularity and overrepresentation at PT Level for specific animal phobias. Herpetophobia can be considered a sub-concept of PT Animal phobia.

**CR Number: 2019106005** **Implementation Date:** 26-Apr-19 Related CR: 2019106005

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Taste chemical* | Approved as Requested | Proposed LLT | |
| To PT | *Dysgeusia* | | *Taste chemical* | 10082942 Current |
| | | | To PT | |
| | | | *Dysgeusia* | 10013911 |

MSSO Comment: The proposal to add a new LLT Taste chemical to PT Dysgeusia is approved as requested. This change request is based on an external clinical audit of MSSO actions. Upon reconsideration of CR 2018264007 (previously submitted for Version 22.0), the MSSO has decided to add the requested term, Taste chemical, as a sub-concept LLT to PT Dysgeusia. Taste chemical can represent a description of an abnormal taste of a substance, or a perversion of the sense of taste, and will complement a variety of existing LLTs under PT Dysgeusia, such as LLT Taste salty, LLT Taste bitter, LLT Taste metallic, etc.

# Supplemental Update Report

**CR Number: 2019107001** **Implementation Date:** 24-Apr-19 Related CR: 2019107001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Protein intolerance NOS* | Approved Not as Requested | Proposed PT | |
| | | | *Protein intolerance* | 10082917 |
| | | | HLT primary | |
| | | | *Food malabsorption and intolerance syndromes (excl sugar intolerance)* | 10016951 |
| | | | SOC primary | |
| | | | *Metabolism and nutrition disorders* | 10027433 |

MSSO Comment: The proposal to add a new LLT Protein intolerance NOS is approved but not as requested. Only a limited number of proteins induce specific IgE-mediated immune reactions i.e. allergic reactions. Numerous symptoms can be a consequence of food protein intolerance. Gastrointestinal manifestations are the most common clinical presentation, usually without involvement of other organ systems. Besides, although MedDRA currently includes a significant number of terms that contain "NOS", the MSSO currently refrains from adding new concepts with the suffix NOS. The broad concept Protein intolerance, without addition of NOS, will be added as PT to HLT Food malabsorption and intolerance syndromes (excl sugar intolerance) to provide coding options for non-specific protein intolerance reports.

**CR Number: 2019107002** **Implementation Date:** 24-Apr-19 Related CR: 2019107002

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Gelastic seizure* | Approved Not as Requested | Proposed PT | |
| | | | *Gelastic seizure* | 10082918 |
| | | | HLT primary | |
| | | | *Seizures and seizure disorders NEC* | 10039912 |
| | | | SOC primary | |
| | | | *Nervous system disorders* | 10029205 |

MSSO Comment: The proposal to add a new LLT Gelastic seizure is approved but not as requested. Gelastic seizure are characterized by sudden laughter attacks, out of social context, without any particular emotion like joy or happiness. Gelastic seizure will be added as a PT to HLT Seizures and seizure disorders NEC.

**CR Number: 2019107003** **Implementation Date:** 24-Apr-19 Related CR: 2019107003

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Pringle nodule* | Approved as Requested | Proposed LLT | |
| | | | *Pringle nodule* | 10082925 Current |
| | | | To PT | |
| | | | *Tuberous sclerosis complex* | 10080584 |

MSSO Comment: The proposal to add a new LLT Pringle nodule is approved as requested. Pringle nodule refers to the individual nodules of tuberous sclerosis complex. Therefore, Pringle nodule will be added as sub-concept LLT under PT Tuberous sclerosis complex.

# Supplemental Update Report

**CR Number: 2019107004** **Implementation Date:** 24-Apr-19 Related CR: 2019107004

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *TAND* | Approved Not as Requested | Proposed PT | |
| | | | *Tuberous sclerosis complex associated neuropsychiatric disease* | 10082922 |
| | | | HLT primary | |
| | | | *Mental disorders due to a general medical condition NEC* | 10027361 |
| | | | SOC primary | |
| | | | *Psychiatric disorders* | 10037175 |
| | | | HLT secondary | |
| | | | *Nervous system disorders NEC* | 10057185 |
| | | | SOC secondary | |
| | | | *Nervous system disorders* | 10029205 |

MSSO Comment: The proposal to add a new LLT TAND is approved but not as requested. Tuberous sclerosis complex associated neuropsychiatric disorders (TAND) is a new terminology to describe the interrelated functional and clinical manifestations of brain dysfunction in tuberous sclerosis complex, including aggressive behaviors, autism spectrum disorders, intellectual disabilities, psychiatric disorders, neuropsychological deficits, as well as school and occupational difficulties. TAND is not an unique acronym for Tuberous sclerosis complex associated neuropsychiatric disease. Therefore, the spelled out concept Tuberous sclerosis complex associated neuropsychiatric disease will be added as a PT to primary HLT Mental disorders due to a general medical condition NEC and secondary HLT Nervous system disorders NEC.

**CR Number: 2019107005** **Implementation Date:** 24-Apr-19 Related CR: 2019107005

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Biliary catheter insertion* | Approved Not as Requested | Proposed PT | |
| | | | *Biliary catheter insertion* | 10082920 |
| | | | HLT primary | |
| | | | *Biliary tract and gallbladder therapeutic procedures* | 10004675 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment: The proposal to add a new LLT Biliary catheter insertion is approved but not as requested. Biliary drainage is the insertion of a tube into the bile duct. Blockage of the bile ducts can occur for a number of reasons, including gallstones impacted in the ducts, narrowing in the bile ducts after previous surgery and involvement of cancer in the ducts. Biliary catheter insertion will be added as a PT to HLT Biliary tract and gallbladder therapeutic procedures. In related changes, PT Bile duct T-tube insertion and PT Biliary drainage will be merged under the new PT Biliary catheter insertion as sub-concepts. Furthermore, a new LLT Percutaneous transhepatic biliary drainage catheter insertion will be added to new PT Biliary catheter insertion.

# Supplemental Update Report

**CR Number: 2019114001** **Implementation Date:** 24-Apr-19 Related CR: 2019107005

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Bile duct T-tube insertion* | Approved as Requested | PT to merge | |
| To PT | *Biliary catheter insertion* | | *Bile duct T-tube insertion* | 10064673 Current |
| | | | To PT | |
| | | | *Biliary catheter insertion* | 10082920 |

MSSO Comment:

**CR Number: 2019114002** **Implementation Date:** 24-Apr-19 Related CR: 2019107005

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Biliary drainage* | Approved as Requested | PT to merge | |
| To PT | *Biliary catheter insertion* | | *Biliary drainage* | 10063425 Current |
| | | | To PT | |
| | | | *Biliary catheter insertion* | 10082920 |

MSSO Comment:

**CR Number: 2019114003** **Implementation Date:** 24-Apr-19 Related CR: 2019107005

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Percutaneous transhepatic biliary drainage catheter insertion* | Approved as Requested | Proposed LLT | |
| To PT | *Biliary catheter insertion* | | *Percutaneous transhepatic biliary drainage catheter insertion* | 10082923 Current |
| | | | To PT | |
| | | | *Biliary catheter insertion* | 10082920 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019107006** **Implementation Date:** 24-Apr-19 Related CR: 2019107006

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Stent endoprosthesis for colorectal cancer* | Approved Not as Requested | Proposed LLT | |
| | | | *Colonic stent insertion* | 10082926 Current |
| | | | To PT | |
| | | | *Intestinal stent insertion* | 10065664 |

MSSO Comment: The proposal to add a new LLT Stent endoprosthesis for colorectal cancer is approved but not as requested. The requested term will be shortened to a more commonly used description without the specific indication of colorectal cancer, and added as LLT Colonic stent insertion to PT Intestinal stent insertion.

**CR Number: 2019107007** **Implementation Date:** 24-Apr-19 Related CR: 2019107007

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Duodenal perforation repair* | Approved as Requested | Proposed LLT | |
| | | | *Duodenal perforation repair* | 10082927 Current |
| | | | To PT | |
| | | | *Enterorrhaphy* | 10082396 |

MSSO Comment: The proposal to add a new LLT Duodenal perforation repair is approved as requested. Duodenal perforation repair is a surgical intervention nearly always required for gastrointestinal perforation in form of exploratory laparotomy and closure of perforation with peritoneal wash. Duodenal perforation repair will be added as a sub-concept LLT to PT Enterorrhaphy. In a related change, Intestinal perforation repair will be added as a sub-concept LLT to PT Enterorrhaphy.

**CR Number: 2019114004** **Implementation Date:** 24-Apr-19 Related CR: 2019107007

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Intestinal perforation repair* | Approved as Requested | Proposed LLT | |
| To PT | *Enterorrhaphy* | | *Intestinal perforation repair* | 10082924 Current |
| | | | To PT | |
| | | | *Enterorrhaphy* | 10082396 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019107008** **Implementation Date:** 24-Apr-19 Related CR: 2019107008

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Bile duct reconstruction* | Approved Not as Requested | Proposed PT | |
| | | | *Bile duct reconstruction* | 10082921 |
| | | | HLT primary | |
| | | | *Biliary tract and gallbladder therapeutic procedures* | 10004675 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment: The proposal to add a new LLT Bile duct reconstruction is approved but not as requested. Biliary reconstruction describes a variety of surgical procedures to replace portions of the biliary (bile delivery) system that are missing at birth or damaged due to illness such as resection of biliary malignancies, benign biliary strictures, intraoperative injury, and liver transplantation. Bile duct reconstruction will be added as a PT to HLT Biliary tract and gallbladder therapeutic procedures.

**CR Number: 2019107009** **Implementation Date:** 24-Apr-19 Related CR: 2019107009

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Pericardial lipoma* | Approved Not as Requested | Proposed PT | |
| | | | *Pericardial lipoma* | 10082919 |
| | | | HLT primary | |
| | | | *Cardiovascular neoplasms benign* | 10007656 |
| | | | SOC primary | |
| | | | *Neoplasms benign, malignant and unspecified (incl cysts and polyps)* | 10029104 |
| | | | HLT secondary | |
| | | | *Pericardial disorders NEC* | 10034469 |
| | | | SOC secondary | |
| | | | *Cardiac disorders* | 10007541 |

MSSO Comment: The proposal to add a new LLT Pericardial lipoma is approved but not as requested. Pericardial lipomas are slowly growing benign tumors of the pericardium that are asymptomatic unless large in size, where they can cause pressure symptoms. Pericardial lipoma will be added as a PT to primary HLT Cardiovascular neoplasms benign and to secondary HLT Pericardial disorders NEC.

# Supplemental Update Report

**CR Number: 2019107011** **Implementation Date:** 10-May-19 Related CR: 2019107011

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Lung opacity* | Approved as Requested | Proposed PT<br>*Lung opacity* | 10081792 |
| To SMQ | *Eosinophilic pneumonia (SMQ)* | | To SMQ<br>*Eosinophilic pneumonia (SMQ)* | 20000157 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*C* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Lung opacity to Eosinophilic pneumonia (SMQ) as a broad term is approved as requested. This term fits the inclusion criteria for this SMQ for terms for pulmonary conditions possibly indicative of pneumonia. A similar term, PT Lung infiltration, is included as a broad search term, category C.

**CR Number: 2019107012** **Implementation Date:** 10-May-19 Related CR: 2019107012

| Change Requested | Change term status in a SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Rhinocerebral mucormycosis* | Approved as Requested | Proposed PT<br>*Rhinocerebral mucormycosis* | 10076959 |
| To SMQ | *Infective pneumonia (SMQ)* | | To SMQ<br>*Infective pneumonia (SMQ)* | 20000231 |
| Status | *I* | | Status<br>*I* | |

MSSO Comment: The proposal to change status of the term Rhinocerebral mucormycosis in Infective pneumonia (SMQ) to Inactive is approved as requested. This term was promoted from under included broad scope PT Mucormycosis in version 22.1. Since this describes a rhinocerebral infection, it no longer fits the criteria for this SMQ focusing on infective pneumonia, and will be made inactive.

# Supplemental Update Report

**CR Number: 2019107013** **Implementation Date:** 10-May-19 Related CR: 2019107013

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Lung opacity* | Approved as Requested | Proposed PT<br>*Lung opacity* | 10081792 |
| To SMQ | *Interstitial lung disease (SMQ)* | | To SMQ<br>*Interstitial lung disease (SMQ)* | 20000042 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Lung opacity to Interstitial lung disease (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ for terms indicating an interstitial pulmonary reaction. An interstitial pattern is one of the three major patterns of pulmonary opacification. A similar term, PT Lung infiltration, is included as a narrow search term.

**CR Number: 2019107014** **Implementation Date:** 10-May-19 Related CR: 2019107014

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Product confusion* | Approved as Requested | Proposed PT<br>*Product confusion* | 10082712 |
| To SMQ | *Medication errors (SMQ)* | | To SMQ<br>*Medication errors (SMQ)* | 20000224 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Product confusion to Medication errors (SMQ) as a narrow term is approved as requested. Product confusion describe a scenario where the reporter only reports a “confusion” situation with a product without specifically mentioning whether it is because of the packaging, name, or label, etc. Similar product confusion terms are included as narrow scope terms in this SMQ.

# Supplemental Update Report

**CR Number: 2019107015** **Implementation Date:** 10-May-19 Related CR: 2019107015

| Change Requested | Update MedDRA term_scope | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pulmonary mucormycosis* | Approved as Requested | Proposed PT<br>*Pulmonary mucormycosis* | 10078354 |
| To SMQ | *Infective pneumonia (SMQ)* | | To SMQ<br>*Infective pneumonia (SMQ)* | 20000231 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |

MSSO Comment: The proposal to change the scope of the PT Pulmonary mucormycosis in Infective pneumonia (SMQ) to Narrow is approved as requested. Pulmonary mucormycosis was promoted from under included broad scope PT Mucormycosis in version 22.1. Since this term describes a pulmonary infection, the scope of this term will be changed from broad to narrow.

**CR Number: 2019107016** **Implementation Date:** 10-May-19 Related CR: 2019107016

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Acquired factor IX deficiency* | Approved as Requested | Proposed PT<br>*Acquired factor IX deficiency* | 10082747 |
| To SMQ | *Haemorrhage laboratory terms (SMQ)* | | To SMQ<br>*Haemorrhage laboratory terms (SMQ)* | 20000040 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Acquired factor IX deficiency to Haemorrhage laboratory terms (SMQ) as a broad term is approved as requested. This term fits the inclusion criteria for this SMQ for terms relating to coagulation factor deficiencies. Similar terms such as PT Coagulation factor VII level decreased and PT Coagulation factor X level decreased are already included. This term meets criteria for inclusion as a broad search terms for this SMQ.

# Supplemental Update Report

**CR Number: 2019107017** **Implementation Date:** 10-May-19 Related CR: 2019107017

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Acquired factor VIII deficiency* | Approved as Requested | Proposed PT<br>*Acquired factor VIII deficiency* | 10082745 |
| To SMQ | *Haemorrhage laboratory terms (SMQ)* | | To SMQ<br>*Haemorrhage laboratory terms (SMQ)* | 20000040 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Acquired factor VIII deficiency to Haemorrhage laboratory terms (SMQ) as a broad term is approved as requested. This term fits the inclusion criteria for this SMQ for terms relating to coagulation factor deficiencies. Similar terms such as PT Coagulation factor VII level decreased and PT Coagulation factor X level decreased are already included. It meets criteria for inclusion in the broad search terms of this SMQ.

**CR Number: 2019107018** **Implementation Date:** 10-May-19 Related CR: 2019107018

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Acquired factor XI deficiency* | Approved as Requested | Proposed PT<br>*Acquired factor XI deficiency* | 10082746 |
| To SMQ | *Haemorrhage laboratory terms (SMQ)* | | To SMQ<br>*Haemorrhage laboratory terms (SMQ)* | 20000040 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Acquired factor XI deficiency to Haemorrhage laboratory terms (SMQ) as a broad term is approved as requested. This term fits the inclusion criteria for this SMQ for terms relating to coagulation factor deficiencies. Similar terms such as PT Coagulation factor VII level decreased and PT Coagulation factor X level decreased are already included. This term meets the criteria for inclusion as a broad search term for this SMQ.

# Supplemental Update Report

**CR Number: 2019107019** **Implementation Date:** 10-May-19 Related CR: 2019107019

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Cardiofaciocutaneous syndrome* | Approved as Requested | Proposed PT<br>*Cardiofaciocutaneous syndrome* | 10082805 |
| To SMQ | *Congenital, familial and genetic disorders (SMQ)* | | To SMQ<br>*Congenital, familial and genetic disorders (SMQ)* | 20000077 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Cardiofaciocutaneous syndrome to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. Cardiofaciocutaneous syndrome is a multiple congenital anomaly disorder characterized by a distinctive facial appearance, heart defects, and mental retardation. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

**CR Number: 2019107020** **Implementation Date:** 10-May-19 Related CR: 2019107020

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Congenital bilateral perisylvian syndrome* | Approved as Requested | Proposed PT<br>*Congenital bilateral perisylvian syndrome* | 10082716 |
| To SMQ | *Congenital, familial and genetic disorders (SMQ)* | | To SMQ<br>*Congenital, familial and genetic disorders (SMQ)* | 20000077 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Congenital bilateral perisylvian syndrome to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. Congenital bilateral perisylvian syndrome is an extremely rare neurological disorder characterized by partial paralysis of muscles on both sides of the face, tongue, jaws, and throat (pseudobulbar palsy), dysarthria, mastication dysphagia, epilepsy, and mild to severe intellectual disability. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

# Supplemental Update Report

**CR Number: 2019107021** **Implementation Date:** 10-May-19 Related CR: 2019107021

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Anorectal malformation* | Approved as Requested | Proposed PT<br>*Anorectal malformation* | 10082798 |
| To SMQ | *Congenital, familial and genetic disorders (SMQ)* | | To SMQ<br>*Congenital, familial and genetic disorders (SMQ)* | 20000077 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Anorectal malformation to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. Anorectal malformations represents a spectrum of abnormalities ranging from mild anal anomalies to complex cloacal malformations. Defects range from the very minor and easily treated with an excellent functional prognosis, to those that are complex, difficult to manage, are often associated with other anomalies, and have a poor functional prognosis. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

**CR Number: 2019107022** **Implementation Date:** 10-May-19 Related CR: 2019107022

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Extradural haematoma evacuation* | Approved as Requested | Proposed PT<br>*Extradural haematoma evacuation* | 10082797 |
| To SMQ | *Haemorrhage terms (excl laboratory terms) (SMQ)* | | To SMQ<br>*Haemorrhage terms (excl laboratory terms) (SMQ)* | 20000039 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Extradural haematoma evacuation to Haemorrhage terms (excl laboratory terms) (SMQ) as a narrow term is approved as requested. This term, which describes evacuation of haematoma from a specific location in the space between the cranial bones and the dura mater (extradural space), meets criteria for inclusion in this SMQ which is composed of narrow search terms. A related PT Subdural haematoma evacuation is already included in the Category A narrow search terms for this SMQ.

# Supplemental Update Report

**CR Number: 2019107023** **Implementation Date:** 10-May-19 Related CR: 2019107023

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Chronic active Epstein-Barr virus infection* | Approved as Requested | Proposed PT | |
| To SMQ | *Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)* | | *Chronic active Epstein-Barr virus infection* | 10082848 |
| Term scope | *Broad* | | To SMQ | |
| | | | *Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)* | 20000225 |
| | | | Term scope | |
| | | | *Broad* | |
| | | | Term_category | |
| | | | *B* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Chronic active Epstein-Barr virus infection to Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ) as a broad term is approved as requested. DRESS affects multiple organs and is occasionally associated with drug-related reactivation of viruses including Epstein-Barr virus in the setting of drug hypersensitivities. It meets criteria for inclusion as a broad search term in this SMQ. A related PT Epstein-Barr virus infection is already included in the Category B broad search terms of this SMQ.

**CR Number: 2019107024** **Implementation Date:** 10-May-19 Related CR: 2019107024

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Anal blister* | Approved as Requested | Proposed PT | |
| To SMQ | *Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)* | | *Anal blister* | 10082677 |
| Term scope | *Broad* | | To SMQ | |
| | | | *Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ)* | 20000225 |
| | | | Term scope | |
| | | | *Broad* | |
| | | | Term_category | |
| | | | *B* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Anal blister to Drug reaction with eosinophilia and systemic symptoms syndrome (SMQ) as a broad term is approved as requested. Drug reaction with eosinophilia and systemic symptoms syndrome (DRESS) affects multiple organs with heterogenous signs and symptoms including skin manifestations/eruptions such as blisters on the genitals and is occasionally associated with drug-related reactivation of viruses such as Herpes-Simplex virus in the setting of drug hypersensitivities. This term meets the criteria for inclusion as a broad search term for this SMQ. Related PTs: PT Genital blister, PT Rash pustular, and PT Rash vesicular are already included in the Category B, broad search terms of this SMQ.

# Supplemental Update Report

**CR Number: 2019107025** **Implementation Date:** 10-May-19 Related CR: 2019107025

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Anal blister* | Approved as Requested | Proposed PT<br>*Anal blister* | 10082677 |
| To SMQ | *Severe cutaneous adverse reactions (SMQ)* | | To SMQ<br>*Severe cutaneous adverse reactions (SMQ)* | 20000020 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Anal blister to Severe cutaneous adverse reactions (SMQ) as a broad term is approved as requested. Anal blister is a type of SCAR (Severe Cutaneous Adverse Reaction) that represents the signs/symptoms included in the criteria for the diagnoses of DRESS. It meets criteria for inclusion as a broad search term in this SMQ. Related PTs: PT Blister and PT Mucosa vesicle are already included in the Category A, as broad search terms for this SMQ.

**CR Number: 2019107026** **Implementation Date:** 10-May-19 Related CR: 2019107026

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Anaesthesia eye* | Approved as Requested | Proposed PT<br>*Anaesthesia eye* | 10082764 |
| To SMQ | *Guillain-Barre syndrome (SMQ)* | | To SMQ<br>*Guillain-Barre syndrome (SMQ)* | 20000131 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Anaesthesia eye to Guillain-Barre syndrome (SMQ) as a broad term is approved as requested. This term meets the criteria for inclusion in the broad search terms of this SMQ. A related PT, Hypoaesthesia eye, is already included in the broad search terms.

# Supplemental Update Report

**CR Number: 2019107027** **Implementation Date:** 10-May-19 Related CR: 2019107027

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Congenital bilateral perisylvian syndrome* | Approved as Requested | Proposed PT | |
| To SMQ | *Convulsions (SMQ)* | | *Congenital bilateral perisylvian syndrome* | 10082716 |
| Term scope | *Narrow* | | To SMQ | |
| | | | *Convulsions (SMQ)* | 20000079 |
| | | | Term scope | |
| | | | *Narrow* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Congenital bilateral perisylvian syndrome to Convulsions (SMQ) as a narrow term is approved as requested. Congenital bilateral perisylvian syndrome is a neurological condition characterized by pseudobulbar palsy, cognitive deficits, and bilateral perisylvian abnormalities on imaging studies. All patients had diplegia of the facial pharyngeal, and masticatory muscles, of variable severity. In one study, epilepsy was present in 87% of patients and commonly consisted of atypical absence, atonic/ tonic, tonic-clonic seizures, and, less frequently, partial attacks. Seizures were poorly controlled in 55%. As a condition which features seizures as a prominent part of its clinical signature, this disorder meets the criteria for inclusion in the narrow search terms of this SMQ. Another condition, PT Double cortex syndrome, which is also characterized by structural brain abnormalities and frequent seizures, is already included in the narrow search terms.

**CR Number: 2019107028** **Implementation Date:** 10-May-19 Related CR: 2019107028

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Phrenic nerve injury* | Approved as Requested | Proposed PT | |
| To SMQ | *Accidents and injuries (SMQ)* | | *Phrenic nerve injury* | 10082761 |
| Term scope | *Narrow* | | To SMQ | |
| | | | *Accidents and injuries (SMQ)* | 20000135 |
| | | | Term scope | |
| | | | *Narrow* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Phrenic nerve injury to Accidents and injuries (SMQ) as a narrow term is approved as requested. This term, which describes a specific type if injury, meets the criteria for inclusion in the narrow search terms of this SMQ.

# Supplemental Update Report

**CR Number: 2019107029** **Implementation Date:** 10-May-19 Related CR: 2019107029

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Scrotal injury* | Approved as Requested | Proposed PT<br>*Scrotal injury* | 10082770 |
| To SMQ | *Accidents and injuries (SMQ)* | | To SMQ<br>*Accidents and injuries (SMQ)* | 20000135 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Scrotal injury to Accidents and injuries (SMQ) as a narrow term is approved as requested. This term, which describes a specific type of injury, meets the criteria for inclusion in the narrow search terms of this SMQ.

**CR Number: 2019107030** **Implementation Date:** 10-May-19 Related CR: 2019107030

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Extradural haematoma evacuation* | Approved as Requested | Proposed PT<br>*Extradural haematoma evacuation* | 10082797 |
| To SMQ | *Haemorrhagic central nervous system vascular conditions (SMQ)* | | To SMQ<br>*Haemorrhagic central nervous system vascular conditions (SMQ)* | 20000064 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Extradural haematoma evacuation to Haemorrhagic central nervous system vascular conditions (SMQ) as a narrow term is approved as requested. This term describes a procedure for the removal of an abnormal collection of blood sequestered between the extradural space and skull. The related PTs: PT Subdural haematoma evacuation and PT Intracerebral haematoma evacuation are already included in this SMQ which is entirely comprised of narrow search terms.

# Supplemental Update Report

**CR Number: 2019107031** **Implementation Date:** 10-May-19 Related CR: 2019107031

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Infusion related hypersensitivity reaction* | Approved as Requested | Proposed PT<br>*Infusion related hypersensitivity reaction* | 10082742 |
| To SMQ | *Hypersensitivity (SMQ)* | | To SMQ<br>*Hypersensitivity (SMQ)* | 20000214 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Infusion related hypersensitivity reaction to Hypersensitivity (SMQ) as a narrow term is approved as requested. New term for version 22.1 which fulfills the criteria i.e all terms indicative of potential drug /vaccine related hypersensitivity/allergic reaction as a narrow in scope term. Closely related PT Infusion related reaction is included an narrow PT as well.

**CR Number: 2019107032** **Implementation Date:** 10-May-19 Related CR: 2019107032

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Muscle strength abnormal* | Approved as Requested | Proposed PT<br>*Muscle strength abnormal* | 10082799 |
| To SMQ | *Rhabdomyolysis/myopathy (SMQ)* | | To SMQ<br>*Rhabdomyolysis/myopathy (SMQ)* | 20000002 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Muscle strength abnormal to Rhabdomyolysis/myopathy (SMQ) as a broad term is approved as requested. New term for version 22.1 which fulfills the criteria as a broad in scope term. Physical examination for the diagnosis of myopathy/rhabdomyolysis includes tests of muscle strength. Related PT Muscular weakness is broad as well.

# Supplemental Update Report

**CR Number: 2019107033** **Implementation Date:** 10-May-19 Related CR: 2019107033

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pituitary scan abnormal* | Approved as Requested | Proposed PT<br>*Pituitary scan abnormal* | 10082812 |
| To SMQ | *Malignancy related therapeutic and diagnostic procedures (SMQ)* | | To SMQ<br>*Malignancy related therapeutic and diagnostic procedures (SMQ)* | 20000093 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Pituitary scan abnormal to Malignancy related therapeutic and diagnostic procedures (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms such as PT Scan abdomen abnormal are already included. All terms in this SMQ are narrow scope.

**CR Number: 2019107034** **Implementation Date:** 10-May-19 Related CR: 2019107034

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Radiotherapy to tongue* | Approved as Requested | Proposed PT<br>*Radiotherapy to tongue* | 10082850 |
| To SMQ | *Malignancy related therapeutic and diagnostic procedures (SMQ)* | | To SMQ<br>*Malignancy related therapeutic and diagnostic procedures (SMQ)* | 20000093 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Radiotherapy to tongue to Malignancy related therapeutic and diagnostic procedures (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar radiotherapy terms are already included. All terms in this SMQ are narrow scope.

# Supplemental Update Report

**CR Number: 2019107035** **Implementation Date:** 10-May-19 Related CR: 2019107035

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Solitary fibrous tumour* | Approved as Requested | Proposed PT<br>*Solitary fibrous tumour* | 10082804 |
| To SMQ | *Non-haematological tumours of unspecified malignancy (SMQ)* | | To SMQ<br>*Non-haematological tumours of unspecified malignancy (SMQ)* | 20000230 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Solitary fibrous tumour to Non-haematological tumours of unspecified malignancy (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar tumour terms of unspecified malignancy are already included. All terms in this SMQ are narrow scope.

**CR Number: 2019107036** **Implementation Date:** 10-May-19 Related CR: 2019107036

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Neutrophil gelatinase-associated lipocalin increased* | Approved as Requested | Proposed PT<br>*Neutrophil gelatinase-associated lipocalin increased* | 10082703 |
| To SMQ | *Acute renal failure (SMQ)* | | To SMQ<br>*Acute renal failure (SMQ)* | 20000003 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Neutrophil gelatinase-associated lipocalin increased to Acute renal failure (SMQ) as a broad term is approved as requested. Neutrophil gelatinase-associated lipocalin (NGAL) is a member of the lipocalin family that is expressed at low levels in several human tissues, and rapidly released from renal tubular cells in response to various insults to the kidney. Serum and urinary NGAL are promising emerging biomarkers for early detection of acute kidney injury. Like other investigation terms, this new term will be added to the broad scope of this SMQ.

# Supplemental Update Report

**CR Number: 2019107037** **Implementation Date:** 10-May-19 Related CR: 2019107037

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Neutrophil gelatinase-associated lipocalin increased* | Approved as Requested | Proposed PT<br>*Neutrophil gelatinase-associated lipocalin increased* | 10082703 |
| To SMQ | *Chronic kidney disease (SMQ)* | | To SMQ<br>*Chronic kidney disease (SMQ)* | 20000213 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Neutrophil gelatinase-associated lipocalin increased to Chronic kidney disease (SMQ) as a broad term is approved as requested. Several recent studies have also defined the role of Neutrophil gelatinase-associated lipocalin (NGAL) in chronic kidney disease and showed serum and urinary NGAL levels are a marker of kidney disease and severity in chronic kidney disease. Like other investigation terms, this new term will be added to the broad scope of this SMQ.

**CR Number: 2019107038** **Implementation Date:** 10-May-19 Related CR: 2019107038

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vascular access steal syndrome* | Approved as Requested | Proposed PT<br>*Vascular access steal syndrome* | 10082739 |
| To SMQ | *Chronic kidney disease (SMQ)* | | To SMQ<br>*Chronic kidney disease (SMQ)* | 20000213 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Vascular access steal syndrome to Chronic kidney disease (SMQ) as a broad term is approved as requested. In nephrology, vascular access steal syndrome is a syndrome caused by ischemia resulting from a vascular access device (such as an arteriovenous fistula or synthetic vascular graft–AV fistula) installed to provide access for the inflow and outflow of blood during hemodialysis. Like other dialysis related complications, this term will be added to the broad scope of this SMQ.

# Supplemental Update Report

**CR Number: 2019107039** **Implementation Date:** 10-May-19 Related CR: 2019107039

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Anal fistula repair* | Approved as Requested | Proposed PT<br>*Anal fistula repair* | 10082792 |
| To SMQ | *Gastrointestinal perforation (SMQ)* | | To SMQ<br>*Gastrointestinal perforation (SMQ)* | 20000107 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Anal fistula repair to Gastrointestinal perforation (SMQ) as a narrow term is approved as requested. Both fistulas and fistula repair terms are part of this SMQ.

**CR Number: 2019107040** **Implementation Date:** 10-May-19 Related CR: 2019107040

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Jejunojejunostomy* | Approved as Requested | Proposed PT<br>*Jejunojejunostomy* | 10082699 |
| To SMQ | *Gastrointestinal perforation, ulcer, haemorrhage, obstruction non-specific findings/procedures (SMQ)* | | To SMQ<br>*Gastrointestinal perforation, ulcer, haemorrhage, obstruction non-specific findings/procedures (SMQ)* | 20000104 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Jejunojejunostomy to Gastrointestinal perforation, ulcer, haemorrhage, obstruction non-specific findings/procedures (SMQ) as a broad term is approved as requested. Different forms of enterostomy (such as PT Enterostomy closure, PT Ileostomy, PT Jejunostomy closure, PT Jejunostomy) are part of the broad scope of this SMQ.

# Supplemental Update Report

**CR Number: 2019107041** **Implementation Date:** 10-May-19 Related CR: 2019107041

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pituitary scan abnormal* | Approved as Requested | Proposed PT<br>*Pituitary scan abnormal* | 10082812 |
| To SMQ | *Hyponatraemia/SIADH (SMQ)* | | To SMQ<br>*Hyponatraemia/SIADH (SMQ)* | 20000141 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Pituitary scan abnormal to Hyponatraemia/SIADH (SMQ) as a broad term is approved as requested. Though imaging techniques are not the most relevant diagnostic element in SIADH, there is an association of SIADH with the absence of the normal hyper-intense signal of the neurohypophysis, confirming the usefulness of MRI as a tool to visualize ADH processing. Besides, pituitary adenomas may cause SIADH by compression of the pituitary stalk. This PT will be added to the broad scope of this SMQ.

**CR Number: 2019107042** **Implementation Date:** 10-May-19 Related CR: 2019107042

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *AST/ALT ratio abnormal* | Approved as Requested | Proposed PT<br>*AST/ALT ratio abnormal* | 10082832 |
| To SMQ | *Liver related investigations, signs and symptoms (SMQ)* | | To SMQ<br>*Liver related investigations, signs and symptoms (SMQ)* | 20000008 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT AST/ALT ratio abnormal to Liver related investigations, signs and symptoms (SMQ) as a narrow term is approved as requested. The AST/ALT ratio is the ratio between the concentrations of the enzymes aspartate transaminase (AST) and alanine transaminase, also known as alanine aminotransferase (ALT) in the blood. Different proportions of this ratio may help to differentiate between different hepatopathies, as well as hepatic from inflammatory muscle conditions. The term will be added to the narrow scope of this SMQ.

# Supplemental Update Report

**CR Number: 2019107043** **Implementation Date:** 10-May-19 Related CR: 2019107043

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Acquired factor IX deficiency* | Approved as Requested | Proposed PT | |
| To SMQ | *Liver-related coagulation and bleeding disturbances (SMQ)* | | *Acquired factor IX deficiency* | 10082747 |
| Term scope | *Narrow* | | To SMQ | |
| | | | *Liver-related coagulation and bleeding disturbances (SMQ)* | 20000015 |
| | | | Term scope | |
| | | | *Narrow* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Acquired factor IX deficiency to Liver-related coagulation and bleeding disturbances (SMQ) as a narrow term is approved as requested. Though in most instances acquired hemophilia is caused by autoantibodies against clotting factors, it can also be due to advanced hepatopathy, especially in end-stage liver disease.

**CR Number: 2019107044** **Implementation Date:** 10-May-19 Related CR: 2019107044

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Acquired factor VIII deficiency* | Approved as Requested | Proposed PT | |
| To SMQ | *Liver-related coagulation and bleeding disturbances (SMQ)* | | *Acquired factor VIII deficiency* | 10082745 |
| Term scope | *Narrow* | | To SMQ | |
| | | | *Liver-related coagulation and bleeding disturbances (SMQ)* | 20000015 |
| | | | Term scope | |
| | | | *Narrow* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Acquired factor VIII deficiency to Liver-related coagulation and bleeding disturbances (SMQ) as a narrow term is approved as requested. Though in most instances acquired hemophilia is caused by autoantibodies against clotting factors, it can also be due to advanced hepatopathy, especially in end-stage liver disease.

# Supplemental Update Report

**CR Number: 2019107045** **Implementation Date:** 10-May-19 Related CR: 2019107045

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Acquired factor XI deficiency* | Approved as Requested | Proposed PT<br>*Acquired factor XI deficiency* | 10082746 |
| To SMQ | *Liver-related coagulation and bleeding disturbances (SMQ)* | | To SMQ<br>*Liver-related coagulation and bleeding disturbances (SMQ)* | 20000015 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Acquired factor XI deficiency to Liver-related coagulation and bleeding disturbances (SMQ) as a narrow term is approved as requested. Though in most instances acquired hemophilia is caused by autoantibodies against clotting factors, it can also be due to advanced hepatopathy, especially in end-stage liver disease.

**CR Number: 2019107046** **Implementation Date:** 10-May-19 Related CR: 2019107046

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Lip scab* | Approved as Requested | Proposed PT<br>*Lip scab* | 10082767 |
| To SMQ | *Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ)* | | To SMQ<br>*Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ)* | 20000114 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Lip scab to Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ) as a narrow term is approved as requested. Buccal aspects of lips are considered part of the oropharynx.

# Supplemental Update Report

**CR Number: 2019107047** **Implementation Date:** 10-May-19 Related CR: 2019107047

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Oral mucosal scab* | Approved as Requested | Proposed PT<br>*Oral mucosal scab* | 10082769 |
| To SMQ | *Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ)* | | To SMQ<br>*Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ)* | 20000114 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Oral mucosal scab to Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ) as a narrow term is approved as requested. Oral mucosa disorders, signs and symptoms are part of this SMQ.

**CR Number: 2019107048** **Implementation Date:** 10-May-19 Related CR: 2019107048

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Hyperaesthesia eye* | Approved as Requested | Proposed PT<br>*Hyperaesthesia eye* | 10082768 |
| To SMQ | *Corneal disorders (SMQ)* | | To SMQ<br>*Corneal disorders (SMQ)* | 20000156 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Hyperaesthesia eye to Corneal disorders (SMQ) as a broad term is approved as requested. PT Hyperaesthesia eye, added in version 22.1, an abnormal increase in sensation of the eye, is a non-specific concept, which often refers to increased sensitivity of the cornea, for example after Herpes zoster ophthalmicus. Inflammation, trauma, and other disorders of the cornea may also result in increased sensitivity to light. PT Hyperaesthesia eye, a symptom often associated with corneal disorders, will be added as a broad scope term to Corneal disorders (SMQ). PT Photophobia, PT Abnormal sensation in eye, and PT Eye irritation are currently broad terms in this SMQ.

# Supplemental Update Report

**CR Number: 2019107049** **Implementation Date:** 10-May-19 Related CR: 2019107049

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Anaesthesia eye* | Approved as Requested | Proposed PT<br>*Anaesthesia eye* | 10082764 |
| To SMQ | *Corneal disorders (SMQ)* | | To SMQ<br>*Corneal disorders (SMQ)* | 20000156 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Anaesthesia eye to Corneal disorders (SMQ) as a broad term is approved as requested. PT Anaesthesia eye was added in version 22.1. Anaesthesia of the eye is a rather general concept that relates to a loss of sensation of the eye. Often, the concept pertains to corneal anesthesia caused by impairment to the ophthalmic division of the trigeminal nerve which provides sensation to the cornea. Corneal anesthesia is commonly caused by infection (such as Herpes zoster), diabetes, trauma or surgery. PT Anaesthesia eye will be added as a broad scope term to Corneal disorders (SMQ), as the term is often used with respect to the loss of corneal sensation. PT Hypoaesthesia eye is currently a broad term in this SMQ.

**CR Number: 2019107050** **Implementation Date:** 10-May-19 Related CR: 2019107050

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Hyperaesthesia eye* | Approved as Requested | Proposed PT<br>*Hyperaesthesia eye* | 10082768 |
| To SMQ | *Glaucoma (SMQ)* | | To SMQ<br>*Glaucoma (SMQ)* | 20000146 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Hyperaesthesia eye to Glaucoma (SMQ) as a broad term is approved as requested. PT Hyperaesthesia eye, added in version 22.1, an abnormal increase in sensation of the eye, is a non-specific concept. In acute glaucoma associated with significantly increased intraocular pressure, the eye is often painful to touch, and sensitive to light. PT Hyperaesthesia eye will be added to Glaucoma (SMQ) as a broad scope term because it fulfills the following inclusion criterion, "Signs, symptoms, diagnoses, and test results that are not exclusively specific to glaucoma but may have additional value by identifying potential cases." Photophobia is currently a broad term in this SMQ.

# Supplemental Update Report

**CR Number: 2019107051** **Implementation Date:** 10-May-19 Related CR: 2019107051

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Glycated albumin increased* | Approved as Requested | Proposed PT | |
| To SMQ | *Hyperglycaemia/new onset diabetes mellitus (SMQ)* | | *Glycated albumin increased* | 10082836 |
| Term scope | *Narrow* | | To SMQ | |
| | | | *Hyperglycaemia/new onset diabetes mellitus (SMQ)* | 20000041 |
| | | | Term scope | |
| | | | *Narrow* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Glycated albumin increased to Hyperglycaemia/new onset diabetes mellitus (SMQ) as a narrow term is approved as requested. PT Glycated albumin increased, added in version 22.1, can be an indicator of hyperglycaemia. Glycated albumin reflects short-term (2–3 weeks) mean glycemic levels. Glycated albumin values are not affected by changes in erythrocyte lifespan and thus measurement of glycated albumin is not influenced by anemia or other conditions. Also, glycated albumin is reported to serve as a better indicator of glycemic control than HbA1c in diabetic patients on dialysis. PT Glycated albumin increased fulfills the inclusion criterion "Abnormalities of insulin or glucose metabolism expected in patients with diabetes mellitus or hyperglycemia," of Hyperglycaemia/new onset diabetes mellitus (SMQ), and will be added as a narrow scope term to this SMQ. PT Glycosylated haemoglobin increased is an existing narrow term in Hyperglycaemia/new onset diabetes mellitus (SMQ).

**CR Number: 2019107052** **Implementation Date:** 10-May-19 Related CR: 2019107052

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Glycated albumin decreased* | Approved as Requested | Proposed PT | |
| To SMQ | *Hypoglycaemia (SMQ)* | | *Glycated albumin decreased* | 10082837 |
| Term scope | *Broad* | | To SMQ | |
| | | | *Hypoglycaemia (SMQ)* | 20000226 |
| | | | Term scope | |
| | | | *Broad* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Glycated albumin decreased to Hypoglycaemia (SMQ) as a broad term is approved as requested. PT Glycated albumin decreased was added in version 22.1. Glycated albumin reflects short-term (2–3 weeks) mean glycemic levels, and thus potentially may indicate hypoglycaemia if below the normal reference range. PT Glycated albumin decreased will be added as a broad scope PT to Hypoglycaemia (SMQ) because it fulfills the following inclusion criterion: "Terms for relevant laboratory findings supporting the diagnosis of hypoglycemia." Synonym LLT Blood glycoalbumin decreased, was moved from PT Fructosamine decreased, currently a broad PT in Hypoglycaemia (SMQ), to new PT Glycated albumin decreased.

# Supplemental Update Report

**CR Number: 2019107053** **Implementation Date:** 10-May-19 Related CR: 2019107053

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Rhinocerebral mucormycosis* | Approved as Requested | Proposed PT | |
| To SMQ | *Ocular infections (SMQ)* | | *Rhinocerebral mucormycosis* | 10076959 |
| Term scope | *Broad* | | To SMQ | |
| | | | *Ocular infections (SMQ)* | 20000183 |
| | | | Term scope | |
| | | | *Broad* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Rhinocerebral mucormycosis to Ocular infections (SMQ) as a broad term is approved as requested. LLT Rhino-orbital-cerebral mucormycosis was moved from PT Mucormycosis to PT Rhinocerebral mucormycosis in version 21.1. Rhinocerebral mucormycosis is a rare opportunistic infection of the sinuses, nasal passages, oral cavity, and brain caused by saprophytic fungi. The infection may extend posteriorly to the orbital apex, leading to orbital apex syndrome. The optic nerve may be affected, resulting in vision loss. Involvement of the superior orbital fissure and its contents, such as cranial nerves III, IV, and VI, and branches of V1 and V2, may cause diplopia, ophthalmoplegia, and sensory loss to the corresponding areas of the cornea and face. PT Rhinocerebral mucormycosis warrants addition as a broad scope term to Ocular infections (SMQ) because this cranial fungus infection often extends to the orbit and the ocular tissues.

**CR Number: 2019107054** **Implementation Date:** 10-May-19 Related CR: 2019107054

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Hyperaesthesia eye* | Approved as Requested | Proposed PT | |
| To SMQ | *Retinal disorders (SMQ)* | | *Hyperaesthesia eye* | 10082768 |
| Term scope | *Broad* | | To SMQ | |
| | | | *Retinal disorders (SMQ)* | 20000158 |
| | | | Term scope | |
| | | | *Broad* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Hyperaesthesia eye to Retinal disorders (SMQ) as a broad term is approved as requested. PT Hyperaesthesia eye, added in version 22.1, an abnormal increase in sensation of the eye, is a non-specific concept, which often refers to increased sensitivity of the cornea, and/or an increased sensitivity to light. Retinitis, an inflammatory condition of the retina associated with a variety of etiologies, often results in an increased sensitivity to light. PT Hyperaesthesia eye will be added as a broad scope term to Retinal disorders (SMQ), as it fulfills the inclusion criterion "Terms for signs and symptoms of visual disturbance." PT Photophobia is a broad term in this SMQ.

# Supplemental Update Report

**CR Number: 2019107055** **Implementation Date:** 10-May-19 Related CR: 2019107055

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Disruption of the photoreceptor inner segment-outer segment* | Approved as Requested | Proposed PT<br>*Disruption of the photoreceptor inner segment-outer segment* | 10082802 |
| To SMQ | *Retinal disorders (SMQ)* | | To SMQ<br>*Retinal disorders (SMQ)* | 20000158 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Disruption of the photoreceptor inner segment-outer segment to Retinal disorders (SMQ) as a narrow term is approved as requested. PT Disruption of the photoreceptor inner segment-outer segment, added in version 22.1, is a retinal disorder that has been observed in association with conditions such as macular holes, epiretinal membranes and Joubert Syndrome. Degeneration or pathology of the junction between the inner segment and the outer segment of the retinal photoreceptor layers may compromise visual acuity. PT Disruption of the photoreceptor inner segment-outer segment will be added as a narrow scope term to Retinal disorder (SMQ), because it represents a specific retinal pathologic condition.

**CR Number: 2019108001** **Implementation Date:** 25-Apr-19 Related CR: 2019108001

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pseudomonal skin infection* | Approved Not as Requested | Proposed PT<br>*Pseudomonal skin infection* | 10082928 |
| HLT primary | *Pseudomonal infections* | | HLT primary<br>*Pseudomonal infections* | 10037132 |
| SOC primary | *Infections and infestations* | | SOC primary<br>*Infections and infestations* | 10021881 |
| | | | HLT secondary<br>*Skin and subcutaneous tissue bacterial infections* | 10040788 |
| | | | SOC secondary<br>*Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment: The proposal to add a new PT Pseudomonal skin infection to primary HLT Pseudomonal infections in SOC Infections and infestations and secondary HLT Skin and subcutaneous tissue infections NEC in SOC Skin and subcutaneous tissue disorders is approved but not as requested. PT Pseudomonal skin infection will be linked to a more specific secondary HLT Skin and subcutaneous tissue bacterial infections. Cutaneous manifestations of Pseudomonas infections may range from trivial cutaneous localized lesions such as those involving the nails, toe webs, or external auditory canal, to extensive manifestations such as ecthyma gangrenosum.

# Supplemental Update Report

**CR Number: 2019109001** **Implementation Date:** 24-Apr-19 Related CR: 2019109001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Heart ache* | Rejected | | |

MSSO Comment: The proposal to add a new term Heart ache is not approved. "Heart ache" is a considerably nonspecific colloquial expression that may relate to physical chest discomfort, or to emotional anguish, despondency, grief, etc., and is thus excessively ambiguous for inclusion as a MedDRA term. For your coding needs, please consider existing terms relevant to the reported information, such as, but not limited to, LLTs under PT Chest pain, PT Chest discomfort, PT Angina pectoris, or terms under HLT Emotional and mood disturbances NEC, or under HLT Mood alterations with depressive symptoms, etc.

**CR Number: 2019109002** **Implementation Date:** 26-Apr-19 Related CR: 2019109002

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Other corticoadrenal overactivity* | Approved as Requested | Proposed LLT | |
| From PT | *Hyperadrenalism* | | *Other corticoadrenal overactivity* | 10031867 Non-Current |
| To PT | *Hyperadrenocorticism* | | From PT | |
| | | | *Hyperadrenalism* | 10020562 |
| | | | To PT | |
| | | | *Hyperadrenocorticism* | 10020564 |

MSSO Comment: The proposal to move the LLT Other corticoadrenal overactivity from PT Hyperadrenalism to PT Hyperadrenocorticism is approved as requested. Although LLT Other corticoadrenal overactivity is a noncurrent term, the proposed move from PT Hyperadrenalism to PT Hyperadrenocorticism, is intended to reflect an improved hierarchical conceptual alignment of terms representing increased activity of the adrenal cortex.

# Supplemental Update Report

**CR Number: 2019111001** **Implementation Date:** 25-Apr-19 Related CR: 2019111001

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vestibular Paroxysmia* | Approved Not as Requested | Proposed PT | |
| | | | *Vestibular paroxysmia* | 10082929 |
| | | | HLT primary | |
| | | | *Inner ear disorders NEC* | 10023566 |
| | | | SOC primary | |
| | | | *Ear and labyrinth disorders* | 10013993 |
| | | | HLT secondary | |
| | | | *Auditory nerve disorders* | 10003788 |
| | | | SOC secondary | |
| | | | *Nervous system disorders* | 10029205 |

MSSO Comment: The proposal to add a new PT Vestibular Paroxysmia is approved but not as requested. Vestibular paroxysmia is the name given to the syndrome caused by vascular compression of the vestibulocochlear nerve. Chronic external pressure on this nerve from an adjacent blood vessel is thought to lead to demyelination, decreasing its firing threshold and making the nerve susceptible to excessive stimulation and causing repetitive vertigo attacks. Vestibular paroxysmia will be renamed according to MedDRA capitalization rules, and will be added as a PT, with a primary link to HLT Inner ear disorders NEC, and secondary links to HLT Auditory nerve disorders and HLT Cerebrovascular and spinal vascular disorders NEC.

**CR Number: 2019115002** **Implementation Date:** 25-Apr-19 Related CR: 2019111001

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vestibular paroxysmia* | Approved as Requested | Proposed PT | |
| To HLT | *Cerebrovascular and spinal vascular disorders NEC* | | *Vestibular paroxysmia* | 10082929 |
| | | | To HLT | |
| | | | *Cerebrovascular and spinal vascular disorders NEC* | 10008193 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019112001** **Implementation Date:** 25-Apr-19 Related CR: 2019112001

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Partial lung lobectomy* | Rejected | | |
| From PT | *Pulmonary resection* | | | |
| To PT | *Lung lobectomy* | | | |

MSSO Comment: The proposal to move the LLT Partial lung lobectomy from PT Pulmonary resection to PT Lung lobectomy is not approved. A lung partial lobectomy is a quasy-synonym of LLT Lung segmentectomy (or wedge resection), which is also under PT Pulmonary resection. In these procedures only a small piece of lung is removed. Thus, LLT Partial lung lobectomy is better aligned in current location, despite the common word lobectomy in its name with the PT Lung lobectomy.

**CR Number: 2019112002** **Implementation Date:** 25-Apr-19 Related CR: 2019112002

| Change Requested | Change Status of LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| LLT to change | *Lung function* | Rejected | | |
| Status | *non-current* | | | |

MSSO Comment: The proposal to change status of LLT Lung function to non-current is not approved. LLT Lung function, a MedDRA term since Version 2.1, is appropriately placed as a current term subordinate to PT Pulmonary function test, because the wording of this term represents an investigational concept, rather than a disorder concept. Therefore it would not be appropriate to change LLT Lung function to non-current status, or to move the LLT to SOC Respiratory, thoracic and mediastinal disorders. (LLT Lung function abnormal and LLT Lung function decreased, cited in the initial justification, are also investigational terms.) Please note that a significant number of other LLT and PT terms in SOC Investigations are not qualified with "test" because such terms inherently convey investigation concepts.

**CR Number: 2019112003** **Implementation Date:** 25-Apr-19 Related CR: 2019112003

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Liver tumor hemorrhage* | Rejected | | |

MSSO Comment: The proposal to add a new term Liver tumor hemorrhage is not approved. MedDRA refrains from adding new terms that are a combination of haemorrhagic tumours of specific pathological types, or occurring at particular anatomical sites. The requested term can be represented by split coding, for example, using LLT Liver tumour and LLT Tumour haemorrhage.

# Supplemental Update Report

**CR Number: 2019112004** **Implementation Date:** 25-Apr-19 Related CR: 2019112004

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Pulmonary interstitial shadow* | Rejected | | |
| From PT | *Chest X-ray abnormal* | | | |
| To PT | *Pulmonary disorder* | | | |

MSSO Comment: The proposal to move the LLT Pulmonary interstitial shadow from PT Chest X-ray abnormal to PT Pulmonary disorder is not approved. LLT Pulmonary interstitial shadow is appropriately placed as a sub-concept of PT Chest X-ray abnormal, because it is a description of an abnormal diagnostic imaging finding, rather than the name of a disorder or a pathological condition, per se.

**CR Number: 2019112005** **Implementation Date:** 26-Apr-19 Related CR: 2019112005

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Cardiovascular somatic symptom disorder* | Approved Not as Requested | Proposed PT | |
| From HLT | *Somatic symptom disorders* | | *Cardiovascular somatic symptom disorder* | 10078078 |
| To HLT | *Cardiac disorders NEC* | | Old Primary SOC | |
| | | | *Psychiatric disorders* | 10037175 |
| | | | New Primary SOC | |
| | | | *Cardiac disorders* | 10007541 |

MSSO Comment: The proposal to move the PT Cardiovascular somatic symptom disorder from HLT Somatic symptom disorders to HLT Cardiac disorders NEC is approved but not as requested. The primary SOC for PT Cardiovascular somatic symptom disorder will be changed from SOC Psychiatric disorders to SOC Cardiac disorders to have it represented at the site of manifestation.

**CR Number: 2019112006** **Implementation Date:** 26-Apr-19 Related CR: 2019112006

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Chronic idiopathic pain syndrome* | Approved Not as Requested | Proposed PT | |
| From HLT | *Somatic symptom disorders* | | *Chronic idiopathic pain syndrome* | 10078098 |
| To HLT | *Sensory abnormalities NEC* | | Old Primary SOC | |
| | | | *Psychiatric disorders* | 10037175 |
| | | | New Primary SOC | |
| | | | *Nervous system disorders* | 10029205 |

MSSO Comment: The proposal to move the PT Chronic idiopathic pain syndrome from HLT Somatic symptom disorders to HLT Sensory abnormalities NEC is approved but not as requested. The primary SOC for PT Chronic idiopathic pain syndrome will be changed from SOC Psychiatric disorders to SOC Nervous system disorders to have it represented at the site of manifestation.

# Supplemental Update Report

**CR Number: 2019112007** **Implementation Date:** 26-Apr-19 Related CR: 2019112007

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Cutaneous somatic symptom disorder* | Approved Not as Requested | Proposed PT | |
| From HLT | *Somatic symptom disorders* | | *Cutaneous somatic symptom disorder* | 10078081 |
| To HLT | *Dermatitis and eczema* | | Old Primary SOC | |
| | | | *Psychiatric disorders* | 10037175 |
| | | | New Primary SOC | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment: The proposal to move the PT Cutaneous somatic symptom disorder from HLT Somatic symptom disorders to HLT Dermatitis and eczema is approved but not as requested. The primary SOC for PT Cutaneous somatic symptom disorder will be changed from SOC Psychiatric disorders to SOC Skin and subcutaneous tissue disorders to have it represented at the site of manifestation.

**CR Number: 2019112008** **Implementation Date:** 26-Apr-19 Related CR: 2019112008

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Gastrointestinal somatic symptom disorder* | Approved Not as Requested | Proposed PT | |
| From HLT | *Somatic symptom disorders* | | *Gastrointestinal somatic symptom disorder* | 10078079 |
| To HLT | *Gastrointestinal signs and symptoms NEC* | | Old Primary SOC | |
| | | | *Psychiatric disorders* | 10037175 |
| | | | New Primary SOC | |
| | | | *Gastrointestinal disorders* | 10017947 |

MSSO Comment: The proposal to move the PT Gastrointestinal somatic symptom disorder from HLT Somatic symptom disorders to HLT Gastrointestinal signs and symptoms NEC is approved but not as requested. The primary SOC for PT Gastrointestinal somatic symptom disorder will be changed from SOC Psychiatric disorders to SOC Gastrointestinal disorders to have it represented at the site of manifestation.

# Supplemental Update Report

**CR Number: 2019112009** **Implementation Date:** 26-Apr-19 Related CR: 2019112009

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Neurologic somatic symptom disorder* | Approved Not as Requested | Proposed PT | |
| From HLT | *Somatic symptom disorders* | | *Neurologic somatic symptom disorder* | 10078080 |
| To HLT | *Paralysis and paresis (excl cranial nerve)* | | Old Primary SOC | |
| | | | *Psychiatric disorders* | 10037175 |
| | | | New Primary SOC | |
| | | | *Nervous system disorders* | 10029205 |

MSSO Comment: The proposal to move the PT Neurologic somatic symptom disorder from HLT Somatic symptom disorders to HLT Paralysis and paresis (excl cranial nerve) is approved but not as requested. The primary SOC for PT Neurologic somatic symptom disorder will be changed from SOC Psychiatric disorders to SOC Nervous system disorders to have it represented at the site of manifestation. In a related change, PT Neurologic somatic symptom disorder will be moved from HLT Paralysis and paresis (excl cranial nerve) to HLT Neurological signs and symptoms NEC for better alignment. Furthermore, PT Psychogenic seizure will be linked to HLT Seizures and seizure disorders NEC. PT Psychogenic seizure will then have its primary SOC reassigned from SOC Psychiatric disorders to SOC Nervous system disorders. In addition, PT Somatic symptom disorder of pregnancy will be linked to HLT Maternal complications of pregnancy NEC. Then PT Somatic symptom disorder of pregnancy will have its primary SOC reassigned from SOC Psychiatric disorders to SOC Pregnancy, puerperium and perinatal conditions.

**CR Number: 2019116006** **Implementation Date:** 26-Apr-19 Related CR: 2019112009

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Neurologic somatic symptom disorder* | Approved as Requested | Proposed PT | |
| From HLT | *Paralysis and paresis (excl cranial nerve)* | | *Neurologic somatic symptom disorder* | 10078080 |
| To HLT | *Neurological signs and symptoms NEC* | | From HLT | |
| | | | *Paralysis and paresis (excl cranial nerve)* | 10033800 |
| | | | To HLT | |
| | | | *Neurological signs and symptoms NEC* | 10029306 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019116007** **Implementation Date:** 26-Apr-19 Related CR: 2019112009

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Psychogenic seizure* | Approved as Requested | Proposed PT | |
| | | | *Psychogenic seizure* | 10058895 |
| To HLT | *Seizures and seizure disorders NEC* | | To HLT | |
| | | | *Seizures and seizure disorders NEC* | 10039912 |

MSSO Comment:

**CR Number: 2019116008** **Implementation Date:** 26-Apr-19 Related CR: 2019112009

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Psychogenic seizure* | Approved as Requested | Proposed PT | |
| | | | *Psychogenic seizure* | 10058895 |
| Old Primary SOC | *Psychiatric disorders* | | Old Primary SOC | |
| | | | *Psychiatric disorders* | 10037175 |
| New Primary SOC | *Nervous system disorders* | | New Primary SOC | |
| | | | *Nervous system disorders* | 10029205 |

MSSO Comment:

**CR Number: 2019116009** **Implementation Date:** 26-Apr-19 Related CR: 2019112009

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Somatic symptom disorder of pregnancy* | Approved as Requested | Proposed PT | |
| | | | *Somatic symptom disorder of pregnancy* | 10078085 |
| To HLT | *Maternal complications of pregnancy NEC* | | To HLT | |
| | | | *Maternal complications of pregnancy NEC* | 10026909 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019116010** **Implementation Date:** 26-Apr-19 Related CR: 2019112009

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Somatic symptom disorder of pregnancy* | Approved as Requested | Proposed PT | |
| Old Primary SOC | *Psychiatric disorders* | | *Somatic symptom disorder of pregnancy* | 10078085 |
| New Primary SOC | *Pregnancy, puerperium and perinatal conditions* | | Old Primary SOC | |
| | | | *Psychiatric disorders* | 10037175 |
| | | | New Primary SOC | |
| | | | *Pregnancy, puerperium and perinatal conditions* | 10036585 |

MSSO Comment:

**CR Number: 2019112010** **Implementation Date:** 26-Apr-19 Related CR: 2019112010

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Polydipsia psychogenic* | Approved Not as Requested | Proposed PT | |
| From HLT | *Somatic symptom disorders* | | *Polydipsia psychogenic* | 10036069 |
| To HLT | *Fluid intake increased* | | Old Primary SOC | |
| | | | *Psychiatric disorders* | 10037175 |
| | | | New Primary SOC | |
| | | | *Metabolism and nutrition disorders* | 10027433 |

MSSO Comment: The proposal to move the PT Polydipsia psychogenic from HLT Somatic symptom disorders to HLT Fluid intake increased is approved but not as requested. The primary SOC for PT Polydipsia psychogenic will be changed from SOC Psychiatric disorders to SOC Metabolism and nutrition disorders to have it represented at the site of manifestation.

# Supplemental Update Report

**CR Number: 2019112011** **Implementation Date:** 26-Apr-19 Related CR: 2019112011

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Psychogenic dysuria* | Approved Not as Requested | Proposed PT | |
| From HLT | *Somatic symptom disorders* | | *Psychogenic dysuria* | 10037195 |
| To HLT | *Bladder and urethral symptoms* | | Old Primary SOC | |
| | | | *Psychiatric disorders* | 10037175 |
| | | | New Primary SOC | |
| | | | *Renal and urinary disorders* | 10038359 |

MSSO Comment: The proposal to move the PT Psychogenic dysuria from HLT Somatic symptom disorders to HLT Bladder and urethral symptoms is approved but not as requested. The primary SOC for PT Psychogenic dysuria will be changed from SOC Psychiatric disorders to SOC Renal and urinary disorders to have it represented at the site of manifestation.

**CR Number: 2019112012** **Implementation Date:** 26-Apr-19 Related CR: 2019112012

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Psychogenic movement disorder* | Approved Not as Requested | Proposed PT | |
| From HLT | *Somatic symptom disorders* | | *Psychogenic movement disorder* | 10072376 |
| To HLT | *Dyskinesias and movement disorders NEC* | | Old Primary SOC | |
| | | | *Psychiatric disorders* | 10037175 |
| | | | New Primary SOC | |
| | | | *Nervous system disorders* | 10029205 |

MSSO Comment: The proposal to move the PT Psychogenic movement disorder from HLT Somatic symptom disorders to HLT Dyskinesias and movement disorders NEC is approved but not as requested. The primary SOC for PT Psychogenic movement disorder will be changed from SOC Psychiatric disorders to SOC Nervous system disorders to have it represented at the site of manifestation.

# Supplemental Update Report

**CR Number: 2019112013** **Implementation Date:** 26-Apr-19 Related CR: 2019112013

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Psychogenic respiratory distress* | Approved Not as Requested | Proposed PT | |
| From HLT | *Somatic symptom disorders* | | *Psychogenic respiratory distress* | 10072630 |
| To HLT | *Breathing abnormalities* | | Old Primary SOC | |
| | | | *Psychiatric disorders* | 10037175 |
| | | | New Primary SOC | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |

MSSO Comment: The proposal to move the PT Psychogenic respiratory distress from HLT Somatic symptom disorders to HLT Breathing abnormalities is approved but not as requested. The primary SOC for PT Psychogenic respiratory distress will be changed from SOC Psychiatric disorders to SOC Respiratory, thoracic and mediastinal disorders to have it represented at the site of manifestation.

**CR Number: 2019112014** **Implementation Date:** 26-Apr-19 Related CR: 2019112014

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Psychogenic tremor* | Approved Not as Requested | Proposed PT | |
| From HLT | *Somatic symptom disorders* | | *Psychogenic tremor* | 10072377 |
| To HLT | *Tremor (excl congenital)* | | Old Primary SOC | |
| | | | *Psychiatric disorders* | 10037175 |
| | | | New Primary SOC | |
| | | | *Nervous system disorders* | 10029205 |

MSSO Comment: The proposal to move the PT Psychogenic tremor from HLT Somatic symptom disorders to HLT Tremor (excl congenital) is approved but not as requested. The primary SOC for PT Psychogenic tremor will be changed from SOC Psychiatric disorders to SOC Nervous system disorders to have it represented at the site of manifestation.

# Supplemental Update Report

**CR Number: 2019112015** **Implementation Date:** 26-Apr-19 Related CR: 2019112015

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Somatoform genitourinary disorder* | Approved Not as Requested | Proposed PT | |
| From HLT | *Somatic symptom disorders* | | *Somatoform genitourinary disorder* | 10077253 |
| To HLT | *Genital and urinary tract disorders NEC* | | Old Primary SOC | |
| | | | *Psychiatric disorders* | 10037175 |
| | | | New Primary SOC | |
| | | | *Renal and urinary disorders* | 10038359 |

MSSO Comment: The proposal to move the PT Somatoform genitourinary disorder from HLT Somatic symptom disorders to HLT Genital and urinary tract disorders NEC is approved but not as requested. The primary SOC for PT Somatoform genitourinary disorder will be changed from SOC Psychiatric disorders to SOC Renal and urinary disorders to have it represented at the site of manifestation.

**CR Number: 2019112016** **Implementation Date:** 26-Apr-19 Related CR: 2019112016

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Torticollis psychogenic* | Approved Not as Requested | Proposed PT | |
| From HLT | *Somatic symptom disorders* | | *Torticollis psychogenic* | 10044076 |
| To HLT | *Muscle tone abnormalities* | | Old Primary SOC | |
| | | | *Psychiatric disorders* | 10037175 |
| | | | New Primary SOC | |
| | | | *Musculoskeletal and connective tissue disorders* | 10028395 |

MSSO Comment: The proposal to move the PT Torticollis psychogenic from HLT Somatic symptom disorders to HLT Muscle tone abnormalities is approved but not as requested. The primary SOC for PT Torticollis psychogenic will be changed from SOC Psychiatric disorders to SOC Musculoskeletal and connective tissue disorders to have it represented at the site of manifestation.

# Supplemental Update Report

**CR Number: 2019112017** **Implementation Date:** 26-Apr-19 Related CR: 2019112017

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vomiting psychogenic* | Approved Not as Requested | Proposed PT | |
| From HLT | *Somatic symptom disorders* | | *Vomiting psychogenic* | 10047709 |
| To HLT | *Nausea and vomiting symptoms* | | Old Primary SOC | |
| | | | *Psychiatric disorders* | 10037175 |
| | | | New Primary SOC | |
| | | | *Gastrointestinal disorders* | 10017947 |

MSSO Comment: The proposal to move the PT Vomiting psychogenic from HLT Somatic symptom disorders to HLT Nausea and vomiting symptoms is approved but not as requested. The primary SOC for PT Vomiting psychogenic will be changed from SOC Psychiatric disorders to SOC Gastrointestinal disorders to have it represented at the site of manifestation.

**CR Number: 2019113001** **Implementation Date:** 26-Apr-19 Related CR: 2019113001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Dacryocystocele* | Approved as Requested | Proposed PT | |
| | | | *Dacryocystocele* | 10082947 Current |
| | | | HLT primary | |
| | | | *Lacrimal system disorders congenital* | 10023638 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary | |
| | | | *Lid, lash and lacrimal structural disorders* | 10024446 |
| | | | SOC secondary | |
| | | | *Eye disorders* | 10015919 |

MSSO Comment: The proposal to add a new term Dacryocystocele is approved as requested. Congenital dacryocystocele occurs when the nasolacrimal duct is obstructed and amniotic fluid or mucus is trapped in the tear sac. Dacryocystocele will be added as a new PT to primary HLT Lacrimal system disorders congenital and secondary HLT Lid, lash and lacrimal structural disorders. In a related change, contrary to its congenital counterpart, PT Dacryocystocele acquired will be added and linked to HLT Lid, lash and lacrimal structural disorders.

# Supplemental Update Report

**CR Number: 2019115014** **Implementation Date:** 26-Apr-19 Related CR: 2019113001

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Dacryocystocele acquired* | Approved as Requested | Proposed PT | |
| HLT primary | *Lid, lash and lacrimal structural disorders* | | *Dacryocystocele acquired* | 10082948 Current |
| SOC primary | *Eye disorders* | | HLT primary | |
| | | | *Lid, lash and lacrimal structural disorders* | 10024446 |
| | | | SOC primary | |
| | | | *Eye disorders* | 10015919 |

MSSO Comment:

**CR Number: 2019113002** **Implementation Date:** 25-Apr-19 Related CR: 2019113002

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Vascular access site hypoesthesia* | Approved Not as Requested | Proposed PT | |
| To PT | *Vascular access site complication* | | *Vascular access site hypoaesthesia* | 10082931 |
| | | | HLT primary | |
| | | | *Cardiac and vascular procedural complications* | 10007602 |
| | | | SOC primary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |
| | | | HLT secondary | |
| | | | *Complications associated with device NEC* | 10069785 |
| | | | SOC secondary | |
| | | | *General disorders and administration site conditions* | 10018065 |

MSSO Comment: The proposal to add a new LLT Vascular access site hypoesthesia to PT Vascular access site complication is approved but not as requested. Vascular access site hypoaesthesia will be added in line with similar vascular access site terms as PT under primary HLT Cardiac and vascular procedural complications, secondary HLT Complications associated with device NEC, secondary HLT Paraesthesias and dysaesthesias and secondary HLT Non-site specific vascular disorders NEC. In addition, American English spelling counterpart LLT Vascular access site hypoesthesia will be added to PT Vascular access site hypoaesthesia.

# Supplemental Update Report

**CR Number: 2019115003** **Implementation Date:** 25-Apr-19 Related CR: 2019113002

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vascular access site hypoaesthesia* | Approved as Requested | Proposed PT | |
| | | | *Vascular access site hypoaesthesia* | 10082931 |
| To HLT | *Non-site specific vascular disorders NEC* | | To HLT | |
| | | | *Non-site specific vascular disorders NEC* | 10047067 |

MSSO Comment:

**CR Number: 2019115004** **Implementation Date:** 25-Apr-19 Related CR: 2019113002

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vascular access site hypoaesthesia* | Approved as Requested | Proposed PT | |
| | | | *Vascular access site hypoaesthesia* | 10082931 |
| To HLT | *Paraesthesias and dysaesthesias* | | To HLT | |
| | | | *Paraesthesias and dysaesthesias* | 10033788 |

MSSO Comment:

**CR Number: 2019115005** **Implementation Date:** 25-Apr-19 Related CR: 2019113002

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Vascular access site hypoesthesia* | Approved as Requested | Proposed LLT | |
| | | | *Vascular access site hypoesthesia* | 10082932 Current |
| To PT | *Vascular access site hypoaesthesia* | | To PT | |
| | | | *Vascular access site hypoaesthesia* | 10082931 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019113003** **Implementation Date:** 25-Apr-19 Related CR: 2019113003

| Change Requested | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|
| Add a New Term | | | |
| Proposed Term *Pathological tooth fracture* | Approved as Requested | Proposed PT | |
| | | *Pathological tooth fracture* | 10082930 |
| | | HLT primary | |
| | | *Dental disorders NEC* | 10044037 |
| | | SOC primary | |
| | | *Gastrointestinal disorders* | 10017947 |
| | | HLT secondary | |
| | | *Site specific injuries NEC* | 10040759 |
| | | SOC secondary | |
| | | *Injury, poisoning and procedural complications* | 10022117 |

MSSO Comment: The proposal to add a new term Pathological tooth fracture is approved as requested. Pathological tooth fracture may result from a mild injury of an already diseased tooth. A clear indication of a fracture in the tooth is the early signs of damage on the pulp. A cracked tooth is not a disease, but is instead a factor that can facilitate periodontal and pulpal disease which may consequently lead to bio-mechanical dental problems such as tooth fractures. Pathological tooth fracture will be added as a new PT to primary HLT Dental disorders NEC and secondary HLT Site specific injuries NEC.

**CR Number: 2019113004** **Implementation Date:** 25-Apr-19 Related CR: 2019113004

| Change Requested | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|
| Add a New PT | | | |
| Proposed PT *3-Dimensional vasculography* | Approved as Requested | Proposed PT | |
| | | *3-Dimensional vasculography* | 10082933 |
| | | HLT primary | |
| | | *Cardiac imaging procedures* | 10007574 |
| | | SOC primary | |
| | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT 3-Dimensional vasculography is approved as requested. 3-Dimensional vasculography is a non-invasive ultrasonic technique for early identification and management of life threatening cardiovascular diseases, most commonly cardiac. It provides a detailed analysis of cardiovascular haemodynamics, electrodynamics and pulmony pathology, usually creating a three dimensional representation of the heart from a circulatory perspective. 3-Dimensional vasculography will be added as a PT to HLT Cardiac imaging procedures.

# Supplemental Update Report

**CR Number: 2019113005** **Implementation Date:** 25-Apr-19 Related CR: 2019113005

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Computerised tomogram pancreas* | Approved as Requested | Proposed PT | |
| | | | *Computerised tomogram pancreas* | 10082934 |
| HLT primary | *Gastrointestinal and abdominal imaging procedures* | | HLT primary | |
| | | | *Gastrointestinal and abdominal imaging procedures* | 10017963 |
| SOC primary | *Investigations* | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Computerised tomogram pancreas to primary HLT Gastrointestinal and abdominal imaging procedures in SOC Investigations is approved as requested. Computerised tomography (CT) scans of the pancreas can provide more detailed information about the pancreas than standard X-rays of the abdomen. In a related change, American English spelling counterpart LLT Computerized tomogram pancreas will be added to new PT Computerised tomogram pancreas. Also, the commonly used abbreviated synonym LLT CT scan pancreas will be added to new PT Computerised tomogram pancreas. Furthermore, the two qualified PTs, PT Computerised tomogram pancreas normal and PT Computerised tomogram pancreas abnormal will be added to HLT Gastrointestinal and abdominal imaging procedures. In addition, the American English spelling, LLT Computerized tomogram pancreas normal will be added to new PT Computerised tomogram pancreas normal. Also, the American English spelling, LLT Computerized tomogram pancreas abnormal to new PT Computerised tomogram pancreas abnormal.

**CR Number: 2019115006** **Implementation Date:** 25-Apr-19 Related CR: 2019113005

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Computerized tomogram pancreas* | Approved as Requested | Proposed LLT | |
| | | | *Computerized tomogram pancreas* | 10082937 Current |
| To PT | *Computerised tomogram pancreas* | | To PT | |
| | | | *Computerised tomogram pancreas* | 10082934 |

MSSO Comment:

**CR Number: 2019115007** **Implementation Date:** 25-Apr-19 Related CR: 2019113005

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *CT scan pancreas* | Approved as Requested | Proposed LLT | |
| | | | *CT scan pancreas* | 10082938 Current |
| To PT | *Computerised tomogram pancreas* | | To PT | |
| | | | *Computerised tomogram pancreas* | 10082934 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019115008** **Implementation Date:** 25-Apr-19 Related CR: 2019113005

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Computerised tomogram pancreas normal* | Approved as Requested | Proposed PT<br>*Computerised tomogram pancreas normal* | 10082935 |
| HLT primary | *Gastrointestinal and abdominal imaging procedures* | | HLT primary<br>*Gastrointestinal and abdominal imaging procedures* | 10017963 |
| SOC primary | *Investigations* | | SOC primary<br>*Investigations* | 10022891 |

MSSO Comment:

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**CR Number: 2019115009** **Implementation Date:** 25-Apr-19 Related CR: 2019113005

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Computerised tomogram pancreas abnormal* | Approved as Requested | Proposed PT<br>*Computerised tomogram pancreas abnormal* | 10082936 |
| HLT primary | *Gastrointestinal and abdominal imaging procedures* | | HLT primary<br>*Gastrointestinal and abdominal imaging procedures* | 10017963 |
| SOC primary | *Investigations* | | SOC primary<br>*Investigations* | 10022891 |

MSSO Comment:

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**CR Number: 2019115010** **Implementation Date:** 25-Apr-19 Related CR: 2019113005

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Computerized tomogram pancreas normal* | Approved as Requested | Proposed LLT<br>*Computerized tomogram pancreas normal* | 10082939 Current |
| To PT | *Computerised tomogram pancreas normal* | | To PT<br>*Computerised tomogram pancreas normal* | 10082935 |

MSSO Comment:

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# Supplemental Update Report

**CR Number: 2019115011** **Implementation Date:** 25-Apr-19 Related CR: 2019113005

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Computerized tomogram pancreas abnormal* | Approved as Requested | Proposed LLT | | |
| To PT | *Computerised tomogram pancreas abnormal* | | *Computerized tomogram pancreas abnormal* | 10082940 | Current |
| | | | To PT | | |
| | | | *Computerised tomogram pancreas abnormal* | 10082936 | |

MSSO Comment:

**CR Number: 2019113006** **Implementation Date:** 25-Apr-19 Related CR: 2019113006

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Paranasal sinus hypoplasia* | Approved as Requested | Proposed PT | |
| HLT primary | *Nasal disorders congenital* | | *Paranasal sinus hypoplasia* | 10082941 |
| SOC primary | *Congenital, familial and genetic disorders* | | HLT primary | |
| | | | *Nasal disorders congenital* | 10028739 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary | |
| | | | *Paranasal sinus disorders (excl infections and neoplasms)* | 10040743 |
| | | | SOC secondary | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |

MSSO Comment: The proposal to add a new PT Paranasal sinus hypoplasia to primary HLT Nasal disorders congenital in SOC Congenital, familial and genetic disorders is approved as requested. Hypoplasia of paranasal sinuses is rather rare. It can lead to problems in diagnosis, as they are commonly misdiagnosed as infections or neoplasms involving sinuses. Hypoplasia of frontal and sphenoid sinuses appear to have been more frequently reported than maxillary sinus hypoplasia. PT Paranasal sinus hypoplasia will also be linked to secondary HLT Paranasal sinus disorders (excl infections and neoplasms).

# Supplemental Update Report

**CR Number: 2019113007** **Implementation Date:** 26-Apr-19 Related CR: 2019113007

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Biopsy site itching/pruritus* | Approved Not as Requested | Proposed LLT | |
| | | | *Biopsy site itching* | 10082945 Current |
| | | | To PT | |
| | | | *Post procedural pruritus* | 10082943 |

MSSO Comment: The proposal to add a new term Biopsy site itching/pruritus is approved but not as requested. Frequent complications to skin biopsies include bleeding at the biopsy site, hematoma, or infection. Some patients may experience a hypersensitivity reaction, with evidence of erythema, pruritus, or vesicles. The requested term will be modified to Biopsy site itching and added as an LLT to PT Post procedural pruritus. In a related change, Post procedural pruritus will be added as a PT to primary HLT Non-site specific procedural complications and secondary HLT Pruritus NEC.

**CR Number: 2019116003** **Implementation Date:** 26-Apr-19 Related CR: 2019113007

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Post procedural pruritus* | Approved as Requested | Proposed PT | |
| HLT primary | *Non-site specific procedural complications* | | *Post procedural pruritus* | 10082943 |
| SOC primary | *Injury, poisoning and procedural complications* | | HLT primary | |
| | | | *Non-site specific procedural complications* | 10029559 |
| | | | SOC primary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |
| | | | HLT secondary | |
| | | | *Pruritus NEC* | 10049293 |
| | | | SOC secondary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019113008** **Implementation Date:** 26-Apr-19 Related CR: 2019113008

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Biopsy site redness/erythema* | Approved Not as Requested | Proposed LLT | |
| | | | *Biospy site redness* | 10082946 Current |
| | | | To PT | |
| | | | *Post procedural erythema* | 10082944 |

MSSO Comment: The proposal to add a new term Biopsy site redness/erythema is approved but not as requested. Frequent complications to skin biopsies include bleeding at the biopsy site, hematoma, or infection. Some patients may experience a hypersensitivity reaction, with evidence of erythema, pruritus, or vesicles. The requested term will be modified to Biospy site redness and added as an LLT to PT Post procedural erythema. In a related change, Post procedural erythema will be added as a PT to primary HLT Non-site specific procedural complications and secondary HLT Erythemas.

**CR Number: 2019116004** **Implementation Date:** 26-Apr-19 Related CR: 2019113008

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Post procedural erythema* | Approved as Requested | Proposed PT | |
| HLT primary | *Non-site specific procedural complications* | | *Post procedural erythema* | 10082944 |
| SOC primary | *Injury, poisoning and procedural complications* | | HLT primary | |
| | | | *Non-site specific procedural complications* | 10029559 |
| | | | SOC primary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |
| | | | HLT secondary | |
| | | | *Erythemas* | 10015151 |
| | | | SOC secondary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019115001** **Implementation Date:** 10-Jun-19 Related CR: 2019115001

| Change Requested | Update SMQ_description | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed SMQ | *Extravasation events (injections, infusions and implants) (SMQ)* | Approved as Requested | Proposed SMQ<br>*Extravasation events (injections, infusions and implants) (SMQ)* | 20000136 |
| SMQ description | *See SMQ description* | | SMQ description<br>*See SMQ description* | |

MSSO Comment: The proposal to update the description of the Extravasation events (injections, infusions and implants) (SMQ) is approved as requested. The description in the SMQ list file for SMQ Extravasation events (injections, infusions and implants) has been updated to remove exclusion criteria not relevant to the scope of the SMQ including a reference to a "PT Inappropriate device irritation of tissue" which is not a MedDRA term.

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**CR Number: 2019115012** **Implementation Date:** 10-May-19 Related CR: 2019115012

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *IgA vasculitis* | Approved After Suspension | Proposed LLT<br>*IgA vasculitis* | 10082959 Current |
| | | | To PT<br>*Henoch-Schonlein purpura* | 10019617 |

MSSO Comment: The proposal to add a new term IgA vasculitis is approved as requested after suspension. Immunoglobulin A–associated vasculitis (synonym of Henoch-Schönlein purpura) is vasculitis that affects primarily small vessels. It occurs most often in children. Common manifestations include palpable purpura, arthralgias, gastrointestinal (GI) symptoms and signs, and glomerulonephritis. IgA vasculitis will be added as a synonym LLT to PT Henoch-Schonlein purpura. In a related change, LLT Immunoglobulin A–associated vasculitis will also be added as a synonym LLT to PT Henoch-Schonlein purpura.

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**CR Number: 2019130005** **Implementation Date:** 10-May-19 Related CR: 2019115012

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Immunoglobulin A-associated vasculitis* | Approved as Requested | Proposed LLT<br>*Immunoglobulin A-associated vasculitis* | 10082960 Current |
| To PT | *Henoch-Schonlein purpura* | | To PT<br>*Henoch-Schonlein purpura* | 10019617 |

MSSO Comment:

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# Supplemental Update Report

**CR Number: 2019115013** **Implementation Date:** 10-May-19 Related CR: 2019115013

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Intraductal papillary mucinous neoplasm of pancreas* | Rejected After Suspension | | |
| HLT primary | *Gastrointestinal neoplasms malignancy unspecified NEC* | | | |
| SOC primary | *Neoplasms benign, malignant and unspecified (incl cysts and polyps)* | | | |

MSSO Comment: The proposal to add a new PT Intraductal papillary mucinous neoplasm of pancreas to primary HLT Gastrointestinal neoplasms malignancy unspecified NEC in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) and secondary HLT Pancreatic neoplasms in SOC Gastrointestinal disorders is not approved after suspension. Concept exists in PT Intraductal papillary mucinous neoplasm. WHO histological classification of tumors of the exocrine pancreas classifies it as benign. PT Intraductal papillary-mucinous carcinoma of pancreas represents the malignant evolution of this type of tumor. In a related change, however, the HLT in the second SOC for PT Intraductal papillary mucinous neoplasm will be changed from HLT Benign neoplasms gastrointestinal (excl oral cavity) to HLT Pancreatic neoplasms for better alignment and to be grouped under the same HLT as PT Intraductal papillary-mucinous carcinoma of pancreas.

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**CR Number: 2019130006** **Implementation Date:** 10-May-19 Related CR: 2019115013

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Intraductal papillary mucinous neoplasm* | Approved as Requested | Proposed PT | |
| From HLT | *Benign neoplasms gastrointestinal (excl oral cavity)* | | *Intraductal papillary mucinous neoplasm* | 10070999 |
| To HLT | *Pancreatic neoplasms* | | From HLT | |
| | | | *Benign neoplasms gastrointestinal (excl oral cavity)* | 10017988 |
| | | | To HLT | |
| | | | *Pancreatic neoplasms* | 10033632 |

MSSO Comment:

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**CR Number: 2019115015** **Implementation Date:** 10-May-19 Related CR: 2019115015

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *NECK TENDERNESS* | Rejected After Suspension | | |

MSSO Comment: The proposal to add a new LLT NECK TENDERNESS is not approved after suspension. MedDRA cannot provide a specific term pertaining to tenderness of every possible anatomical location. Consider existing PT Tenderness and PT Neck pain (and its LLTs) for your coding needs.

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# Supplemental Update Report

**CR Number: 2019116001** **Implementation Date:** 10-May-19 Related CR: 2019116001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Computerised tomogram neck* | Approved After Suspension | Proposed PT | |
| | | | *Computerised tomogram neck* | 10082961 |
| | | | HLT primary | |
| | | | *Musculoskeletal and soft tissue imaging procedures* | 10028386 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new term Computerised tomogram neck is approved as requested after suspension. A computerised tomogram (CT) of the neck can provide more detailed information than standard X-rays. A CT scan of the neck, produces images of the soft tissues and organs of the neck, including, for example, the muscles, throat, tonsils, adenoids, airways, thyroid, and other glands, and blood vessels and upper spinal cord. Computerised tomogram neck will be added as a PT to HLT Musculoskeletal and soft tissue imaging procedures. In a related change, American spelling counterpart LLT Computerized tomogram neck, and the commonly used abbreviated synonym LLT CT scan neck, will be both added to new PT Computerised tomogram neck.

**CR Number: 2019130007** **Implementation Date:** 10-May-19 Related CR: 2019116001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Computerized tomogram neck* | Approved as Requested | Proposed LLT | |
| To PT | *Computerised tomogram neck* | | *Computerized tomogram neck* | 10082962 Current |
| | | | To PT | |
| | | | *Computerised tomogram neck* | 10082961 |

MSSO Comment:

**CR Number: 2019130008** **Implementation Date:** 10-May-19 Related CR: 2019116001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *CT scan neck* | Approved as Requested | Proposed LLT | |
| To PT | *Computerised tomogram neck* | | *CT scan neck* | 10082963 Current |
| | | | To PT | |
| | | | *Computerised tomogram neck* | 10082961 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019116002** **Implementation Date:** 10-May-19 Related CR: 2019116002

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *High-sensitivity C-reactive protein* | Approved After Suspension | Proposed LLT<br>*High-sensitivity C-reactive protein*<br>To PT<br>*C-reactive protein* | <br>10082964 Current<br><br>10006824 |

MSSO Comment: The proposal to add a new term High-sensitivity C-reactive protein is approved as requested after suspension. High-sensitivity C-reactive protein is a marker of inflammation that predicts incident myocardial infarction, stroke, peripheral arterial disease, and sudden cardiac death among healthy individuals with no history of cardiovascular disease, and recurrent events and death in patients with acute or stable coronary syndromes. High-sensitivity C-reactive protein will be added as a sub-concept LLT to PT C-reactive protein.

**CR Number: 2019116005** **Implementation Date:** 10-May-19 Related CR: 2019116005

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Carinaplasty* | Approved After Suspension | Proposed PT<br>*Carinaplasty*<br>HLT primary<br>*Tracheal therapeutic procedures*<br>SOC primary<br>*Surgical and medical procedures* | <br>10082965<br><br>10044297<br><br>10042613 |

MSSO Comment: The proposal to add a new term Carinaplasty is approved as requested after suspension. Carinaplasty, a reconstruction of the tracheal carina, is performed following procedures such as pneumonectomy or resection of tracheobronchial angle tumors to restore the anatomical integrity of the trachea. Carinaplasty will be added as a PT to HLT Tracheal therapeutic procedures.

**CR Number: 2019116011** **Implementation Date:** 20-May-19 Related CR: 2019116011

| Change Requested | Change Status of LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| LLT to change | *Other and unspecified nonspecific immunological findings* | Approved After Suspension | LLT to change<br>*Other and unspecified nonspecific immunological findings*<br>Status<br>*non-current* | <br>10031608 Non-Current |
| Status | *non-current* | | | |

MSSO Comment: The proposal to change status of LLT Other and unspecified nonspecific immunological findings to non-current is approved as requested after suspension. LLT Other and unspecified nonspecific immunological findings is a rather ambiguous term that does not represent a clear meaning, and therefore warrants a change of status from current to non-current.

# Supplemental Update Report

**CR Number: 2019116012** **Implementation Date:** 10-May-19 Related CR: 2019116012

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Dorsal root ganglion block* | Approved After Suspension | Proposed PT | |
| HLT primary | *Spine and spinal cord therapeutic procedures* | | *Dorsal root ganglion block* | 10082966 |
| SOC primary | *Surgical and medical procedures* | | HLT primary | |
| | | | *Spine and spinal cord therapeutic procedures* | 10041590 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment: The proposal to add a new PT Dorsal root ganglion block to primary HLT Spine and spinal cord therapeutic procedures in SOC Surgical and medical procedures is approved as requested after suspension. A dorsal root ganglion block is an injection of local anaesthetic and steroid around the dorsal root ganglion. Dorsal root ganglion blocks are used mainly for localised radicular pain (sciatic leg or arm pain) where simpler measures have not helped. This procedure is also used as an adjunct in predicting the outcome of decompressive surgery in people with pain as a consequence of potential lumbosacral nerve root compression.

**CR Number: 2019116013** **Implementation Date:** 10-May-19 Related CR: 2019116013

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Product dosage form identification issue* | Approved After Suspension | Proposed LLT | |
| To PT | *Product dosage form issue* | | *Product dosage form identification issue* | 10082967 Current |
| | | | To PT | |
| | | | *Product dosage form issue* | 10069232 |

MSSO Comment: The proposal to add a new LLT Product dosage form identification issue to PT Product dosage form issue is approved as requested after suspension. Product dosage form identification issue will be added as an LLT to PT Product dosage form issue to represent problems in the identification of the physical form in which a drug is produced for administration to recipient (tablets, capsules, cream etc.).

**CR Number: 2019119001** **Implementation Date:** 10-May-19 Related CR: 2019119001

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Adenosquamous carcinoma of the esophagus* | Approved Not as Requested After Suspension | Proposed LLT | |
| HLT primary | *Oesophageal neoplasms malignant* | | *Esophageal adenosquamous carcinoma* | 10082969 Current |
| SOC primary | *Gastrointestinal disorders* | | To PT | |
| | | | *Oesophageal adenosquamous carcinoma* | 10082968 |

MSSO Comment: The proposal to add a new PT Adenosquamous carcinoma of the esophagus to primary HLT Oesophageal neoplasms malignant in SOC Gastrointestinal disorders is approved but not as requested after suspension. Adenosquamous carcinoma of the esophagus is an uncommon type of esophageal cancer that contains both adenocarcinoma and squamous cell carcinoma elements. Because its clinical features are basically identical to those of other types of esophageal cancer, the diagnosis of this disease is dependent on histopathological examination. The proposed term will be renamed to conform with other existing esophageal malignancies in MedDRA, and will be added as LLT Esophageal adenosquamous carcinoma to a new PT Oesophageal adenosquamous carcinoma, which represents its British spelling. In a related change, Oesophageal adenosquamous carcinoma will be added as a PT to bi-axial HLT Oesophageal neoplasms malignant which will be linked to primary SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps) and secondary SOC Gastrointestinal disorders.

# Supplemental Update Report

**CR Number: 2019130012** **Implementation Date:** 10-May-19 Related CR: 2019119001

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Oesophageal adenosquamous carcinoma* | Approved as Requested | Proposed PT | |
| HLT primary | *Oesophageal neoplasms malignant* | | *Oesophageal adenosquamous carcinoma* | 10082968 |
| SOC primary | *Neoplasms benign, malignant and unspecified (incl cysts and polyps)* | | HLT primary | |
| | | | *Oesophageal neoplasms malignant* | 10030176 |
| | | | SOC primary | |
| | | | *Neoplasms benign, malignant and unspecified (incl cysts and polyps)* | 10029104 |
| | | | HLT secondary | |
| | | | *Oesophageal neoplasms malignant* | 10030176 |
| | | | SOC secondary | |
| | | | *Gastrointestinal disorders* | 10017947 |

MSSO Comment:

**CR Number: 2019121001** **Implementation Date:** 22-May-19 Related CR: 2019121001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Esophageal-pulmonary fistula* | Approved After Suspension | Proposed LLT | |
| | | | *Esophageal-pulmonary fistula* | 10083016 Current |
| | | | To PT | |
| | | | *Oesophageal-pulmonary fistula* | 10083015 |

MSSO Comment: The proposal to add a new term Esophageal-pulmonary fistula is approved as requested after suspension. Oesophageal respiratory fistulae, either congenital or acquired, are abnormal communications between the oesophagus and the respiratory system. Most acquired oesophageal respiratory fistulae are of the oesophageal tracheal and oesophageal bronchial type and are caused by infections or malignant neoplasms, whereas oesophageal-pulmonary fistulae are rare. Esophageal-pulmonary fistula will be added as an LLT to the British English counterpart PT Oesophageal-pulmonary fistula. In a related change, PT Oesophageal-pulmonary fistula will be added to primary HLT Gastrointestinal fistulae, secondary HLT Parenchymal lung disorders NEC and secondary HLT Respiratory tract and thoracic cavity procedural complications.

# Supplemental Update Report

**CR Number: 2019142003** **Implementation Date:** 22-May-19 Related CR: 2019121001

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Oesophageal-pulmonary fistula* | Approved as Requested | Proposed PT | |
| HLT primary | *Gastrointestinal fistulae* | | *Oesophageal-pulmonary fistula* | 10083015 |
| SOC primary | *Gastrointestinal disorders* | | HLT primary | |
| | | | *Gastrointestinal fistulae* | 10017952 |
| | | | SOC primary | |
| | | | *Gastrointestinal disorders* | 10017947 |
| | | | HLT secondary | |
| | | | *Parenchymal lung disorders NEC* | 10033979 |
| | | | SOC secondary | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |

MSSO Comment:

**CR Number: 2019142004** **Implementation Date:** 22-May-19 Related CR: 2019121001

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Oesophageal-pulmonary fistula* | Approved as Requested | Proposed PT | |
| To HLT | *Respiratory tract and thoracic cavity procedural complications* | | *Oesophageal-pulmonary fistula* | 10083015 |
| | | | To HLT | |
| | | | *Respiratory tract and thoracic cavity procedural complications* | 10052823 |

MSSO Comment:

# Supplemental Update Report

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

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Alexander disease* | Approved After Suspension | Proposed PT | |
| | | | *Alexander disease* | 10083059 |
| | | | HLT primary | |
| | | | *Central nervous system disorders congenital NEC* | 10009713 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary | |
| | | | *Leukodystrophies* | 10068202 |
| | | | SOC secondary | |
| | | | *Nervous system disorders* | 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 alignement.

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

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Leukodystrophy* | Approved as Requested | Proposed PT | |
| From HLT | *Demyelinating disorders NEC* | | *Leukodystrophy* | 10024381 |
| To HLT | *Leukodystrophies* | | From HLT | |
| | | | *Demyelinating disorders NEC* | 10012302 |
| | | | To HLT | |
| | | | *Leukodystrophies* | 10068202 |

MSSO Comment:

# Supplemental Update Report

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

| Change Requested | Change Status of LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| LLT to change | *Lepromatous leprosy (type I)* | Approved After Suspension | LLT to change | |
| Status | *non-current* | | *Lepromatous leprosy (type I)* | 10024228 Non-Current |
| | | | Status | |
| | | | *non-current* | |

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 which do not include a “type I”.

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

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Rhinobronchial syndrome* | Approved Not as Requested After Suspension | Proposed LLT | |
| HLT primary | *Respiratory tract disorders NEC* | | *Rhinobronchial syndrome* | 10083062 Current |
| SOC primary | *Respiratory, thoracic and mediastinal disorders* | | To PT | |
| | | | *Upper-airway cough syndrome* | 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

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

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Viral load abnormal* | Approved After Suspension | Proposed PT<br>*Viral load abnormal* | 10083060 |
| HLT primary | *Virus identification and serology* | | HLT primary<br>*Virus identification and serology* | 10047490 |
| SOC primary | *Investigations* | | SOC primary<br>*Investigations* | 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

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

MSSO Comment: The proposal to add a new 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

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Exposure to mould* | Approved as Requested | PT to merge | |
| To PT | *Exposure to fungus* | | *Exposure to mould* | 10072074 Current |
| | | | To PT | |
| | | | *Exposure to fungus* | 10083061 |

MSSO Comment:

**CR Number: 2019122001** **Implementation Date:** 10-May-19 Related CR: 2019122001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Acquired fibrinogen deficiency* | Approved as Requested | Proposed LLT | |
| | | | *Acquired fibrinogen deficiency* | 10082951 Current |
| | | | To PT | |
| | | | *Hypofibrinogenaemia* | 10051125 |

MSSO Comment: The proposal to add a new LLT Acquired fibrinogen deficiency is approved as requested. Acquired hypofibrinogenemia (Factor I deficiency) is most frequently caused by hemodilution and consumption of clotting factors. Common signs and symptoms include muscle ache, tight and shiny appearance of skin, upset stomach, vomit that is black and syrupy or bright red, red- or black-colored stool, and heavy menstrual bleeding in women. Acquired fibrinogen deficiency will be added as a sub-concept LLT to PT Hypofibrinogenaemia. In a related change, PT Acquired afibrinogenaemia will be demoted under PT Hypofibrinogenaemia since they are used synonymously.

# Supplemental Update Report

**CR Number: 2019130003** **Implementation Date:** 10-May-19 Related CR: 2019122001

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Acquired afibrinogenaemia* | Approved as Requested | PT to merge | |
| To PT | *Hypofibrinogenaemia* | | *Acquired afibrinogenaemia* | 10000531 Current |
| | | | To PT | |
| | | | *Hypofibrinogenaemia* | 10051125 |

MSSO Comment:

**CR Number: 2019123001** **Implementation Date:** 10-May-19 Related CR: 2019123001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *TORCH infection* | Approved as Requested | Proposed PT | |
| | | | *TORCH infection* | 10082952 |
| | | | HLT primary | |
| | | | *Infections congenital NEC* | 10021880 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary | |
| | | | *Congenital neonatal infections* | 10028929 |
| | | | SOC secondary | |
| | | | *Pregnancy, puerperium and perinatal conditions* | 10036585 |

MSSO Comment: The proposal to add a new term TORCH infection is approved as requested. "TORCH" is an acronym for Toxoplasmosis, Other (syphilis, varicella-zoster, parvovirus B19), Rubella, Cytomegalovirus (CMV), and Herpes infections. TORCH infections are acquired by the mother and transmitted to the child either transplacentally or during delivery (peripartum). While each infection is distinct, there are many similarities in how these infections present in the neonates and at the same time may be clinically silent in the mothers. It is important to consider TORCH infections whenever a neonate presents with intrauterine growth restriction (IUGR), microcephaly, cardiac defects, intracranial calcifications, conjunctivitis, hearing loss, rash, hepatosplenomegaly, or thrombocytopenia. TORCH infection will be added as a PT to primary HLT Infections congenital NEC and to secondary HLT Congenital neonatal infections.

# Supplemental Update Report

**CR Number: 2019123002** **Implementation Date:** 10-May-19 Related CR: 2019123002

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *TORCH syndrome* | Approved as Requested | Proposed LLT | |
| | | | *TORCH syndrome* | 10082953 Current |
| | | | To PT | |
| | | | *TORCH infection* | 10082952 |

MSSO Comment: The proposal to add a new term TORCH syndrome is approved as requested. TORCH syndrome will be added as synonym LLT to PT TORCH infection added in change request 2019123001.

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**CR Number: 2019126001** **Implementation Date:** 10-May-19 Related CR: 2019126001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Robotic Surgery* | Approved Not as Requested | Proposed PT | |
| To PT | *Therapeutic procedure* | | *Robotic surgery* | 10082954 |
| | | | HLT primary | |
| | | | *Therapeutic procedures NEC* | 10027700 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment: The proposal to add a new LLT Robotic Surgery to PT Therapeutic procedure is approved but not as requested. Robotic surgery is a type of minimally invasive surgery using miniaturized surgical instruments that fit through a series of quarter-inch incisions and are mounted on separate robotic arms, allowing the surgeon maximum range of motion and precision. Robotic surgery, with the capitalization corrected to conform to MedDRA conventions, will be added as a PT to HLT Therapeutic procedures NEC.

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**CR Number: 2019126002** **Implementation Date:** 10-May-19 Related CR: 2019126002

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Endoscopic papillosphincterotomy* | Approved as Requested | Proposed LLT | |
| | | | *Endoscopic papillosphincterotomy* | 10082955 Current |
| | | | To PT | |
| | | | *Pancreatobiliary sphincterotomy* | 10052376 |

MSSO Comment: The proposal to add a new LLT Endoscopic papillosphincterotomy is approved as requested. Endoscopic papillosphincterotomy, a technique in the treatment of pathologies of hepatic bile ducts, will be added as sub-concept LLT to PT Pancreatobiliary sphincterotomy.

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# Supplemental Update Report

**CR Number: 2019126003** **Implementation Date:** 10-May-19 Related CR: 2019126003

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Dose counter malfunction* | Approved Not as Requested | Proposed LLT | |
| To PT | *Device difficult to use* | | *Dose counter malfunction* | 10082956 Current |
| | | | To PT | |
| | | | *Device malfunction* | 10063829 |

MSSO Comment: The proposal to add a new LLT Dose counter malfunction to PT Device difficult to use is approved but not as requested. This specific LLT is intended to capture a possible malfunction related to dosage delivery devices such as pen or inhaler dose counters. The proposed term will added as LLT Dose counter malfunction to PT Device malfunction.

**CR Number: 2019126004** **Implementation Date:** 10-May-19 Related CR: 2019126004

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Difficulty dialing the dose* | Approved as Requested | Proposed LLT | |
| To PT | *Device difficult to use* | | *Difficulty dialing the dose* | 10082957 Current |
| | | | To PT | |
| | | | *Device difficult to use* | 10069853 |

MSSO Comment: The proposal to add a new LLT Difficulty dialing the dose to PT Device difficult to use is approved as requested. Difficulty dialing the dose captures the specific event of a user having difficulty to dial a dose for a dose delivery device. Difficulty dialing the dose will be added as a sub-concept LLT to PT Device difficult to use.

# Supplemental Update Report

**CR Number: 2019127002** **Implementation Date:** 10-May-19 Related CR: 2019127002

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *PRIDE syndrome* | Approved as Requested | Proposed PT<br>*PRIDE syndrome* | 10082958 |
| | | | HLT primary<br>*Acnes* | 10000497 |
| | | | SOC primary<br>*Skin and subcutaneous tissue disorders* | 10040785 |
| | | | HLT secondary<br>*Poisoning and toxicity* | 10035777 |
| | | | SOC secondary<br>*Injury, poisoning and procedural complications* | 10022117 |

MSSO Comment: The proposal to add a new term PRIDE syndrome is approved as requested. The spectrum of cutaneous manifestations caused by various EGFR inhibitors is known as the PRIDE (Papulopustules and/or Paronychia, Regulatory abnormalities of hair growth, Itching, and Dryness due to EGFR inhibitors) syndrome. PRIDE syndrome will be added as a PT to primary HLT Acnes and secondary HLT Poisoning and toxicity.

**CR Number: 2019128001** **Implementation Date:** 13-May-19 Related CR: 2019128001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Mucosal rash* | Approved as Requested | Proposed LLT<br>*Mucosal rash* | 10082983 Current |
| To PT | *Enanthema* | | To PT<br>*Enanthema* | 10014579 |

MSSO Comment: The proposal to add a new LLT Mucosal rash to PT Enanthema is approved as requested. A mucosal rash is an eruption in a mucous tissue, and therefore can be considered a to be a synonym of enanthema.

# Supplemental Update Report

**CR Number: 2019128002** **Implementation Date:** 13-May-19 Related CR: 2019128002

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Device ineffective for unapproved indication* | Approved as Requested | Proposed LLT | |
| To PT | *Therapeutic product ineffective for unapproved indication* | | *Device ineffective for unapproved indication* | 10082984 Current |
| | | | To PT | |
| | | | *Therapeutic product ineffective for unapproved indication* | 10060770 |

MSSO Comment: The proposal to add a new LLT Device ineffective for unapproved indication to PT Therapeutic product ineffective for unapproved indication is approved as requested. Device ineffective for unapproved indication is a sub-concept of PT Therapeutic product ineffective for unapproved indication.

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**CR Number: 2019128003** **Implementation Date:** 13-May-19 Related CR: 2019128003

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Skin haemorrhage* | Approved as Requested | Proposed PT | |
| From HLT | *Bruising, ecchymosis and purpura* | | *Skin haemorrhage* | 10064265 |
| To HLT | *Haemorrhages NEC* | | From HLT | |
| | | | *Bruising, ecchymosis and purpura* | 10006513 |
| | | | To HLT | |
| | | | *Haemorrhages NEC* | 10018987 |

MSSO Comment: The proposal to move the PT Skin haemorrhage from HLT Bruising, ecchymosis and purpura to HLT Haemorrhages NEC is approved as requested. Since the PT Skin haemorrhage is often used to represent hemorrhages external to any of the skin layers, the term will be moved from its current secondary location in HLT Bruising, ecchymosis and purpura to the broader in meaning HLT Haemorrhages NEC. Unspecified forms of bleeding into the skin, which are not specified as ecchymosis or purpura, can be represented by existing PT Haemorrhage subcutaneous and PT Mucocutaneous haemorrhage.

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**CR Number: 2019128004** **Implementation Date:** 13-May-19 Related CR: 2019128004

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Nasal mucosal rash* | Rejected | | |

MSSO Comment: The proposal to add a new PT Nasal mucosal rash is not approved. The expression Nasal mucosal rash can't be found in literature even in association with the use of nasal sprays. Please consider the broad LLT Mucocutaneous rash or if reports refer to nasal spray reactions with LLT Application site rash for your coding needs.

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# Supplemental Update Report

**CR Number: 2019128005** **Implementation Date:** 13-May-19 Related CR: 2019128005

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Rash gum* | Approved Not as Requested | Proposed LLT | |
| From PT | *Gingival disorder* | | *Rash gum* | 10049379 Current |
| | | | From PT | |
| | | | *Gingival disorder* | 10018280 |
| | | | To PT | |
| | | | *Oral mucosal eruption* | 10030997 |

MSSO Comment: The proposal to promote the LLT Rash gum from PT Gingival disorder is approved but not as requested. There are a variety of diseases that may cause eruptions of the oral mucosa including the gingiva including recurrent intraoral herpes simplex, herpes labialis, lichen planus, varicella-zoster virus infection, infectious mononucleosis, HIV infection, histoplasmosis, and mucous membrane pemphigoid. The LLT Rash gum will be moved from PT Gingival disorder to PT Oral mucosal eruption.

**CR Number: 2019128006** **Implementation Date:** 13-May-19 Related CR: 2019128006

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Taste alteration* | Rejected | | |
| From PT | *Taste disorder* | | | |
| To PT | *Dysgeusia* | | | |

MSSO Comment: The proposal to move the LLT Taste alteration from PT Taste disorder to PT Dysgeusia is not approved. Despite Dorland's Definition, perversion and and alteration are not synonyms depending on context they are used. The meaning of perversion is most often used in context with negative alterations and LLT Taste perversion therefore is best placed under PT Dysgeusia whereas LLT Taste alteration, LLT Taste changed and LLT Taste altered are appropriately subordinated to the more "neutral" PT Taste disorder.

**CR Number: 2019128007** **Implementation Date:** 13-May-19 Related CR: 2019128007

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Taste altered* | Rejected | | |
| From PT | *Taste disorder* | | | |
| To PT | *Dysgeusia* | | | |

MSSO Comment: The proposal to move the LLT Taste altered from PT Taste disorder to PT Dysgeusia is not approved. Despite Dorland's Definition, perversion and and alteration are not synonyms depending on context they are used. The meaning of perversion is most often used in context with negative alterations and LLT Taste perversion therefore is best placed under PT Dysgeusia whereas LLT Taste alteration, LLT Taste changed and LLT Taste altered are appropriately subordinated to the more "neutral" PT Taste disorder.

# Supplemental Update Report

**CR Number:** **2019128008** **Implementation Date:** 13-May-19 Related CR: 2019128008

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Taste changed* | Rejected | | |
| From PT | *Taste disorder* | | | |
| To PT | *Dysgeusia* | | | |

MSSO Comment: The proposal to move the LLT Taste changed from PT Taste disorder to PT Dysgeusia is not approved. Despite Dorland's Definition, perversion and and alteration are not synonyms depending on context they are used. The meaning of perversion is most often used in context with negative alterations and LLT Taste perversion therefore is best placed under PT Dysgeusia whereas LLT Taste alteration, LLT Taste changed and LLT Taste altered are appropriately subordinated to the more "neutral" PT Taste disorder.

**CR Number:** **2019128009** **Implementation Date:** 13-May-19 Related CR: 2019128009

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Gastrointestinal tract biopsy* | Approved as Requested | Proposed PT | |
| HLT primary | *Gastrointestinal histopathology procedures* | | *Gastrointestinal tract biopsy* | 10082977 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Gastrointestinal histopathology procedures* | 10017962 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Gastrointestinal tract biopsy to primary HLT Gastrointestinal histopathology procedures in SOC Investigations is approved as requested. A biopsy of the gastrointestinal tract is the removal and examination, of tissue from any part of the gastrointestinal tract, often using endoscopic instrumentation, which is performed to establish a precise diagnosis.

**CR Number:** **2019128010** **Implementation Date:** 13-May-19 Related CR: 2019128010

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Penis lesion* | Rejected | | |

MSSO Comment: The proposal to add a new term Penis lesion is not approved. As stated in Section 5.1 of the MedDRA Introductory Guide, lesion terms may be considered for inclusion in MedDRA when the word “lesion” is part of a medical concept, e.g., PT Glomerulonephritis minimal lesion or a well-documented medical concept, e.g., LLT Brain lesion. However, the term will not be added when adding a broad “lesion” term only adds an additional imprecise term to existing “disorder” concepts. For your coding needs, please consider LLT Penis disorder, LLT Unspecified disorder of penis, or another LLT under PT Penis disorder.

# Supplemental Update Report

**CR Number: 2019128011** **Implementation Date:** 13-May-19 Related CR: 2019128011

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Rectal surgery* | Approved Not as Requested | Proposed LLT | |
| HLT primary | *Anorectal therapeutic procedures* | | *Rectal surgery* | 10082981 Current |
| SOC primary | *Surgical and medical procedures* | | To PT | |
| | | | *Anorectal operation* | 10050622 |

MSSO Comment: The proposal to add a new PT Rectal surgery to primary HLT Anorectal therapeutic procedures in SOC Surgical and medical procedures is approved but not as requested. Rectal surgery represents an unspecified surgical procedure of the rectum. Rectal surgery will be added as a sub-concept LLT to PT Anorectal operation.

**CR Number: 2019128012** **Implementation Date:** 13-May-19 Related CR: 2019128012

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pycnodysostosis* | Approved as Requested | Proposed PT | |
| | | | *Pycnodysostosis* | 10082973 |
| | | | HLT primary | |
| | | | *Non-site specific bone disorders congenital* | 10029509 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary | |
| | | | *Non-site specific bone disorders congenital* | 10029509 |
| | | | SOC secondary | |
| | | | *Musculoskeletal and connective tissue disorders* | 10028395 |

MSSO Comment: The proposal to add a new PT Pycnodysostosis is approved as requested. Pycnodysostosis is a rare genetic disorder characterized by distinctive facial features and skeletal malformations. Affected individuals may have osteosclerosis, a condition characterized by abnormal hardening and increased density of bone. The abnormality of the bones of affected individuals cause the bones to be fragile and brittle. Affected individuals are prone to repeated fractures. Affected individuals may fail to grow and can be shorter than would otherwise be expected. Pycnodysostosis will be added as a PT to primary HLT Non-site specific bone disorders congenital (primary SOC Congenital, familial and genetic disorders and secondary SOC Musculoskeletal and connective tissue disorders). In a related change, the HLT for PT Acrodysostosis will changed from HLT Musculoskeletal disorders congenital NEC to HLT Non-site specific bone disorders congenital for consistent mapping of similar malformation concepts.

# Supplemental Update Report

**CR Number: 2019133014** **Implementation Date:** 13-May-19 Related CR: 2019128012

| Change Requested | Link (move) a PT to another HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Acrodysostosis* | Approved as Requested | Proposed PT | |
| From HLT | *Musculoskeletal disorders congenital NEC* | | *Acrodysostosis* | 10079856 |
| To HLT | *Non-site specific bone disorders congenital* | | From HLT | |
| | | | *Musculoskeletal disorders congenital NEC* | 10029513 |
| | | | To HLT | |
| | | | *Non-site specific bone disorders congenital* | 10029509 |

MSSO Comment:

**CR Number: 2019128013** **Implementation Date:** 13-May-19 Related CR: 2019128013

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Chondronecrosis* | Approved as Requested | Proposed PT | |
| | | | *Chondronecrosis* | 10082974 |
| | | | HLT primary | |
| | | | *Cartilage disorders* | 10007709 |
| | | | SOC primary | |
| | | | *Musculoskeletal and connective tissue disorders* | 10028395 |
| | | | HLT secondary | |
| | | | *Non-site specific necrosis and vascular insufficiency NEC* | 10029558 |
| | | | SOC secondary | |
| | | | *Vascular disorders* | 10047065 |

MSSO Comment: The proposal to add a new term Chondronecrosis is approved as requested. Chondronecrosis, the necrosis of cartilage tissue, will be added as a new PT to primary HLT Cartilage disorders, and to secondary HLT Non-site specific necrosis and vascular insufficiency NEC.

# Supplemental Update Report

**CR Number: 2019128014** **Implementation Date:** 13-May-19 Related CR: 2019128014

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Female reproductive tract disorder* | Approved as Requested | Proposed PT | |
| | | | *Female reproductive tract disorder* | 10082971 |
| | | | HLT primary | |
| | | | *Reproductive tract disorders NEC (excl neoplasms)* | 10027696 |
| | | | SOC primary | |
| | | | *Reproductive system and breast disorders* | 10038604 |

MSSO Comment: The proposal to add a new PT Female reproductive tract disorder is approved as requested. A female reproductive tract disorder is an unspecified abnormality of a female reproductive organ or tissue. Female reproductive tract disorder will be added as a new PT to HLT Reproductive tract disorders NEC (excl neoplasms). In a related change, PT Genital disorder female will be demoted as sub-concept LLT to new PT Female reproductive tract disorder.

**CR Number: 2019133015** **Implementation Date:** 13-May-19 Related CR: 2019128014

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Genital disorder female* | Approved as Requested | PT to merge | |
| To PT | *Female reproductive tract disorder* | | *Genital disorder female* | 10061176 Current |
| | | | To PT | |
| | | | *Female reproductive tract disorder* | 10082971 |

MSSO Comment:

**CR Number: 2019128015** **Implementation Date:** 13-May-19 Related CR: 2019128015

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Male reproductive tract disorder* | Approved as Requested | Proposed PT | |
| | | | *Male reproductive tract disorder* | 10082975 |
| | | | HLT primary | |
| | | | *Reproductive tract disorders NEC (excl neoplasms)* | 10027696 |
| | | | SOC primary | |
| | | | *Reproductive system and breast disorders* | 10038604 |

MSSO Comment: The proposal to add a new PT Male reproductive tract disorder is approved as requested. A male reproductive tract disorder is an unspecified abnormality of a male reproductive organ or tissue. Male reproductive tract disorder will be added as a new PT to HLT Reproductive tract disorders NEC (excl neoplasms). In a related change, PT Genital disorder male will be demoted as a sub-concept LLT to new PT Male reproductive tract disorder.

# Supplemental Update Report

**CR Number: 2019133016** **Implementation Date:** 13-May-19 Related CR: 2019128015

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Genital disorder male* | Approved as Requested | PT to merge | |
| To PT | *Male reproductive tract disorder* | | *Genital disorder male* | 10061177 Current |
| | | | To PT | |
| | | | *Male reproductive tract disorder* | 10082975 |

MSSO Comment:

**CR Number: 2019128016** **Implementation Date:** 13-May-19 Related CR: 2019128016

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Precancerous lesion* | Approved as Requested | Proposed PT | |
| | | | *Precancerous lesion* | 10082978 |
| | | | HLT primary | |
| | | | *Trophic disorders* | 10044694 |
| | | | SOC primary | |
| | | | *General disorders and administration site conditions* | 10018065 |

MSSO Comment: The proposal to add a new PT Precancerous lesion is approved as requested. A precancerous condition is a condition or lesion involving abnormal cells which are associated with an increased risk of developing into cancer. Precancerous lesion will be added as PT to HLT Trophic disorders.

**CR Number: 2019128017** **Implementation Date:** 13-May-19 Related CR: 2019128017

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Gastric neoplasm excision* | Rejected | | |
| To PT | *Stomach lesion excision* | | | |

MSSO Comment: The proposal to add a new LLT Gastric neoplasm excision to PT Stomach lesion excision is not approved. MedDRA cannot provide a unique term for the excision of every possible site specific neoplasm. The proposed term can be represented by split coding with LLT Tumour excision and as the underlying causality the LLT Gastric neoplasm.

# Supplemental Update Report

**CR Number: 2019128018** **Implementation Date:** 13-May-19 Related CR: 2019128018

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Antithrombin III abnormal* | Approved as Requested | Proposed PT | |
| HLT primary | *Coagulation and bleeding analyses* | | *Antithrombin III abnormal* | 10082979 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Coagulation and bleeding analyses* | 10009728 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Antithrombin III abnormal to primary HLT Coagulation and bleeding analyses in SOC Investigations is approved as requested. Antithrombin III is a protein in the blood that blocks abnormal blood clots from forming. Antithrombin III abnormal provides a term for test results where it is unknown whether the results are increased/decreased represented in PTs Antithrombin III increased/Antithrombin III decreased.

**CR Number: 2019128019** **Implementation Date:** 13-May-19 Related CR: 2019128019

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Conjoined twins separation* | Approved as Requested | Proposed PT | |
| | | | *Conjoined twins separation* | 10082972 |
| | | | HLT primary | |
| | | | *Therapeutic procedures NEC* | 10027700 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment: The proposal to add a new PT Conjoined twins separation is approved as requested. Twin separation surgery occurs when doctors separate twins who are born conjoined at birth. Conjoined twins are attached together, both inside their bodies by sharing certain organs or body parts, as well as outside through the skin. Conjoined twins separation will be added as PT to HLT Therapeutic procedures NEC.

**CR Number: 2019128020** **Implementation Date:** 13-May-19 Related CR: 2019128020

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Neonatal fungal infection* | Rejected | | |

MSSO Comment: The proposal to add a new PT Neonatal fungal infection is not approved. Most fungal infections in neonates are due to Candida species; only a much smaller number of infections are attributed to other fungal pathogens such as Malassezia, Zygomycetes, or Aspergillus. Please refer to slit coding with PT Neonatal infection and PT Fungal infection for the few cases which may not be candida.

# Supplemental Update Report

**CR Number: 2019128021** **Implementation Date:** 13-May-19 Related CR: 2019128021

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Lithopedion* | Approved as Requested | Proposed PT | |
| HLT primary | *Stillbirth and foetal death* | | *Lithopedion* | 10082976 |
| SOC primary | *Pregnancy, puerperium and perinatal conditions* | | HLT primary | |
| | | | *Stillbirth and foetal death* | 10053173 |
| | | | SOC primary | |
| | | | *Pregnancy, puerperium and perinatal conditions* | 10036585 |
| | | | HLT secondary | |
| | | | *Death and sudden death* | 10011907 |
| | | | SOC secondary | |
| | | | *General disorders and administration site conditions* | 10018065 |

MSSO Comment: The proposal to add a new PT Lithopedion to primary HLT Stillbirth and foetal death in SOC Pregnancy, puerperium and perinatal conditions is approved as requested. Lithopedion, a dead fetus that has become stony or petrified in utero, will also be secondarily linked to HLT Death and sudden death.

**CR Number: 2019128022** **Implementation Date:** 13-May-19 Related CR: 2019128022

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Metatropic dwarfism* | Approved Not as Requested | Proposed LLT | |
| | | | *Metatropic dwarfism* | 10082982 Current |
| | | | To PT | |
| | | | *Metatropic dysplasia* | 10082970 |

MSSO Comment: The proposal to add a new PT Metatropic dwarfism is approved but not as requested. Metatropic dysplasia is a rare spondyloepimetaphyseal dysplasia characterized by a long trunk and short limbs in infancy followed by severe and progressive kyphoscoliosis causing a reversal in proportions during childhood (short trunk and long limbs) and a final short stature in adulthood. The requested term Metatropic dwarfism will be added as synonym LLT to a new PT Metatropic dysplasia which will be added in a related change to primary HLT Non-site specific bone disorders congenital.

# Supplemental Update Report

**CR Number: 2019133017** **Implementation Date:** 13-May-19 Related CR: 2019128022

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Metatropic dysplasia* | Approved as Requested | Proposed PT | |
| HLT primary | *Non-site specific bone disorders congenital* | | *Metatropic dysplasia* | 10082970 |
| SOC primary | *Congenital, familial and genetic disorders* | | HLT primary | |
| | | | *Non-site specific bone disorders congenital* | 10029509 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |

MSSO Comment:

**CR Number: 2019128023** **Implementation Date:** 13-May-19 Related CR: 2019128023

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Mucocutaneous disorder* | Approved as Requested | Proposed PT | |
| HLT primary | *Skin and subcutaneous conditions NEC* | | *Mucocutaneous disorder* | 10082980 |
| SOC primary | *Skin and subcutaneous tissue disorders* | | HLT primary | |
| | | | *Skin and subcutaneous conditions NEC* | 10042356 |
| | | | SOC primary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |
| | | | HLT secondary | |
| | | | *Mucosal findings abnormal* | 10028114 |
| | | | SOC secondary | |
| | | | *General disorders and administration site conditions* | 10018065 |

MSSO Comment: The proposal to add a new PT Mucocutaneous disorder to primary HLT Skin and subcutaneous conditions NEC in SOC Skin and subcutaneous tissue disorders is approved as requested. Mucocutaneous disorder represents a broad term for any type of diseases made up of or involving both typical skin and mucous membrane. PT Mucocutaneous disorder will also be linked to secondary HLT Mucosal findings abnormal.

# Supplemental Update Report

**CR Number: 2019129001** **Implementation Date:** 15-May-19 Related CR: 2019129001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Erythrodermic atopic dermatitis* | Approved Not as Requested | Proposed PT | |
| | | | *Erythrodermic atopic dermatitis* | 10082985 |
| | | | HLT primary | |
| | | | *Exfoliative conditions* | 10015664 |
| | | | SOC primary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |
| | | | HLT secondary | |
| | | | *Allergies to foods, food additives, drugs and other chemicals* | 10001737 |
| | | | SOC secondary | |
| | | | *Immune system disorders* | 10021428 |

MSSO Comment: The proposal to add a new LLT Erythrodermic atopic dermatitis is approved but not as requested. Some forms of atopic dermatitis can be associated with erythroderma, especially in a patient with a late onset of the disease, and it is often associated with higher severity and risk of skin exfoliation. Erythrodermic atopic dermatitis will be added as a PT to primary HLT Exfoliative conditions and secondary HLT Allergies to foods, food additives, drugs and other chemicals.

**CR Number: 2019129002** **Implementation Date:** 15-May-19 Related CR: 2019129002

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Dependence on Steroids* | Approved Not as Requested | Proposed PT | |
| | | | *Steroid dependence* | 10082986 |
| | | | HLT primary | |
| | | | *Therapeutic and nontherapeutic responses* | 10043409 |
| | | | SOC primary | |
| | | | *General disorders and administration site conditions* | 10018065 |

MSSO Comment: The proposal to add a new LLT Dependence on Steroids is approved but not as requested. The requested term refers to the chronic need of steroid treatment such as immunologic diseases, COPD, etc. The proposed term will be renamed and added as PT Steroid dependence to HLT Therapeutic and nontherapeutic responses.

# Supplemental Update Report

**CR Number: 2019129003** **Implementation Date:** 15-May-19 Related CR: 2019129003

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Eyelid scar* | Approved as Requested | Proposed PT | |
| HLT primary | *Eye injuries NEC* | | *Eyelid scar* | 10082987 |
| SOC primary | *Injury, poisoning and procedural complications* | | HLT primary | |
| | | | *Eye injuries NEC* | 10027674 |
| | | | SOC primary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |
| | | | HLT secondary | |
| | | | *Ocular injuries NEC* | 10030047 |
| | | | SOC secondary | |
| | | | *Eye disorders* | 10015919 |

MSSO Comment: The proposal to add a new PT Eyelid scar to primary HLT Eye injuries NEC in SOC Injury, poisoning and procedural complications and secondary HLT Ocular injuries NEC in SOC Eye disorders is approved as requested. Eyelid scarring may occur due to trauma, surgery, radiation to the face, thermal and chemical burns and as a consequence can alter the natural curvature of the eyelid and interfere with effective lid closure causing ocular surface diseases with impact on protection of the eye (e.g., lubrication issues, irritation and pain, dry eye, blurry vision, entropion or ectropion, and corneal damage). PT Eyelid scar will also be linked to secondary HLT Skin injuries and mechanical dermatoses.

**CR Number: 2019135018** **Implementation Date:** 15-May-19 Related CR: 2019129003

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Eyelid scar* | Approved as Requested | Proposed PT | |
| To HLT | *Skin injuries and mechanical dermatoses* | | *Eyelid scar* | 10082987 |
| | | | To HLT | |
| | | | *Skin injuries and mechanical dermatoses* | 10040877 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019129004** **Implementation Date:** 15-May-19 Related CR: 2019129004

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Death by homicide* | Rejected | | |
| HLT primary | *Death and sudden death* | | | |
| SOC primary | *General disorders and administration site conditions* | | | |

MSSO Comment: The proposal to add a new PT Death by homicide to primary HLT Death and sudden death in SOC General disorders and administration site conditions is not approved. The requested concept represents a combination of event and etiology which can be split coded with LLT Victim of homicide and LLT Death.

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**CR Number: 2019129005** **Implementation Date:** 15-May-19 Related CR: 2019129005

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Athletic pubalgia* | Approved Not as Requested | Proposed LLT | |
| HLT primary | *Non-site specific injuries NEC* | | *Athletic pubalgia* | 10082989 Current |
| SOC primary | *Injury, poisoning and procedural complications* | | To PT | |
| | | | *Muscle strain* | 10050031 |

MSSO Comment: The proposal to add a new PT Athletic pubalgia to primary HLT Non-site specific injuries NEC in SOC Injury, poisoning and procedural complications is approved but not as requested. Gilmore's groin is a fairly common injury in kicking sports such as football (soccer), Gaelic football and rugby. The condition is also known as athletic pubalgia. Similarly to current LLT Gilmore's groin, the proposed term Athletic pubalgia will be added as a sub-concept LLT to PT Muscle strain.

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**CR Number: 2019129006** **Implementation Date:** 15-May-19 Related CR: 2019129006

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Sports hernia* | Approved Not as Requested | Proposed LLT | |
| To PT | *Athletic pubalgia* | | *Sports hernia* | 10082988 Current |
| | | | To PT | |
| | | | *Muscle strain* | 10050031 |

MSSO Comment: The proposal to add a new LLT Sports hernia to PT Athletic pubalgia is approved but not as requested. Despite its name, a sports hernia is not actually a hernia. The condition's true name is athletic pubalgia. Although the symptoms are similar, the pain and pressure from sports hernias are caused by torn tendons that attach to the pelvis instead of an abdominal muscle separation and protrusion of intestine or other soft tissue. Sports hernia, synonym of Athletic pubalgia (please see change request 2019129005) will also be added as sub-concept LLT to PT Muscle strain.

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# Supplemental Update Report

**CR Number: 2019130001** **Implementation Date:** 16-May-19 Related CR: 2019130001

| Change Requested | Rename PT/LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Term to modify | *LUMBAR syndrome* | Approved as Requested | Term to modify | |
| Replacement term | *Lumbar syndrome* | | *LUMBAR syndrome* | 10066910 Non-Current |
| | | | Replacement term | |
| | | | *Lumbar syndrome* | 10066910 Non-Current |

MSSO Comment: The proposal to rename PT/LLT LUMBAR syndrome to Lumbar syndrome is approved as requested. This change is proposed to return LLT LUMBAR syndrome to the original spelling LLT Lumbar syndrome as it was in MedDRA Version 21.1. New terms PT Congenital LUMBAR syndrome in SOC Congenital, familial and genetic disorders and LLT Lumbar pain syndrome in SOC Musculoskeletal and connective tissue disorders have been added in MedDRA Version 22.1 to distinguish between these different concepts.

**CR Number: 2019130002** **Implementation Date:** 15-May-19 Related CR: 2019130002

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Acroanesthesia* | Approved as Requested | Proposed LLT | |
| | | | *Acroanesthesia* | 10082990 Current |
| | | | To PT | |
| | | | *Anaesthesia* | 10002091 |

MSSO Comment: The proposal to add a new term Acroanesthesia is approved as requested. Acroanaesthesia is the loss of sensation in the extremities. Acroanesthesia will be added as a sub-concept LLT to PT Anaesthesia. In a related change, the British English counterpart Acroanaesthesia will also be added as an LLT to PT Anaesthesia.

**CR Number: 2019135019** **Implementation Date:** 15-May-19 Related CR: 2019130002

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Acroanaesthesia* | Approved as Requested | Proposed LLT | |
| To PT | *Anaesthesia* | | *Acroanaesthesia* | 10082991 Current |
| | | | To PT | |
| | | | *Anaesthesia* | 10002091 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019130004** **Implementation Date:** 15-May-19 Related CR: 2019130004

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Adrenal rest tumor of the testis* | Approved Not as Requested | Proposed LLT | |
| From PT | *Testis cancer* | | *Adrenal rest tumour of the testis* | 10001379 |
| To PT | *Benign neoplasm of testis* | | From PT | |
| | | | *Testis cancer* | 10057644 |
| | | | HLT primary | |
| | | | *Reproductive neoplasms male benign NEC* | 10038598 |
| | | | SOC primary | |
| | | | *Neoplasms benign, malignant and unspecified (incl cysts and polyps)* | 10029104 |
| | | | HLT secondary | |
| | | | *Testicular and epididymal neoplasms* | 10029108 |
| | | | SOC secondary | |
| | | | *Reproductive system and breast disorders* | 10038604 |

MSSO Comment: The proposal to move the LLT Adrenal rest tumor of the testis from PT Testis cancer to PT Benign neoplasm of testis is approved but not as requested. Testicular adrenal rest tumours are benign intratesticular masses that occur in male patients with congenital adrenal hyperplasia, with more than 90% of cases caused by a deficiency of 21-a-hydroxylase. These tumours originate from aberrant adrenal cells in the testes and can impair both spermatogenesis and endocrine testicular function. LLT Adrenal rest tumour of the testis will be promoted from PT Testis cancer and promoted to a PT term concept then linked to primary HLT Reproductive neoplasms male benign NEC, and to secondary HLT Testicular and epididymal neoplasms. In a related change, the American English spelling LLT Adrenal rest tumor of the testis will also be moved from PT Testis cancer to new PT Adrenal rest tumour of the testis.

**CR Number: 2019135020** **Implementation Date:** 15-May-19 Related CR: 2019130004

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Adrenal rest tumor of the testis* | Approved as Requested | Proposed LLT | |
| From PT | *Testis cancer* | | *Adrenal rest tumor of the testis* | 10062374 Current |
| To PT | *Adrenal rest tumour of the testis* | | From PT | |
| | | | *Testis cancer* | 10057644 |
| | | | To PT | |
| | | | *Adrenal rest tumour of the testis* | 10001379 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019130009** **Implementation Date:** 15-May-19 Related CR: 2019130009

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Infectious Peritonitis* | Rejected | | |
| From PT | *Peritonitis* | | | |

MSSO Comment: The proposal to promote the LLT Infectious Peritonitis from PT Peritonitis is not approved. Since most unqualified cases of peritonitis appear to be due to an infection, the current placement of PT Peritonitis and its LLT Infectious Peritonitis, primarily to the SOC Infections and infestations is appropriate. The proposed promotion of LLT Infectious peritonitis would likely result in signal dilution. PT/LLT Noninfectious peritonitis, of course, remains as an alternate coding option to represent noninfectious etiologies of peritonitis.

**CR Number: 2019130010** **Implementation Date:** 15-May-19 Related CR: 2019130010

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Infectious peritonitis* | Rejected | | |
| From PT | *Peritonitis* | | | |

MSSO Comment: The proposal to promote the LLT Infectious peritonitis from PT Peritonitis is not approved. This change request is a duplicate request of change request 2019130009.

**CR Number: 2019130011** **Implementation Date:** 15-May-19 Related CR: 2019130011

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Esophageal bypass* | Approved as Requested | Proposed LLT | |
| | | | *Esophageal bypass* | 10082993 Current |
| | | | To PT | |
| | | | *Oesophageal bypass* | 10082992 |

MSSO Comment: The proposal to add a new term Esophageal bypass is approved as requested. An oesophageal bypass can provide good palliation and allow for the use of subsequent therapeutic options. There are a variety of indications for oesophageal bypass surgery. Reconstructive bypass surgery with or without concurrent oesophagectomy may be performed in tracheoesophageal fistula, previous oesophagectomy without reconstruction, and, in some cases, obstruction due to lye ingestion. Bypass surgery is also performed in cases of unresectable oesophageal cancer. Esophageal bypass will be added as an LLT to a new PT Oesophageal bypass. In a related change, PT Oesophageal bypass, the British English counterpart of Esophageal bypass, will be added to HLT Oesophageal therapeutic procedures.

# Supplemental Update Report

**CR Number: 2019135021** **Implementation Date:** 15-May-19 Related CR: 2019130011

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Oesophageal bypass* | Approved as Requested | Proposed PT | |
| HLT primary | *Oesophageal therapeutic procedures* | | *Oesophageal bypass* | 10082992 |
| SOC primary | *Surgical and medical procedures* | | HLT primary | |
| | | | *Oesophageal therapeutic procedures* | 10030179 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment:

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**CR Number: 2019133001** **Implementation Date:** 15-May-19 Related CR: 2019133001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Intravitreal implant migration* | Approved as Requested | Proposed LLT | |
| | | | *Intravitreal implant migration* | 10082994 Current |
| | | | To PT | |
| | | | *Device dislocation* | 10064684 |

MSSO Comment: The proposal to add a new term Intravitreal implant migration is approved as requested. Intraocular implants are often sustianed release biodegradable matrix products implanted into the posterior chamber of the eye. Migration of such implants may cause adverse events as well as efficacy issues. Intravitreal implant migration will be added as a sub-concept LLT to PT Device dislocation.

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

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Drug delivery system issue* | Approved After Suspension | Proposed LLT | |
| From PT | *Device issue* | | *Drug delivery system issue* | 10074961 |
| | | | From PT | |
| | | | *Device issue* | 10069868 |
| | | | HLT primary | |
| | | | *Product quality issues NEC* | 10069324 |
| | | | SOC primary | |
| | | | *Product issues* | 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.

# Supplemental Update Report

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

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

MSSO Comment:

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**CR Number: 2019133003** **Implementation Date:** 17-May-19 Related CR: 2019133003

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Cardiac valve atheroma* | Approved as Requested | Proposed LLT | |
| | | | *Cardiac valve atheroma* | 10082998 Current |
| | | | To PT | |
| | | | *Cardiac valve sclerosis* | 10061082 |

MSSO Comment: The proposal to add a new LLT Cardiac valve atheroma is approved as requested. Cardiac valve atheroma, lipoid plaques on the surface of any of the cardiac valves, will be added as a sub-concept LLT to PT Cardiac valve sclerosis.

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**CR Number: 2019133004** **Implementation Date:** 17-May-19 Related CR: 2019133004

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Choreiform dyskinesia* | Approved as Requested | Proposed LLT | |
| | | | *Choreiform dyskinesia* | 10083001 Current |
| | | | To PT | |
| | | | *Chorea* | 10008748 |

MSSO Comment: The proposal to add a new LLT Choreiform dyskinesia is approved as requested. Dyskinesias are abnormal involuntary movements characterised by an excessive amount of movement. Typically, these movements are choreiform in nature. They may be caused by systemic, metabolic, endocrinologic, structural, vascular, infectious or inherited degenerative conditions, or be toxin- or drug-induced. Choreiform dyskinesia will be added as sub-concept LLT to PT Chorea.

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# Supplemental Update Report

**CR Number: 2019133005** **Implementation Date:** 17-May-19 Related CR: 2019133005

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Chronic bronchiolitis* | Approved as Requested | Proposed LLT<br>*Chronic bronchiolitis* | 10082999 Current |
| | | | To PT<br>*Bronchiolitis* | 10006448 |

MSSO Comment: The proposal to add a new LLT Chronic bronchiolitis is approved as requested. Bronchiolitis primarily affects the small conducting airways (3 mm or less in diameter), with limited involvement of the interstitium. Chronic bronchiolitis will be added as sub-concept LLT to PT Bronchiolitis, aligned with LLT Acute bronchiolitis.

**CR Number: 2019133006** **Implementation Date:** 17-May-19 Related CR: 2019133006

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Oesophageal abscess* | Approved Not as Requested | Proposed PT<br>*Oesophageal abscess* | 10082996 |
| | | | HLT primary<br>*Abdominal and gastrointestinal infections* | 10017967 |
| | | | SOC primary<br>*Infections and infestations* | 10021881 |
| | | | HLT secondary<br>*Oesophageal infections* | 10030173 |
| | | | SOC secondary<br>*Gastrointestinal disorders* | 10017947 |

MSSO Comment: The proposal to add a new LLT Oesophageal abscess is approved but not as requested. Oesophageal abscess, caused by infection from fungi, yeast, or bacteria, or as rare complication of a surgical interverntion such as esophagoscopy, will be added as PT to primary HLT Abdominal and gastrointestinal infections and to secondary HLT Oesophageal infections. In a related change, the American spelled counterpart LLT Esophageal abscess will be added to the new PT Oesophageal abscess. Also, PT Paraoesophageal abscess will be demoted as a sub-concept LLT to new PT Oesophageal abscess.

# Supplemental Update Report

**CR Number: 2019137001** **Implementation Date:** 17-May-19 Related CR: 2019133006

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Esophageal abscess* | Approved as Requested | Proposed LLT | |
| To PT | *Oesophageal abscess* | | *Esophageal abscess* | 10083003 Current |
| | | | To PT | |
| | | | *Oesophageal abscess* | 10082996 |

MSSO Comment:

**CR Number: 2019137002** **Implementation Date:** 17-May-19 Related CR: 2019133006

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Paraoesophageal abscess* | Approved as Requested | PT to merge | |
| To PT | *Oesophageal abscess* | | *Paraoesophageal abscess* | 10056086 Current |
| | | | To PT | |
| | | | *Oesophageal abscess* | 10082996 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019133007** **Implementation Date:** 17-May-19 Related CR: 2019133007

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Cholinergic rebound syndrome* | Approved Not as Requested | Proposed PT | |
| | | | *Cholinergic rebound syndrome* | 10082997 |
| | | | HLT primary | |
| | | | *Autonomic nervous system disorders* | 10003839 |
| | | | SOC primary | |
| | | | *Nervous system disorders* | 10029205 |
| | | | HLT secondary | |
| | | | *Withdrawal and rebound effects* | 10068756 |
| | | | SOC secondary | |
| | | | *General disorders and administration site conditions* | 10018065 |

MSSO Comment: The proposal to add a new LLT Cholinergic rebound syndrome is approved but not as requested. Rebound cholinergic syndrome is a rare, but well known unwanted phenomenon occurring after abrupt clozapine discontinuation. Cholinergic rebound syndrome will be added as PT to primary HLT Autonomic nervous system disorders and to secondary HLT Withdrawal and rebound effects.

**CR Number: 2019133008** **Implementation Date:** 17-May-19 Related CR: 2019133008

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Cholinergic withdrawal syndrome* | Approved as Requested | Proposed LLT | |
| | | | *Cholinergic withdrawal syndrome* | 10083000 Current |
| | | | To PT | |
| | | | *Cholinergic rebound syndrome* | 10082997 |

MSSO Comment: The proposal to add a new LLT Cholinergic withdrawal syndrome is approved as requested. Cholinergic withdrawal syndrome will be added as a sub-concept LLT to the new PT Cholinergic rebound syndrome, added in change request 2019133007.

**CR Number: 2019133009** **Implementation Date:** 17-May-19 Related CR: 2019133009

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Chest abscess* | Rejected | | |

MSSO Comment: The proposal to add a new LLT Chest abscess is not approved. Chest abscess is a vague expression as it may refer to the following medical concepts such as; Chest wall abscess, Mediastinal abscess or Breast abscess etc. Please review existing more specific LLT/PTs available in MedDRA.

# Supplemental Update Report

**CR Number: 2019133010** **Implementation Date:** 17-May-19 Related CR: 2019133010

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Chronic lung disease* | Approved as Requested | Proposed LLT | |
| | | | *Chronic lung disease* | 10083002 Current |
| | | | To PT | |
| | | | *Chronic respiratory disease* | 10061768 |

MSSO Comment: The proposal to add a new LLT Chronic lung disease is approved as requested. Chronic lung disease is a broad umbrella term which may refer to several specific lung diseases such as asthma, COPD, chronic bronchitis, emphysema etc... and will be placed as an LLT to PT Chronic respiratory disease.

**CR Number: 2019133011** **Implementation Date:** 17-May-19 Related CR: 2019133011

| Change Requested | Change Status of LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| LLT to change | *Transaminitis* | Rejected | | |
| Status | *non-current* | | | |

MSSO Comment: The proposal to change status of LLT Transaminitis to non-current is not approved. In medicine, the presence of elevated transaminases, commonly the transaminases alanine transaminase (ALT) and aspartate transaminase (AST), may be an indicator of liver damage. Other terms employed include transaminasemia, elevated liver enzymes, and transaminitis which some sources consider pathologically meaningless but still used in English and other languages. Furthermore, as LLT Transaminitis has been in MedDRA since version 4.1 and frequently used in databases, changing the status to non-current may have an impact on legacy data.

**CR Number: 2019133012** **Implementation Date:** 17-May-19 Related CR: 2019133012

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Colon atonic* | Approved Not as Requested | Proposed LLT | |
| From PT | *Megacolon* | | *Colon atonic* | 10009939 Current |
| To PT | *Ileus paralytic* | | From PT | |
| | | | *Megacolon* | 10027110 |
| | | | To PT | |
| | | | *Intestinal atony* | 10068577 |

MSSO Comment: The proposal to move the LLT Colon atonic from PT Megacolon to PT Ileus paralytic is approved but not as requested. Atonic colon occurs when there is a lack of normal muscle tone or strength in the colon. Also, known as lazy colon or colon stasis, it may result in chronic constipation. Atonic colon is not a synonym of megacolon or paralytic ileus and will be best represented as an independend concpet in MedDRA. Therefore, LLT Colon atonic and LLT Colonic atony will be moved from PT Megacolon to a new broader PT Intestinal atony. In a related change, LLT Intestinal atony will be promoted from PT Ileus paralytic to PT status and linked to HLT Gastrointestinal atonic and hypomotility disorders NEC.

# Supplemental Update Report

**CR Number: 2019137003** **Implementation Date:** 17-May-19 Related CR: 2019133012

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Intestinal atony* | Approved as Requested | Proposed LLT | |
| From PT | *Ileus paralytic* | | *Intestinal atony* | 10068577 |
| HLT primary | *Gastrointestinal atonic and hypomotility disorders NEC* | | From PT | |
| | | | *Ileus paralytic* | 10021333 |
| | | | HLT primary | |
| | | | *Gastrointestinal atonic and hypomotility disorders NEC* | 10017933 |
| | | | SOC primary | |
| | | | *Gastrointestinal disorders* | 10017947 |

MSSO Comment:

**CR Number: 2019133013** **Implementation Date:** 17-May-19 Related CR: 2019133013

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Colonic atony* | Approved Not as Requested | Proposed LLT | |
| From PT | *Megacolon* | | *Colonic atony* | 10009985 Current |
| To PT | *Ileus paralytic* | | From PT | |
| | | | *Megacolon* | 10027110 |
| | | | To PT | |
| | | | *Intestinal atony* | 10068577 |

MSSO Comment: The proposal to move the LLT Colonic atony from PT Megacolon to PT Ileus paralytic is approved but not as requested. Atonic colon occurs when there is a lack of normal muscle tone or strength in the colon. Also, known as lazy colon or colon stasis, it may result in chronic constipation. Atonic colon is neither synonym of megacolon nor to paralytic ileus and will be best represented as independend concpet in MedDRA. Therefore, LLT Colonic atony will be moved from PT Megacolon to a new broader PT Intestinal atony. - please see Change request 2019133012 for the promotion of LLT Intestinal atony.

# Supplemental Update Report

**CR Number: 2019134001** **Implementation Date:** 16-May-19 Related CR: 2019134001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Choreiform movement* | Approved as Requested | Proposed LLT | |
| To PT | *Chorea* | | *Choreiform movement* | 10082995 Current |
| | | | To PT | |
| | | | *Chorea* | 10008748 |

MSSO Comment: The proposal to add a new LLT Choreiform movement to PT Chorea is approved as requested. Chorea, a manifestation of a number of acquired and inherited diseases, is an abnormal involuntary movement characterized by brief, abrupt, irregular, unpredictable, non-stereotyped movements. In milder cases, chorea may appear purposeful. The patient often appears fidgety and clumsy. Overall, chorea can affect various body parts, and interfere with speech, swallowing, posture and gait, and disappears in sleep. Choreiform movement, which is essentially a synonym of chorea, will be added as an LLT to PT Chorea.

**CR Number: 2019134002** **Implementation Date:** 21-May-19 Related CR: 2019134002

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Immune-mediated pancytopenia* | Approved as Requested | Proposed PT | |
| | | | *Immune-mediated pancytopenia* | 10083004 |
| | | | HLT primary | |
| | | | *Marrow depression and hypoplastic anaemias* | 10026847 |
| | | | SOC primary | |
| | | | *Blood and lymphatic system disorders* | 10005329 |
| | | | HLT secondary | |
| | | | *Immune and associated conditions NEC* | 10027682 |
| | | | SOC secondary | |
| | | | *Immune system disorders* | 10021428 |

MSSO Comment: The proposal to add a new term Immune-mediated pancytopenia is approved as requested. Drug-induced immune pancytopenia, an example of immune-mediated pancytopenia and an uncommon disorder, has been observed to occur when a therapeutic agent (such as oxaliplatin) induces the production of platelet, red blood cell, and white blood cell antibodies, that induce pancytopenia in the patient. Because immune-mediated pancytopenia usually manifests as an immunologic reaction against one's own blood components, Immune-mediated pancytopenia will be added as a PT to primary HLT Marrow depression and hypoplastic anaemias and secondary HLT Immune and associated conditions NEC.

# Supplemental Update Report

**CR Number:** **2019134003** **Implementation Date:** 21-May-19 Related CR: 2019134003

| Change Requested | Swap a PT with an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Nuclear magnetic resonance imaging* | Approved as Requested | Proposed PT | |
| With LLT | *Magnetic resonance imaging* | | *Nuclear magnetic resonance imaging* | 10029815 Current |
| | | | With LLT | |
| | | | *Magnetic resonance imaging* | 10078223 |

MSSO Comment: The proposal to swap the PT Nuclear magnetic resonance imaging with the LLT Magnetic resonance imaging is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number:** **2019134004** **Implementation Date:** 21-May-19 Related CR: 2019134004

| Change Requested | Swap a PT with an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Nuclear magnetic resonance imaging abnormal* | Approved as Requested | Proposed PT | |
| With LLT | *Magnetic resonance imaging abnormal* | | *Nuclear magnetic resonance imaging abnormal* | 10029816 Current |
| | | | With LLT | |
| | | | *Magnetic resonance imaging abnormal* | 10078224 |

MSSO Comment: The proposal to swap the PT Nuclear magnetic resonance imaging abnormal with the LLT Magnetic resonance imaging abnormal is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number:** **2019134005** **Implementation Date:** 17-May-19 Related CR: 2019134005

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Cervical nerve root impingement* | Approved as Requested | Proposed LLT | |
| From PT | *Radiculopathy* | | *Cervical nerve root impingement* | 10081630 Current |
| To PT | *Cervical radiculopathy* | | From PT | |
| | | | *Radiculopathy* | 10037779 |
| | | | To PT | |
| | | | *Cervical radiculopathy* | 10050217 |

MSSO Comment: The proposal to move the LLT Cervical nerve root impingement from PT Radiculopathy to PT Cervical radiculopathy is approved as requested for better alignment to the anatomically more specific PT concept.

# Supplemental Update Report

**CR Number: 2019134006** **Implementation Date:** 17-May-19 Related CR: 2019134006

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Lumbar nerve root impingement* | Approved as Requested | Proposed LLT | |
| From PT | *Radiculopathy* | | *Lumbar nerve root impingement* | 10081644 Current |
| To PT | *Lumbar radiculopathy* | | From PT | |
| | | | *Radiculopathy* | 10037779 |
| | | | To PT | |
| | | | *Lumbar radiculopathy* | 10050219 |

MSSO Comment: The proposal to move the LLT Lumbar nerve root impingement from PT Radiculopathy to PT Lumbar radiculopathy is approved as requested for better alignment to the anatomically more specific PT concept.

**CR Number: 2019134007** **Implementation Date:** 17-May-19 Related CR: 2019134007

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Thoracic nerve root impingement* | Approved as Requested | Proposed LLT | |
| From PT | *Radiculopathy* | | *Thoracic nerve root impingement* | 10081637 Current |
| To PT | *Thoracic radiculopathy* | | From PT | |
| | | | *Radiculopathy* | 10037779 |
| | | | To PT | |
| | | | *Thoracic radiculopathy* | 10081172 |

MSSO Comment: The proposal to move the LLT Thoracic nerve root impingement from PT Radiculopathy to PT Thoracic radiculopathy is approved as requested for better alignment to the anatomically more specific PT concept.

**CR Number: 2019134008** **Implementation Date:** 17-May-19 Related CR: 2019134008

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Lumbosacral nerve root impingement* | Approved as Requested | Proposed LLT | |
| From PT | *Radiculopathy* | | *Lumbosacral nerve root impingement* | 10081643 Current |
| To PT | *Lumbosacral radiculopathy* | | From PT | |
| | | | *Radiculopathy* | 10037779 |
| | | | To PT | |
| | | | *Lumbosacral radiculopathy* | 10076578 |

MSSO Comment: The proposal to move the LLT Lumbosacral nerve root impingement from PT Radiculopathy to PT Lumbosacral radiculopathy is approved as requested for better alignment to the anatomically more specific PT concept.

# Supplemental Update Report

**CR Number: 2019135001** **Implementation Date:** 21-May-19 Related CR: 2019135001

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Epidermolysis* | Approved as Requested | Proposed PT | |
| | | | *Epidermolysis* | 10053177 |
| Old Primary SOC | *Congenital, familial and genetic disorders* | | Old Primary SOC | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| New Primary SOC | *Skin and subcutaneous tissue disorders* | | New Primary SOC | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment: The proposal to reassign the primary SOC of PT Epidermolysis from current SOC Congenital, familial and genetic disorders to SOC Skin and subcutaneous tissue disorders is approved as requested. Epidermolysis is the general term for loosening of the epidermis. It is a much broader concept than the condition epidermolysis bullosa, a very specific congenital bullous skin condition. Because epidermolysis itself can be an acquired condition, associated with etiologies like trauma or antecedent infection, it is appropriate to change its primary SOC allocation to SOC Skin and subcutaneous tissue disorders. No link to the SOC Congenital, familial and genetic disorders is appropriate for the broad concept of epidermolysis. In a related change, PT Epidermolysis will be delinked from HLT Skin and subcutaneous tissue disorders congenital NEC. Furthermore, because of association with autoimmunity, PT Epidermolysis and PT Acquired epidermolysis bullosa will be linked to HLT Skin autoimmune disorders NEC.

**CR Number: 2019141005** **Implementation Date:** 21-May-19 Related CR: 2019135001

| Change Requested | Unlink a PT from a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Epidermolysis* | Approved as Requested | Proposed PT | |
| | | | *Epidermolysis* | 10053177 |
| From HLT | *Skin and subcutaneous tissue disorders congenital NEC* | | From HLT | |
| | | | *Skin and subcutaneous tissue disorders congenital NEC* | 10040834 |

MSSO Comment:

**CR Number: 2019141006** **Implementation Date:** 21-May-19 Related CR: 2019135001

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Epidermolysis* | Approved as Requested | Proposed PT | |
| | | | *Epidermolysis* | 10053177 |
| To HLT | *Skin autoimmune disorders NEC* | | To HLT | |
| | | | *Skin autoimmune disorders NEC* | 10052738 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019141007** **Implementation Date:** 21-May-19 Related CR: 2019135001

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Acquired epidermolysis bullosa* | Approved as Requested | Proposed PT | |
| To HLT | *Skin autoimmune disorders NEC* | | *Acquired epidermolysis bullosa* | 10056508 |
| | | | To HLT | |
| | | | *Skin autoimmune disorders NEC* | 10052738 |

MSSO Comment:

**CR Number: 2019135002** **Implementation Date:** 21-May-19 Related CR: 2019135002

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *CDKL5 Deficiency Disorder* | Approved Not as Requested | Proposed PT | |
| | | | *CDKL5 deficiency disorder* | 10083005 |
| | | | HLT primary | |
| | | | *Cerebral disorders congenital* | 10052634 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary | |
| | | | *Seizures and seizure disorders NEC* | 10039912 |
| | | | SOC secondary | |
| | | | *Nervous system disorders* | 10029205 |

MSSO Comment: The proposal to add a new term CDKL5 Deficiency Disorder is approved but not as requested. CDKL5 (cyclin-dependent kinase-like 5) deficiency disorder is a rare X-linked genetic disorder characterized as a developmental encephalopathy featuring early infantile onset refractory epilepsy, hypotonia, developmental intellectual and motor disabilities, and cortical visual impairment. The requested term will be added in accordance with MedDRA capitalization conventions as PT CDKL5 deficiency disorder to primary HLT Cerebral disorders congenital, to secondary HLT Seizures and seizure disorders NEC, and secondary HLT Cognitive and attention disorders and disturbances NEC.

# Supplemental Update Report

**CR Number: 2019141008** **Implementation Date:** 21-May-19 Related CR: 2019135002

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *CDKL5 deficiency disorder* | Approved as Requested | Proposed PT | |
| To HLT | *Cognitive and attention disorders and disturbances NEC* | | *CDKL5 deficiency disorder* | 10083005 |
| | | | To HLT | |
| | | | *Cognitive and attention disorders and disturbances NEC* | 10009842 |

MSSO Comment:

**CR Number: 2019135003** **Implementation Date:** 22-May-19 Related CR: 2019135003

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Pulmonary interstitial shadow* | Approved as Requested | Proposed LLT | |
| From PT | *Chest X-ray abnormal* | | *Pulmonary interstitial shadow* | 10037416 Current |
| To PT | *Lung opacity* | | From PT | |
| | | | *Chest X-ray abnormal* | 10008499 |
| | | | To PT | |
| | | | *Lung opacity* | 10081792 |

MSSO Comment: The proposal to move the LLT Pulmonary interstitial shadow from PT Chest X-ray abnormal to PT Lung opacity is approved as requested. Upon further review of change request 2019112004 to move LLT Pulmonary interstitial shadow, LLT Pulmonary interstitial shadow will be moved from PT Chest X-ray abnormal to PT Lung opacity because specific diagnostic imaging findings are usually placed as medical conditions or disorders and not as terms in SOC Investigations.

# Supplemental Update Report

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

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Habit cough* | Approved as Requested | Proposed PT | |
| | | | *Habit cough* | 10082913 |
| Old Primary SOC | *Respiratory, thoracic and mediastinal disorders* | | Old Primary SOC | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |
| New Primary SOC | *Psychiatric disorders* | | New Primary SOC | |
| | | | *Psychiatric disorders* | 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

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Colitis psychogenic* | Approved as Requested | Proposed PT | |
| | | | *Colitis psychogenic* | 10053397 |
| Old Primary SOC | *Gastrointestinal disorders* | | Old Primary SOC | |
| | | | *Gastrointestinal disorders* | 10017947 |
| New Primary SOC | *Psychiatric disorders* | | New Primary SOC | |
| | | | *Psychiatric disorders* | 10037175 |

MSSO Comment:

# Supplemental Update Report

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

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Dysphonia psychogenic* | Approved as Requested | Proposed PT | |
| Old Primary SOC | *Nervous system disorders* | | *Dysphonia psychogenic* | 10013953 |
| New Primary SOC | *Psychiatric disorders* | | Old Primary SOC | |
| | | | *Nervous system disorders* | 10029205 |
| | | | New Primary SOC | |
| | | | *Psychiatric disorders* | 10037175 |

MSSO Comment:

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

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Blindness hysterical* | Approved as Requested | Proposed PT | |
| Old Primary SOC | *Eye disorders* | | *Blindness hysterical* | 10005179 |
| New Primary SOC | *Psychiatric disorders* | | Old Primary SOC | |
| | | | *Eye disorders* | 10015919 |
| | | | New Primary SOC | |
| | | | *Psychiatric disorders* | 10037175 |

MSSO Comment:

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

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Psychogenic pseudosyncope* | Approved as Requested | Proposed PT | |
| Old Primary SOC | *Nervous system disorders* | | *Psychogenic pseudosyncope* | 10075190 |
| New Primary SOC | *Psychiatric disorders* | | Old Primary SOC | |
| | | | *Nervous system disorders* | 10029205 |
| | | | New Primary SOC | |
| | | | *Psychiatric disorders* | 10037175 |

MSSO Comment:

# Supplemental Update Report

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

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Aphonia psychogenic* | Approved as Requested | Proposed PT | |
| | | | *Aphonia psychogenic* | 10002954 |
| Old Primary SOC | *Nervous system disorders* | | Old Primary SOC | |
| | | | *Nervous system disorders* | 10029205 |
| New Primary SOC | *Psychiatric disorders* | | New Primary SOC | |
| | | | *Psychiatric disorders* | 10037175 |

MSSO Comment:

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

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Cardiovascular somatic symptom disorder* | Approved as Requested | Proposed PT | |
| | | | *Cardiovascular somatic symptom disorder* | 10078078 |
| Old Primary SOC | *Cardiac disorders* | | Old Primary SOC | |
| | | | *Cardiac disorders* | 10007541 |
| New Primary SOC | *Psychiatric disorders* | | New Primary SOC | |
| | | | *Psychiatric disorders* | 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 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: 2019135006** **Implementation Date:** 29-May-19 Related CR: 2019135006

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Chronic idiopathic pain syndrome* | Approved as Requested | Proposed PT | |
| Old Primary SOC | *Nervous system disorders* | | *Chronic idiopathic pain syndrome* | 10078098 |
| New Primary SOC | *Psychiatric disorders* | | Old Primary SOC | |
| | | | *Nervous system disorders* | 10029205 |
| | | | New Primary SOC | |
| | | | *Psychiatric disorders* | 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

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Cutaneous somatic symptom disorder* | Approved as Requested | Proposed PT | |
| Old Primary SOC | *Skin and subcutaneous tissue disorders* | | *Cutaneous somatic symptom disorder* | 10078081 |
| New Primary SOC | *Psychiatric disorders* | | Old Primary SOC | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |
| | | | New Primary SOC | |
| | | | *Psychiatric disorders* | 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

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Gastrointestinal somatic symptom disorder* | Approved as Requested | Proposed PT | |
| | | | *Gastrointestinal somatic symptom disorder* | 10078079 |
| Old Primary SOC | *Gastrointestinal disorders* | | Old Primary SOC | |
| | | | *Gastrointestinal disorders* | 10017947 |
| New Primary SOC | *Psychiatric disorders* | | New Primary SOC | |
| | | | *Psychiatric disorders* | 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

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Neurologic somatic symptom disorder* | Approved as Requested | Proposed PT | |
| | | | *Neurologic somatic symptom disorder* | 10078080 |
| Old Primary SOC | *Nervous system disorders* | | Old Primary SOC | |
| | | | *Nervous system disorders* | 10029205 |
| New Primary SOC | *Psychiatric disorders* | | New Primary SOC | |
| | | | *Psychiatric disorders* | 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

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Polydipsia psychogenic* | Approved as Requested | Proposed PT | |
| Old Primary SOC | *Metabolism and nutrition disorders* | | *Polydipsia psychogenic* | 10036069 |
| New Primary SOC | *Psychiatric disorders* | | Old Primary SOC | |
| | | | *Metabolism and nutrition disorders* | 10027433 |
| | | | New Primary SOC | |
| | | | *Psychiatric disorders* | 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

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Psychogenic dysuria* | Approved as Requested | Proposed PT | |
| Old Primary SOC | *Renal and urinary disorders* | | *Psychogenic dysuria* | 10037195 |
| New Primary SOC | *Psychiatric disorders* | | Old Primary SOC | |
| | | | *Renal and urinary disorders* | 10038359 |
| | | | New Primary SOC | |
| | | | *Psychiatric disorders* | 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

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Psychogenic movement disorder* | Approved as Requested | Proposed PT | |
| | | | *Psychogenic movement disorder* | 10072376 |
| Old Primary SOC | *Nervous system disorders* | | Old Primary SOC | |
| | | | *Nervous system disorders* | 10029205 |
| New Primary SOC | *Psychiatric disorders* | | New Primary SOC | |
| | | | *Psychiatric disorders* | 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

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Psychogenic respiratory distress* | Approved as Requested | Proposed PT | |
| | | | *Psychogenic respiratory distress* | 10072630 |
| Old Primary SOC | *Respiratory, thoracic and mediastinal disorders* | | Old Primary SOC | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |
| New Primary SOC | *Psychiatric disorders* | | New Primary SOC | |
| | | | *Psychiatric disorders* | 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

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Psychogenic tremor* | Approved as Requested | Proposed PT | |
| | | | *Psychogenic tremor* | 10072377 |
| Old Primary SOC | *Nervous system disorders* | | Old Primary SOC | |
| | | | *Nervous system disorders* | 10029205 |
| New Primary SOC | *Psychiatric disorders* | | New Primary SOC | |
| | | | *Psychiatric disorders* | 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

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Somatoform genitourinary disorder* | Approved as Requested | Proposed PT | |
| | | | *Somatoform genitourinary disorder* | 10077253 |
| Old Primary SOC | *Renal and urinary disorders* | | Old Primary SOC | |
| | | | *Renal and urinary disorders* | 10038359 |
| New Primary SOC | *Psychiatric disorders* | | New Primary SOC | |
| | | | *Psychiatric disorders* | 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

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Torticollis psychogenic* | Approved as Requested | Proposed PT | |
| Old Primary SOC | *Musculoskeletal and connective tissue disorders* | | *Torticollis psychogenic* | 10044076 |
| New Primary SOC | *Psychiatric disorders* | | Old Primary SOC | |
| | | | *Musculoskeletal and connective tissue disorders* | 10028395 |
| | | | New Primary SOC | |
| | | | *Psychiatric disorders* | 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

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vomiting psychogenic* | Approved as Requested | Proposed PT | |
| Old Primary SOC | *Gastrointestinal disorders* | | *Vomiting psychogenic* | 10047709 |
| New Primary SOC | *Psychiatric disorders* | | Old Primary SOC | |
| | | | *Gastrointestinal disorders* | 10017947 |
| | | | New Primary SOC | |
| | | | *Psychiatric disorders* | 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: 2019140001** **Implementation Date:** 22-May-19 Related CR: 2019140001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Maffucci syndrome* | Approved as Requested | Proposed PT | |
| | | | *Maffucci syndrome* | 10083007 |
| | | | HLT primary | |
| | | | *Cartilage neoplasms benign* | 10007711 |
| | | | SOC primary | |
| | | | *Neoplasms benign, malignant and unspecified (incl cysts and polyps)* | 10029104 |
| | | | HLT secondary | |
| | | | *Benign musculoskeletal and connective tissue neoplasms* | 10004297 |
| | | | SOC secondary | |
| | | | *Musculoskeletal and connective tissue disorders* | 10028395 |

MSSO Comment: The proposal to add a new term Maffucci syndrome is approved as requested. Maffucci syndrome, or Dyschondroplasia haemangiomatosa, Maffucci-Kast-syndrom, Osteochondromatosis-haemangiosis-syndrom, is a rare disorder of bone and soft tissue characterized by multiple enchondromas and hemangiomas. Maffucci syndrome will be added as PT to primary HLT Cartilage neoplasms benign and secondary HLT Benign musculoskeletal and connective tissue neoplasms and to HLT Vascular neoplasms. In a related change, LLT Dyschondroplasia haemangiomatosa and American English spelled LLT Dyschondroplasia hemangiomatosa will be added as synonyms to PT Maffucci syndrome.

**CR Number: 2019141009** **Implementation Date:** 22-May-19 Related CR: 2019140001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Dyschondroplasia haemangiomatosa* | Approved as Requested | Proposed LLT | |
| To PT | *Maffucci syndrome* | | *Dyschondroplasia haemangiomatosa* | 10083009 Current |
| | | | To PT | |
| | | | *Maffucci syndrome* | 10083007 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019141010** **Implementation Date:** 22-May-19 Related CR: 2019140001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Dyschondroplasia hemangiomatosa* | Approved as Requested | Proposed LLT | |
| To PT | *Maffucci syndrome* | | *Dyschondroplasia hemangiomatosa* | 10083008 Current |
| | | | To PT | |
| | | | *Maffucci syndrome* | 10083007 |

MSSO Comment:

**CR Number: 2019141011** **Implementation Date:** 22-May-19 Related CR: 2019140001

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Maffucci syndrome* | Approved as Requested | Proposed PT | |
| To HLT | *Vascular neoplasms* | | *Maffucci syndrome* | 10083007 |
| | | | To HLT | |
| | | | *Vascular neoplasms* | 10057189 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019140002** **Implementation Date:** 22-May-19 Related CR: 2019140002

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Eye infarction* | Approved as Requested | Proposed PT | |
| | | | *Eye infarction* | 10083006 |
| | | | HLT primary | |
| | | | *Ocular bleeding and vascular disorders NEC* | 10030031 |
| | | | SOC primary | |
| | | | *Eye disorders* | 10015919 |
| | | | HLT secondary | |
| | | | *Site specific necrosis and vascular insufficiency NEC* | 10052781 |
| | | | SOC secondary | |
| | | | *Vascular disorders* | 10047065 |

MSSO Comment: The proposal to add a new term Eye infarction is approved as requested. Eye infarction is a broad non-specific expression which may usually, but not exclusively, refer to retinal infarction. Therefore, the unqualified concept Eye infarction will be added as a PT to primary HLT Ocular bleeding and vascular disorders NEC and to secondary HLT Site specific necrosis and vascular insufficiency NEC.

**CR Number: 2019140003** **Implementation Date:** 22-May-19 Related CR: 2019140003

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Pericardial devascularization* | Approved as Requested | Proposed LLT | |
| | | | *Pericardial devascularization* | 10083014 Current |
| | | | To PT | |
| | | | *Sugiura procedure* | 10083010 |

MSSO Comment: The proposal to add a new term Pericardial devascularization is approved as requested. The Sugiura procedure was originally developed to treat bleeding esophageal varices and consisted mainly of an esophagogastric devascularization. It was developed in Japan in 1973 as a nonshunting technique that achieved variceal bleeding hemostasis by interrupting the variceal blood flow along the gastroesophageal junction. The procedure consists primarily of paraesophagogastric devascularization achieved by dividing the perforating veins of the esophagus and the stomach while maintaining the plexus of collaterals that connect the coronary gastric vein to the azygous system. Pericardial devascularization and its British English spelled counterpart Pericardial devascularisation will be added as LLTs to PT Sugiura procedure. In a related change, Sugiura procedure will be added as PT to HLT Gastrointestinal therapeutic procedures NEC. Furthermore, frequently used synonyms Oesophagogastric devascularisation and Esophagogastric devascularization will be added as LLTs to PT Sugiura procedure.

# Supplemental Update Report

**CR Number: 2019141012** **Implementation Date:** 22-May-19 Related CR: 2019140003

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Pericardial devascularisation* | Approved as Requested | Proposed LLT | | |
| To PT | *Sugiura procedure* | | *Pericardial devascularisation* | 10083011 | Current |
| | | | To PT | | |
| | | | *Sugiura procedure* | 10083010 | |

MSSO Comment:

**CR Number: 2019141013** **Implementation Date:** 22-May-19 Related CR: 2019140003

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Sugiura procedure* | Approved as Requested | Proposed PT | |
| HLT primary | *Gastrointestinal therapeutic procedures NEC* | | *Sugiura procedure* | 10083010 |
| SOC primary | *Surgical and medical procedures* | | HLT primary | |
| | | | *Gastrointestinal therapeutic procedures NEC* | 10018013 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 10042613 |

MSSO Comment:

**CR Number: 2019141014** **Implementation Date:** 22-May-19 Related CR: 2019140003

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Esophagogastric devascularization* | Approved as Requested | Proposed LLT | | |
| To PT | *Sugiura procedure* | | *Esophagogastric devascularization* | 10083013 | Current |
| | | | To PT | | |
| | | | *Sugiura procedure* | 10083010 | |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019141015** **Implementation Date:** 22-May-19 Related CR: 2019140003

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Oesophagogastric devascularisation* | Approved as Requested | Proposed LLT | |
| To PT | *Sugiura procedure* | | *Oesophagogastric devascularisation* | 10083012 Current |
| | | | To PT | |
| | | | *Sugiura procedure* | 10083010 |

MSSO Comment:

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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Stereognosis* | 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: 2019140005** **Implementation Date:** 10-Jun-19 Related CR: 2019140005

| Change Requested | Change term status in a SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Subglottic laryngitis* | Approved as Requested | Proposed PT | |
| To SMQ | *Oropharyngeal infections (SMQ)* | | *Subglottic laryngitis* | 10076988 |
| Status | *I* | | To SMQ | |
| | | | *Oropharyngeal infections (SMQ)* | 20000111 |
| | | | Status | |
| | | | *I* | |

MSSO Comment: The proposal to change status of the term Subglottic laryngitis in Oropharyngeal infections (SMQ) to Inactive is approved as requested. Terms that relate to lesions or disorders of larynx and structures below larynx are excluded by SMQ definitions for in- and exclusion criteria. In sync with these definitions, PTs that relate to the glottic or subglottic region, i.e. laryngeal structures, were not considered for inclusion in the SMQ until v18.1. Addition of PT Subglottic laryngitis in v18.1 contradicts the in-and exclusion criteria of Oropharyngeal infections (SMQ) and therefore, PT Subglottic laryngitis should be made inactive.

# Supplemental Update Report

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

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *CARDIA LIGATION THERAPY* | Approved Not as Requested | Proposed LLT | |
| | | | *Cardia variceal ligation* | 10083017 Current |
| | | | To PT | |
| | | | *Gastric variceal ligation* | 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

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Vascular ligation* | Approved Not as Requested | Proposed PT | |
| | | | *Vascular ligation* | 10083018 |
| | | | HLT primary | |
| | | | *Vascular therapeutic procedures NEC* | 10047094 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 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.

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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| 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.

# Supplemental Update Report

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

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Infusion reaction* | Approved as Requested | Proposed LLT<br>*Infusion reaction* | 10083019 Current |
| | | | To PT<br>*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

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| 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.

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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Drug toxicity due to polymorphism* | 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.

# Supplemental Update Report

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

| Change Requested | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|
| Add a New Term | | | |
| Proposed Term *Prothrombin fragment 1.2 level increased* | Approved Not as Requested | Proposed PT | |
| | | *Prothrombin fragment 1.2 increased* | 10083020 |
| | | HLT primary | |
| | | *Coagulation and bleeding analyses* | 10009728 |
| | | SOC primary | |
| | | *Investigations* | 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

| Change Requested | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|
| Add a New Term | | | |
| Proposed Term *Bone necrosis excision* | Approved as Requested | Proposed LLT | |
| | | *Bone necrosis excision* | 10083022 Current |
| | | To PT | |
| | | *Bone debridement* | 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.

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

| Change Requested | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|
| Add a New Term | | | |
| Proposed Term *Drug-induced high blood glucose* | 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.

# Supplemental Update Report

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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Basal cell carcinoma face* | Approved as Requested | Proposed LLT | |
| | | | *Basal cell carcinoma face* | 10083025 Current |
| | | | To PT | |
| | | | *Basal cell carcinoma* | 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.

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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Amygdalolith* | Approved as Requested | Proposed LLT | |
| | | | *Amygdalolith* | 10083023 Current |
| | | | To PT | |
| | | | *Tonsillolith* | 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.

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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Acute-on-chronic subdural hematoma* | Approved Not as Requested | Proposed LLT | |
| | | | *Acute on chronic subdural hematoma* | 10083024 Current |
| | | | To PT | |
| | | | *Subdural haematoma* | 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.

# Supplemental Update Report

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

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Acute on chronic subdural haematoma* | Approved as Requested | Proposed LLT | |
| To PT | *Subdural haematoma* | | *Acute on chronic subdural haematoma* | 10083026 Current |
| | | | To PT | |
| | | | *Subdural haematoma* | 10042361 |

MSSO Comment:

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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Congenital ureteropelvic junction obstruction* | Approved as Requested | Proposed PT | |
| | | | *Congenital ureteropelvic junction obstruction* | 10083021 |
| | | | HLT primary | |
| | | | *Renal and urinary tract disorders congenital NEC* | 10038361 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary | |
| | | | *Renal obstructive disorders* | 10038488 |
| | | | SOC secondary | |
| | | | *Renal and urinary disorders* | 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.

# Supplemental Update Report

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

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Intramyelinic oedema* | Approved as Requested | Proposed PT<br>*Intramyelinic oedema* | 10083038 |
| SOC primary | *Nervous system disorders* | | HLT primary<br>*Demyelinating disorders NEC* | 10012302 |
| | | | SOC primary<br>*Nervous system disorders* | 10029205 |
| | | | HLT secondary<br>*Poisoning and toxicity* | 10035777 |
| | | | SOC secondary<br>*Injury, poisoning and procedural complications* | 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.

**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* | Approved as Requested | Proposed LLT<br>*Intramyelinic edema* | 10083039 Current |
| To PT | *Intramyelinic oedema* | | To PT<br>*Intramyelinic oedema* | 10083038 |

MSSO Comment:

# Supplemental Update Report

**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* | Approved as Requested | Proposed LLT | |
| From PT | *White matter lesion* | | *White matter vacuolation* | 10079757 Current |
| To PT | *Intramyelinic oedema* | | From PT | |
| | | | *White matter lesion* | 10072731 |
| | | | To PT | |
| | | | *Intramyelinic oedema* | 10083038 |

MSSO Comment:

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

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Injection site panniculitis* | Approved as Requested | Proposed PT | |
| HLT primary | *injection site reactions* | | *Injection site panniculitis* | 10083040 |
| SOC primary | *General disorders and administration site conditions* | | HLT primary | |
| | | | *Injection site reactions* | 10022097 |
| | | | SOC primary | |
| | | | *General disorders and administration site conditions* | 10018065 |
| | | | HLT secondary | |
| | | | *Allergic conditions NEC* | 10027654 |
| | | | SOC secondary | |
| | | | *Immune system disorders* | 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 inflmmatory 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.

# Supplemental Update Report

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

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Injection site panniculitis* | Approved as Requested | Proposed PT | |
| To HLT | *Panniculitides* | | *Injection site panniculitis* | 10083040 |
| | | | To HLT | |
| | | | *Panniculitides* | 10033674 |

MSSO Comment:

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

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

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.

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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Vesiculectomy* | Approved as Requested | Proposed PT | |
| | | | *Vesiculectomy* | 10083029 |
| | | | HLT primary | |
| | | | *Male genital tract therapeutic procedures NEC* | 10038591 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 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.

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# Supplemental Update Report

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

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

MSSO Comment:

**CR Number: 2019142016** **Implementation Date:** 24-May-19 Related CR: 2019142016

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Cow's milk intolerance* | Approved Not as Requested | Proposed PT | |
| To PT | *Dairy intolerance* | | *Cow's milk intolerance* | 10011241 Current |
| | | | With LLT | |
| | | | *Dairy intolerance* | 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.

**CR Number: 2019142017** **Implementation Date:** 24-May-19 Related CR: 2019142017

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Stress fecal incontinence* | Approved as Requested | Proposed LLT | |
| | | | *Stress fecal incontinence* | 10083030 Current |
| | | | To PT | |
| | | | *Anal incontinence* | 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.

# Supplemental Update Report

**CR Number: 2019144016** **Implementation Date:** 24-May-19 Related CR: 2019142017

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Stress faecal incontinence* | Approved as Requested | Proposed LLT | |
| To PT | *Anal incontinence* | | *Stress faecal incontinence* | 10083031 Current |
| | | | To PT | |
| | | | *Anal incontinence* | 10077605 |

MSSO Comment:

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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| 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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| 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.

# Supplemental Update Report

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

| Change Requested | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|
| Add a New Term | Approved as Requested | Proposed PT | |
| Proposed Term *Physical examination of joints normal* | | *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.

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

| Change Requested | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|
| Add a New Term | Rejected | | |
| Proposed Term *Post procedural infection bacterial* | | | |

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

| Change Requested | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|
| Add a New Term | Rejected | | |
| Proposed Term *Post procedural infection fungal* | | | |

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.

# Supplemental Update Report

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

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Monocyte chemotactic protein-2 increased* | Approved as Requested | Proposed PT | |
| HLT primary | *Immune response protein analyses NEC* | | *Monocyte chemotactic protein-2 increased* | 10083043 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Immune response protein analyses NEC* | 10021421 |
| | | | SOC primary | |
| | | | *Investigations* | 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 Protien 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.

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

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

MSSO Comment:

# Supplemental Update Report

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

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

MSSO Comment:

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

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Macrophage inflammatory protein - 1 alpha* | Approved as Requested | Proposed PT | |
| HLT primary | *Immune response protein analyses NEC* | | *Macrophage inflammatory protein - 1 alpha* | 10083042 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Immune response protein analyses NEC* | 10021421 |
| | | | SOC primary | |
| | | | *Investigations* | 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.

# Supplemental Update Report

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

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

MSSO Comment:

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

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

MSSO Comment:

# Supplemental Update Report

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

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Interferon beta level* | Approved as Requested | Proposed PT | |
| HLT primary | *Immune response protein analyses NEC* | | *Interferon beta level* | 10083044 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Immune response protein analyses NEC* | 10021421 |
| | | | SOC primary | |
| | | | *Investigations* | 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 (IFNß) 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.

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

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Interferon beta level increased* | Approved as Requested | Proposed PT | |
| HLT primary | *Immune response protein analyses NEC* | | *Interferon beta level increased* | 10083048 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Immune response protein analyses NEC* | 10021421 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment:

# Supplemental Update Report

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

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Interferon beta level decreased* | Approved as Requested | Proposed PT | |
| HLT primary | *Immune response protein analyses NEC* | | *Interferon beta level decreased* | 10083050 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Immune response protein analyses NEC* | 10021421 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment:

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

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Paralytic scoliosis* | Approved as Requested | Proposed PT | |
| HLT primary | *Spine and neck deformities* | | *Paralytic scoliosis* | 10083051 |
| SOC primary | *Musculoskeletal and connective tissue disorders* | | HLT primary | |
| | | | *Spine and neck deformities* | 10012140 |
| | | | SOC primary | |
| | | | *Musculoskeletal and connective tissue disorders* | 10028395 |
| | | | HLT secondary | |
| | | | *Paralysis and paresis (excl cranial nerve)* | 10033800 |
| | | | SOC secondary | |
| | | | *Nervous system disorders* | 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, arthrogryposis 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.

# Supplemental Update Report

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

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Paralytic scoliosis* | Approved as Requested | Proposed PT | |
| To HLT | *Thoracic musculoskeletal disorders* | | *Paralytic scoliosis* | 10083051 |
| | | | To HLT | |
| | | | *Thoracic musculoskeletal disorders* | 10043475 |

MSSO Comment:

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

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Muehrcke lines* | Approved Not as Requested | Proposed LLT | |
| | | | *Muehrcke lines* | 10083052 Current |
| | | | To PT | |
| | | | *Leukonychia* | 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.

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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Primary intimal tear false lumen perfusion* | Approved as Requested | Proposed LLT | |
| | | | *Primary intimal tear false lumen perfusion* | 10083057 Current |
| | | | To PT | |
| | | | *Stent-graft endoleak* | 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.

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# Supplemental Update Report

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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Proximal aorta false lumen perfusion* | Approved as Requested | Proposed LLT<br>*Proximal aorta false lumen perfusion*<br>To PT<br>*Stent-graft endoleak* | <br>10083056 Current<br><br>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.

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

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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Proximal branch false lumen perfusion* | Approved as Requested | Proposed LLT<br>*Proximal branch false lumen perfusion*<br>To PT<br>*Stent-graft endoleak* | <br>10083053 Current<br><br>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.

# Supplemental Update Report

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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Distal branch false lumen perfusion* | Approved as Requested | Proposed LLT<br>*Distal branch false lumen perfusion*<br>To PT<br>*Stent-graft endoleak* | 10083054 Current<br>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.

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

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT<br>From PT<br>To PT | *Rib contusion*<br>*Contusion*<br>*Bone contusion* | Approved as Requested | Proposed LLT<br>*Rib contusion*<br>From PT<br>*Contusion*<br>To PT<br>*Bone contusion* | 10081170 Current<br>10050584<br>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.

# Supplemental Update Report

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

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Cerebral venous sinus thrombosis* | Approved Not as Requested | Proposed PT | |
| | | | *Cerebral venous sinus thrombosis* | 10083037 |
| | | | HLT primary | |
| | | | *Cerebrovascular venous and sinus thrombosis* | 10008209 |
| | | | SOC primary | |
| | | | *Nervous system disorders* | 10029205 |
| | | | HLT secondary | |
| | | | *Cerebrovascular embolism and thrombosis* | 10008205 |
| | | | SOC secondary | |
| | | | *Vascular disorders* | 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.

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

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Intracranial venous sinus thrombosis* | Approved as Requested | PT to merge | |
| To PT | *Cerebral venous sinus thrombosis* | | *Intracranial venous sinus thrombosis* | 10061251 Current |
| | | | To PT | |
| | | | *Cerebral venous sinus thrombosis* | 10083037 |

MSSO Comment:

# Supplemental Update Report

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

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Drug use for misdiagnosis* | Rejected | | |
| To PT | *Product selection error* | | | |

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.

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

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

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.

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

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Receptive language disorder* | Approved as Requested | Proposed LLT | |
| To PT | *Language disorder* | | *Receptive language disorder* | 10083085 Current |
| | | | To PT<br>*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.

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# Supplemental Update Report

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

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| 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

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| 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

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

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Subdural empyema* | Approved as Requested | PT to merge | |
| To PT | *Subdural abscess* | | *Subdural empyema* | 10042360 Current |
| | | | To PT | |
| | | | *Subdural abscess* | 10083083 |

MSSO Comment:

# Supplemental Update Report

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

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Epidural empyema* | Approved as Requested | PT to merge | |
| To PT | *Extradural abscess* | | *Epidural empyema* | 10072822 Current |
| | | | To PT | |
| | | | *Extradural abscess* | 10061846 |

MSSO Comment:

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

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

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Upward migration of renal calculi* | Approved as Requested | Proposed LLT | |
| To PT | *Retrograde migration of renal calculi* | | *Upward migration of renal calculi* | 10083033 Current |
| | | | To PT | |
| | | | *Retrograde migration of renal calculi* | 10083032 |

MSSO Comment:

**CR Number: 2019143008** **Implementation Date:** 03-Jun-19 Related CR: 2019143008

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging abdominal abnormal* | Approved as Requested | Proposed PT | |
| HLT primary | *Gastrointestinal and abdominal imaging procedures* | | *Magnetic resonance imaging abdominal abnormal* | 10083132 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Gastrointestinal and abdominal imaging procedures* | 10017963 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging abdominal abnormal to primary HLT Gastrointestinal and abdominal imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143009** **Implementation Date:** 03-Jun-19 Related CR: 2019143009

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging abdominal* | Approved as Requested | Proposed PT | |
| HLT primary | *Gastrointestinal and abdominal imaging procedures* | | *Magnetic resonance imaging abdominal* | 10083126 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Gastrointestinal and abdominal imaging procedures* | 10017963 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging abdominal to primary HLT Gastrointestinal and abdominal imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

# Supplemental Update Report

**CR Number: 2019143010** **Implementation Date:** 03-Jun-19 Related CR: 2019143010

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging pancreas* | Approved as Requested | Proposed PT | |
| | | | *Magnetic resonance imaging pancreas* | 10083121 |
| HLT primary | *Gastrointestinal and abdominal imaging procedures* | | HLT primary | |
| | | | *Gastrointestinal and abdominal imaging procedures* | 10017963 |
| SOC primary | *Investigations* | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging pancreas to primary HLT Gastrointestinal and abdominal imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143011** **Implementation Date:** 03-Jun-19 Related CR: 2019143011

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging spinal normal* | Approved as Requested | PT to merge | | |
| | | | *Nuclear magnetic resonance imaging spinal normal* | 10073475 | Current |
| To PT | *Magnetic resonance imaging spinal normal* | | To PT | | |
| | | | *Magnetic resonance imaging spinal normal* | 10083138 | |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging spinal normal under PT Magnetic resonance imaging spinal normal is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143012** **Implementation Date:** 03-Jun-19 Related CR: 2019143012

| Change Requested | Swap a PT with an LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed PT | *Nuclear magnetic resonance imaging normal* | Approved as Requested | Proposed PT | | |
| | | | *Nuclear magnetic resonance imaging normal* | 10029823 | Current |
| With LLT | *Magnetic resonance imaging normal* | | With LLT | | |
| | | | *Magnetic resonance imaging normal* | 10078225 | |

MSSO Comment: The proposal to swap the PT Nuclear magnetic resonance imaging normal with the LLT Magnetic resonance imaging normal is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

# Supplemental Update Report

**CR Number: 2019143013** **Implementation Date:** 03-Jun-19 Related CR: 2019143013

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging heart* | Approved as Requested | Proposed PT | |
| HLT primary | *Cardiac imaging procedures* | | *Magnetic resonance imaging heart* | 10083127 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Cardiac imaging procedures* | 10007574 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging heart to primary HLT Cardiac imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143014** **Implementation Date:** 03-Jun-19 Related CR: 2019143014

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging heart* | Approved as Requested | PT to merge | |
| To PT | *Magnetic resonance imaging heart* | | *Nuclear magnetic resonance imaging heart* | 10076374 Current |
| | | | To PT | |
| | | | *Magnetic resonance imaging heart* | 10083127 |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging heart under PT Magnetic resonance imaging heart is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143015** **Implementation Date:** 03-Jun-19 Related CR: 2019143015

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging abdominal abnormal* | Approved as Requested | PT to merge | |
| To PT | *Magnetic resonance imaging abdominal abnormal* | | *Nuclear magnetic resonance imaging abdominal abnormal* | 10058642 Current |
| | | | To PT | |
| | | | *Magnetic resonance imaging abdominal abnormal* | 10083132 |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging abdominal abnormal under PT Magnetic resonance imaging abdominal abnormal is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

# Supplemental Update Report

**CR Number: 2019143016** **Implementation Date:** 03-Jun-19 Related CR: 2019143016

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging abdominal normal* | Approved as Requested | Proposed PT | |
| HLT primary | *Gastrointestinal and abdominal imaging procedures* | | *Magnetic resonance imaging abdominal normal* | 10083135 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Gastrointestinal and abdominal imaging procedures* | 10017963 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging abdominal normal to primary HLT Gastrointestinal and abdominal imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143017** **Implementation Date:** 03-Jun-19 Related CR: 2019143017

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging abdominal normal* | Approved as Requested | PT to merge | |
| To PT | *Magnetic resonance imaging abdominal normal* | | *Nuclear magnetic resonance imaging abdominal normal* | 10058643 Current |
| | | | To PT | |
| | | | *Magnetic resonance imaging abdominal normal* | 10083135 |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging abdominal normal under PT Magnetic resonance imaging abdominal normal is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143018** **Implementation Date:** 03-Jun-19 Related CR: 2019143018

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging abdominal* | Approved as Requested | PT to merge | |
| To PT | *Magnetic resonance imaging abdominal* | | *Nuclear magnetic resonance imaging abdominal* | 10058641 Current |
| | | | To PT | |
| | | | *Magnetic resonance imaging abdominal* | 10083126 |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging abdominal under PT Magnetic resonance imaging abdominal is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

# Supplemental Update Report

**CR Number: 2019143019** **Implementation Date:** 03-Jun-19 Related CR: 2019143019

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging pancreas* | Approved as Requested | PT to merge | |
| To PT | *Magnetic resonance imaging pancreas* | | *Nuclear magnetic resonance imaging pancreas* | 10081952 Current |
| | | | To PT | |
| | | | *Magnetic resonance imaging pancreas* | 10083121 |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging pancreas under PT Magnetic resonance imaging pancreas is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143020** **Implementation Date:** 03-Jun-19 Related CR: 2019143020

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging liver abnormal* | Approved as Requested | Proposed PT | |
| HLT primary | *Hepatobiliary imaging procedures* | | *Magnetic resonance imaging liver abnormal* | 10083123 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Hepatobiliary imaging procedures* | 10019808 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging liver abnormal to primary HLT Hepatobiliary imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143021** **Implementation Date:** 03-Jun-19 Related CR: 2019143021

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging spinal* | Approved as Requested | PT to merge | |
| To PT | *Magnetic resonance imaging spinal* | | *Nuclear magnetic resonance imaging spinal* | 10072232 Current |
| | | | To PT | |
| | | | *Magnetic resonance imaging spinal* | 10083133 |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging spinal under PT Magnetic resonance imaging spinal is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

# Supplemental Update Report

**CR Number: 2019143022** **Implementation Date:** 03-Jun-19 Related CR: 2019143022

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging spinal* | Approved as Requested | Proposed PT | |
| HLT primary | *Central nervous system imaging procedures* | | *Magnetic resonance imaging spinal* | 10083133 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Central nervous system imaging procedures* | 10007950 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging spinal to primary HLT Central nervous system imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143023** **Implementation Date:** 03-Jun-19 Related CR: 2019143023

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging spinal normal* | Approved as Requested | Proposed PT | |
| HLT primary | *Central nervous system imaging procedures* | | *Magnetic resonance imaging spinal normal* | 10083138 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Central nervous system imaging procedures* | 10007950 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging spinal normal to primary HLT Central nervous system imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143024** **Implementation Date:** 03-Jun-19 Related CR: 2019143024

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging spinal abnormal* | Approved as Requested | PT to merge | |
| To PT | *Magnetic resonance imaging spinal abnormal* | | *Nuclear magnetic resonance imaging spinal abnormal* | 10073474 Current |
| | | | To PT | |
| | | | *Magnetic resonance imaging spinal abnormal* | 10083139 |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging spinal abnormal under PT Magnetic resonance imaging spinal abnormal is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

# Supplemental Update Report

**CR Number: 2019143025** **Implementation Date:** 03-Jun-19 Related CR: 2019143025

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging spinal abnormal* | Approved as Requested | Proposed PT | |
| | | | *Magnetic resonance imaging spinal abnormal* | 10083139 |
| HLT primary | *Central nervous system imaging procedures* | | HLT primary | |
| | | | *Central nervous system imaging procedures* | 10007950 |
| SOC primary | *Investigations* | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging spinal abnormal to primary HLT Central nervous system imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143026** **Implementation Date:** 03-Jun-19 Related CR: 2019143026

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging brain* | Approved as Requested | PT to merge | |
| | | | *Nuclear magnetic resonance imaging brain* | 10029817 Current |
| To PT | *Magnetic resonance imaging brain* | | To PT | |
| | | | *Magnetic resonance imaging brain* | 10083128 |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging brain under PT Magnetic resonance imaging brain is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143027** **Implementation Date:** 03-Jun-19 Related CR: 2019143027

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging brain* | Approved as Requested | Proposed PT | |
| | | | *Magnetic resonance imaging brain* | 10083128 |
| HLT primary | *Central nervous system imaging procedures* | | HLT primary | |
| | | | *Central nervous system imaging procedures* | 10007950 |
| SOC primary | *Investigations* | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging brain to primary HLT Central nervous system imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

# Supplemental Update Report

**CR Number: 2019143028** **Implementation Date:** 03-Jun-19 Related CR: 2019143028

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging brain normal* | Approved as Requested | PT to merge | | |
| | | | *Nuclear magnetic resonance imaging brain normal* | 10029819 | Current |
| To PT | *Magnetic resonance imaging brain normal* | | To PT | | |
| | | | *Magnetic resonance imaging brain normal* | 10083129 | |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging brain normal under PT Magnetic resonance imaging brain normal is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143029** **Implementation Date:** 03-Jun-19 Related CR: 2019143029

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging brain normal* | Approved as Requested | Proposed PT | |
| | | | *Magnetic resonance imaging brain normal* | 10083129 |
| HLT primary | *Central nervous system imaging procedures* | | HLT primary | |
| | | | *Central nervous system imaging procedures* | 10007950 |
| SOC primary | *Investigations* | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging brain normal to primary HLT Central nervous system imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143030** **Implementation Date:** 03-Jun-19 Related CR: 2019143030

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging brain abnormal* | Approved as Requested | PT to merge | | |
| | | | *Nuclear magnetic resonance imaging brain abnormal* | 10029818 | Current |
| To PT | *Magnetic resonance imaging brain abnormal* | | To PT | | |
| | | | *Magnetic resonance imaging brain abnormal* | 10083130 | |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging brain abnormal under PT Magnetic resonance imaging brain abnormal is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

# Supplemental Update Report

**CR Number: 2019143031** **Implementation Date:** 03-Jun-19 Related CR: 2019143031

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging brain abnormal* | Approved as Requested | Proposed PT | |
| HLT primary | *Central nervous system imaging procedures* | | *Magnetic resonance imaging brain abnormal* | 10083130 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Central nervous system imaging procedures* | 10007950 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging brain abnormal to primary HLT Central nervous system imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143032** **Implementation Date:** 03-Jun-19 Related CR: 2019143032

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging neck* | Approved as Requested | PT to merge | |
| To PT | *Magnetic resonance imaging neck* | | *Nuclear magnetic resonance imaging neck* | 10080744 Current |
| | | | To PT | |
| | | | *Magnetic resonance imaging neck* | 10083140 |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging neck under PT Magnetic resonance imaging neck is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143033** **Implementation Date:** 03-Jun-19 Related CR: 2019143033

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging neck* | Approved as Requested | Proposed PT | |
| HLT primary | *Musculoskeletal and soft tissue imaging procedures* | | *Magnetic resonance imaging neck* | 10083140 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Musculoskeletal and soft tissue imaging procedures* | 10028386 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging neck to primary HLT Musculoskeletal and soft tissue imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

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**CR Number: 2019143034** **Implementation Date:** 03-Jun-19 Related CR: 2019143034

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging joint* | Approved as Requested | PT to merge | |
| To PT | *Magnetic resonance imaging joint* | | *Nuclear magnetic resonance imaging joint* | 10081781 Current |
| | | | To PT | |
| | | | *Magnetic resonance imaging joint* | 10083134 |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging joint under PT Magnetic resonance imaging joint is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143035** **Implementation Date:** 03-Jun-19 Related CR: 2019143035

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging joint* | Approved as Requested | Proposed PT | |
| HLT primary | *Musculoskeletal and soft tissue imaging procedures* | | *Magnetic resonance imaging joint* | 10083134 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Musculoskeletal and soft tissue imaging procedures* | 10028386 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging joint to primary HLT Musculoskeletal and soft tissue imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143036** **Implementation Date:** 03-Jun-19 Related CR: 2019143036

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging whole body* | Approved as Requested | PT to merge | |
| To PT | *Magnetic resonance imaging whole body* | | *Nuclear magnetic resonance imaging whole body* | 10058644 Current |
| | | | To PT | |
| | | | *Magnetic resonance imaging whole body* | 10083136 |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging whole body under PT Magnetic resonance imaging whole body is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

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**CR Number: 2019143037** **Implementation Date:** 03-Jun-19 Related CR: 2019143037

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging whole body* | Approved as Requested | Proposed PT | |
| HLT primary | *Imaging procedures NEC* | | *Magnetic resonance imaging whole body* | 10083136 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Imaging procedures NEC* | 10021404 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging whole body to primary HLT Imaging procedures NEC in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143038** **Implementation Date:** 03-Jun-19 Related CR: 2019143038

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging liver* | Approved as Requested | PT to merge | |
| To PT | *Magnetic resonance imaging liver* | | *Nuclear magnetic resonance imaging liver* | 10072304 Current |
| | | | To PT | |
| | | | *Magnetic resonance imaging liver* | 10083137 |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging liver under PT Magnetic resonance imaging liver is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143039** **Implementation Date:** 03-Jun-19 Related CR: 2019143039

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging liver* | Approved as Requested | Proposed PT | |
| HLT primary | *Hepatobiliary imaging procedures* | | *Magnetic resonance imaging liver* | 10083137 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Hepatobiliary imaging procedures* | 10019808 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging liver to primary HLT Hepatobiliary imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

# Supplemental Update Report

**CR Number: 2019143040** **Implementation Date:** 03-Jun-19 Related CR: 2019143040

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging liver abnormal* | Approved as Requested | PT to merge | |
| | | | *Nuclear magnetic resonance imaging liver abnormal* | 10080035 Current |
| To PT | *Magnetic resonance imaging liver abnormal* | | To PT | |
| | | | *Magnetic resonance imaging liver abnormal* | 10083123 |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging liver abnormal under PT Magnetic resonance imaging liver abnormal is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143041** **Implementation Date:** 03-Jun-19 Related CR: 2019143041

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging renal* | Approved as Requested | Proposed PT | |
| | | | *Magnetic resonance imaging renal* | 10083131 |
| HLT primary | *Urinary tract imaging procedures* | | HLT primary | |
| | | | *Urinary tract imaging procedures* | 10046570 |
| SOC primary | *Investigations* | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging renal to primary HLT Urinary tract imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143042** **Implementation Date:** 03-Jun-19 Related CR: 2019143042

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging renal* | Approved as Requested | PT to merge | |
| | | | *Nuclear magnetic resonance imaging renal* | 10072303 Current |
| To PT | *Magnetic resonance imaging renal* | | To PT | |
| | | | *Magnetic resonance imaging renal* | 10083131 |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging renal under PT Magnetic resonance imaging renal is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

# Supplemental Update Report

**CR Number: 2019143043** **Implementation Date:** 03-Jun-19 Related CR: 2019143043

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging breast abnormal* | Approved as Requested | Proposed PT | |
| | | | *Magnetic resonance imaging breast abnormal* | 10083124 |
| HLT primary | *Reproductive organ and breast imaging procedures* | | HLT primary | |
| | | | *Reproductive organ and breast imaging procedures* | 10038602 |
| SOC primary | *Investigations* | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging breast abnormal to primary HLT Reproductive organ and breast imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143044** **Implementation Date:** 03-Jun-19 Related CR: 2019143044

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging breast abnormal* | Approved as Requested | PT to merge | |
| | | | *Nuclear magnetic resonance imaging breast abnormal* | 10066293 Current |
| To PT | *Magnetic resonance imaging breast abnormal* | | To PT | |
| | | | *Magnetic resonance imaging breast abnormal* | 10083124 |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging breast abnormal under PT Magnetic resonance imaging breast abnormal is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143045** **Implementation Date:** 03-Jun-19 Related CR: 2019143045

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging breast normal* | Approved as Requested | Proposed PT | |
| | | | *Magnetic resonance imaging breast normal* | 10083125 |
| HLT primary | *Reproductive organ and breast imaging procedures* | | HLT primary | |
| | | | *Reproductive organ and breast imaging procedures* | 10038602 |
| SOC primary | *Investigations* | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging breast normal to primary HLT Reproductive organ and breast imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

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**CR Number: 2019143046** **Implementation Date:** 03-Jun-19 Related CR: 2019143046

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging breast normal* | Approved as Requested | PT to merge | |
| | | | *Nuclear magnetic resonance imaging breast normal* | 10070752 Current |
| To PT | *Magnetic resonance imaging breast normal* | | To PT | |
| | | | *Magnetic resonance imaging breast normal* | 10083125 |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging breast normal under PT Magnetic resonance imaging breast normal is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143047** **Implementation Date:** 03-Jun-19 Related CR: 2019143047

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging breast* | Approved as Requested | Proposed PT | |
| | | | *Magnetic resonance imaging breast* | 10083122 |
| HLT primary | *Reproductive organ and breast imaging procedures* | | HLT primary | |
| | | | *Reproductive organ and breast imaging procedures* | 10038602 |
| SOC primary | *Investigations* | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging breast to primary HLT Reproductive organ and breast imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143048** **Implementation Date:** 03-Jun-19 Related CR: 2019143048

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging breast* | Approved as Requested | PT to merge | |
| | | | *Nuclear magnetic resonance imaging breast* | 10070749 Current |
| To PT | *Magnetic resonance imaging breast* | | To PT | |
| | | | *Magnetic resonance imaging breast* | 10083122 |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging breast under PT Magnetic resonance imaging breast is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

# Supplemental Update Report

**CR Number: 2019143049** **Implementation Date:** 03-Jun-19 Related CR: 2019143049

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging thoracic abnormal* | Approved as Requested | Proposed PT | |
| HLT primary | *Respiratory tract and thoracic imaging procedures* | | *Magnetic resonance imaging thoracic abnormal* | 10083143 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Respiratory tract and thoracic imaging procedures* | 10006476 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging thoracic abnormal to primary HLT Respiratory tract and thoracic imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143050** **Implementation Date:** 03-Jun-19 Related CR: 2019143050

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging thoracic abnormal* | Approved as Requested | PT to merge | |
| To PT | *Magnetic resonance imaging thoracic abnormal* | | *Nuclear magnetic resonance imaging thoracic abnormal* | 10058639 Current |
| | | | To PT | |
| | | | *Magnetic resonance imaging thoracic abnormal* | 10083143 |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging thoracic abnormal under PT Magnetic resonance imaging thoracic abnormal is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

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**CR Number: 2019143051** **Implementation Date:** 03-Jun-19 Related CR: 2019143051

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging thoracic normal* | Approved as Requested | Proposed PT | |
| HLT primary | *Respiratory tract and thoracic imaging procedures* | | *Magnetic resonance imaging thoracic normal* | 10083141 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Respiratory tract and thoracic imaging procedures* | 10006476 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging thoracic normal to primary HLT Respiratory tract and thoracic imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143052** **Implementation Date:** 03-Jun-19 Related CR: 2019143052

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging thoracic normal* | Approved as Requested | PT to merge | |
| To PT | *Magnetic resonance imaging thoracic normal* | | *Nuclear magnetic resonance imaging thoracic normal* | 10058640 Current |
| | | | To PT | |
| | | | *Magnetic resonance imaging thoracic normal* | 10083141 |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging thoracic normal under PT Magnetic resonance imaging thoracic normal is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

**CR Number: 2019143053** **Implementation Date:** 03-Jun-19 Related CR: 2019143053

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Magnetic resonance imaging thoracic* | Approved as Requested | Proposed PT | |
| HLT primary | *Respiratory tract and thoracic imaging procedures* | | *Magnetic resonance imaging thoracic* | 10083142 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Respiratory tract and thoracic imaging procedures* | 10006476 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new PT Magnetic resonance imaging thoracic to primary HLT Respiratory tract and thoracic imaging procedures in SOC Investigations is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

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**CR Number: 2019143054** **Implementation Date:** 03-Jun-19 Related CR: 2019143054

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Nuclear magnetic resonance imaging thoracic* | Approved as Requested | PT to merge | |
| | | | *Nuclear magnetic resonance imaging thoracic* | 10058638 Current |
| To PT | *Magnetic resonance imaging thoracic* | | To PT | |
| | | | *Magnetic resonance imaging thoracic* | 10083142 |

MSSO Comment: The proposal to demote the PT Nuclear magnetic resonance imaging thoracic under PT Magnetic resonance imaging thoracic is approved as requested. MRI was originally called NMRI (nuclear magnetic resonance imaging), but the use of 'nuclear' in the acronym was dropped in favor of magnetic resonance imaging which is now predominantly used in medical literature and clinical descriptions.

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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Omentoplasty* | Approved as Requested | Proposed PT | |
| | | | *Omentoplasty* | 10083067 |
| | | | HLT primary | |
| | | | *Abdominal therapeutic procedures NEC* | 10027653 |
| | | | SOC primary | |
| | | | *Surgical and medical procedures* | 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

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Omental flap operation* | Approved as Requested | PT to merge | |
| | | | *Omental flap operation* | 10075297 Current |
| To PT | *Omentoplasty* | | To PT | |
| | | | *Omentoplasty* | 10083067 |

MSSO Comment:

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

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Omentopexy* | Approved as Requested | PT to merge | |
| To PT | *Omentoplasty* | | *Omentopexy* | 10069422 Current |
| | | | To PT | |
| | | | *Omentoplasty* | 10083067 |

MSSO Comment:

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

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Omental implantation* | Approved as Requested | PT to merge | |
| To PT | *Omentoplasty* | | *Omental implantation* | 10069434 Current |
| | | | To PT | |
| | | | *Omentoplasty* | 10083067 |

MSSO Comment:

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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Radiation osteomyelitis* | Approved as Requested | Proposed LLT | |
| | | | *Radiation osteomyelitis* | 10083068 Current |
| | | | To PT | |
| | | | *Osteoradionecrosis* | 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.

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

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Rhinocerebral mucormycosis* | Approved as Requested | Proposed PT | |
| | | | *Rhinocerebral mucormycosis* | 10076959 |
| To HLT | *Orbital infections, inflammations and irritations* | | To HLT | |
| | | | *Orbital infections, inflammations and irritations* | 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

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Rhinocerebral mucormycosis* | Approved as Requested | Proposed PT | |
| | | | *Rhinocerebral mucormycosis* | 10076959 |
| To HLT | *Fungal upper respiratory tract infections* | | To HLT | |
| | | | *Fungal upper respiratory tract infections* | 10079103 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019143058** **Implementation Date:** 10-Jun-19 Related CR: 2019143058

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Radiotherapy to pharynx* | Approved as Requested | Proposed PT | |
| To SMQ | *Malignancy related therapeutic and diagnostic procedures (SMQ)* | | *Radiotherapy to pharynx* | 10082859 |
| Term scope | *Narrow* | | To SMQ | |
| | | | *Malignancy related therapeutic and diagnostic procedures (SMQ)* | 20000093 |
| | | | Term scope | |
| | | | *Narrow* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Radiotherapy to pharynx to Malignancy related therapeutic and diagnostic procedures (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms for radiotherapy to a specific body area are already included. All terms in this SMQ are narrow scope.

**CR Number: 2019143059** **Implementation Date:** 10-Jun-19 Related CR: 2019143059

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Computerised tomogram pancreas abnormal* | Approved as Requested | Proposed PT | |
| To SMQ | *Malignancy related therapeutic and diagnostic procedures (SMQ)* | | *Computerised tomogram pancreas abnormal* | 10082936 |
| Term scope | *Narrow* | | To SMQ | |
| | | | *Malignancy related therapeutic and diagnostic procedures (SMQ)* | 20000093 |
| | | | Term scope | |
| | | | *Narrow* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Computerised tomogram pancreas abnormal to Malignancy related therapeutic and diagnostic procedures (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms for abnormal CT scans of specific organs are already included. All terms in this SMQ are narrow scope.

# Supplemental Update Report

**CR Number: 2019143060** **Implementation Date:** 10-Jun-19 Related CR: 2019143060

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Neuroendocrine carcinoma of prostate* | Approved as Requested | Proposed PT<br>*Neuroendocrine carcinoma of prostate* | 10082915 |
| To SMQ | *Non-haematological malignant tumours (SMQ)* | | To SMQ<br>*Non-haematological malignant tumours (SMQ)* | 20000228 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Neuroendocrine carcinoma of prostate to Non-haematological malignant tumours (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ for malignant tumors. All terms in this SMQ are narrow scope.

**CR Number: 2019143061** **Implementation Date:** 10-Jun-19 Related CR: 2019143061

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Neuroendocrine carcinoma of prostate* | Approved as Requested | Proposed PT<br>*Neuroendocrine carcinoma of prostate* | 10082915 |
| To SMQ | *Prostate malignant tumours (SMQ)* | | To SMQ<br>*Prostate malignant tumours (SMQ)* | 20000202 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Neuroendocrine carcinoma of prostate to Prostate malignant tumours (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria for this SMQ. Similar terms for histologically defined types of prostate cancer are included in this SMQ as narrow terms.

# Supplemental Update Report

**CR Number: 2019143062** **Implementation Date:** 10-Jun-19 Related CR: 2019143062

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Dacryocystocele acquired* | Approved as Requested | Proposed PT | |
| To SMQ | *Lacrimal disorders (SMQ)* | | *Dacryocystocele acquired* | 10082948 Current |
| Term scope | *Narrow* | | To SMQ | |
| | | | *Lacrimal disorders (SMQ)* | 20000176 |
| | | | Term scope | |
| | | | *Narrow* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Dacryocystocele acquired to Lacrimal disorders (SMQ) as a narrow term is approved as requested. PT Dacryocystocele acquired, added in Version 22.1, refers to a distended lacrimal sac and manifests as a bluish cystic swelling at and below the medial canthal area. Acquired dacryocystocele can be idiopathic or a complication of dacryocystitis, trauma, surgery, tumours or punctal agenesis. PT Dacryocystocele acquired will be added as a narrow scope term to Lacrimal disorders (SMQ), as it fulfills the inclusion criterion, "Terms for diseases and disorders of lacrimal gland and duct. All terms in this SMQ are narrow.

**CR Number: 2019143063** **Implementation Date:** 10-Jun-19 Related CR: 2019143063

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Peripheral vein thrombus extension* | Approved as Requested | Proposed PT | |
| To SMQ | *Embolic and thrombotic events, venous (SMQ)* | | *Peripheral vein thrombus extension* | 10082853 |
| Term scope | *Narrow* | | To SMQ | |
| | | | *Embolic and thrombotic events, venous (SMQ)* | 20000084 |
| | | | Term scope | |
| | | | *Narrow* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Peripheral vein thrombus extension to Embolic and thrombotic events, venous (SMQ) as a narrow term is approved as requested. This term fits the inclusion criteria of this SMQ for terms related to venous thrombosis. All terms in this SMQ are narrow scope.

# Supplemental Update Report

**CR Number: 2019143064** **Implementation Date:** 10-Jun-19 Related CR: 2019143064

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *CFTR gene mutation* | Approved as Requested | Proposed PT<br>*CFTR gene mutation* | 10082864 |
| To SMQ | *Congenital, familial and genetic disorders (SMQ)* | | To SMQ<br>*Congenital, familial and genetic disorders (SMQ)* | 20000077 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT CFTR gene mutation to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. Mutations of the CFTR gene affecting chloride ion channel function lead to dysregulation of epithelial fluid transport in the lung, pancreas and other organs, resulting in cystic fibrosis. Complications include thickened mucus in the lungs with frequent respiratory infections and pancreatic insufficiency giving rise to malnutrition and diabetes. These conditions lead to chronic disability and reduced life expectancy. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

**CR Number: 2019143065** **Implementation Date:** 10-Jun-19 Related CR: 2019143065

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Congenital LUMBAR syndrome* | Approved as Requested | Proposed PT<br>*Congenital LUMBAR syndrome* | 10082949 |
| To SMQ | *Congenital, familial and genetic disorders (SMQ)* | | To SMQ<br>*Congenital, familial and genetic disorders (SMQ)* | 20000077 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Congenital LUMBAR syndrome to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. Congenital LUMBAR syndrome is a rare group of conditions where the hallmark feature is a segmental lumbosacral hemangioma over the middle of the lower back. LUMBAR is an acronym for Lower body hemangioma and other cutaneous defects, Urogenital anomalies, Myelopathy, Bone deformities, Anorectal malformations and arterial anomalies, and Renal anomalies. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope. Similar PT PHACES syndrome is already included.

# Supplemental Update Report

**CR Number: 2019143066** **Implementation Date:** 10-Jun-19 Related CR: 2019143066

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Dacryocystocele* | Approved as Requested | Proposed PT | |
| To SMQ | *Congenital, familial and genetic disorders (SMQ)* | | *Dacryocystocele* | 10082947 Current |
| Term scope | *Narrow* | | To SMQ | |
| | | | *Congenital, familial and genetic disorders (SMQ)* | 20000077 |
| | | | Term scope | |
| | | | *Narrow* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Dacryocystocele to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. Dacryocystocele often presents shortly after birth. It occurs when the nasolacrimal duct is obstructed and amniotic fluid or mucus (secreted by lacrimal sac goblet cells) is trapped in the tear sac. Therapeutic probing is indicated in cases which are not relieved of symptoms by conservative methods and development of dacryocystitis to prevent subsequent preseptal/orbital cellulitis and sepsis. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

**CR Number: 2019143067** **Implementation Date:** 10-Jun-19 Related CR: 2019143067

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Papillon-Lefevre syndrome* | Approved as Requested | Proposed PT | |
| To SMQ | *Congenital, familial and genetic disorders (SMQ)* | | *Papillon-Lefevre syndrome* | 10082856 |
| Term scope | *Narrow* | | To SMQ | |
| | | | *Congenital, familial and genetic disorders (SMQ)* | 20000077 |
| | | | Term scope | |
| | | | *Narrow* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Papillon-Lefevre syndrome to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. Papillon-Lefevre syndrome is a very rare syndrome of autosomal recessive inheritance characterized by palmar-plantar hyperkeratosis and early onset of a severe destructive periodontitis leading to premature loss of both primary and permanent dentitions. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

# Supplemental Update Report

**CR Number: 2019143068** **Implementation Date:** 10-Jun-19 Related CR: 2019143068

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Paranasal sinus hypoplasia* | Approved as Requested | Proposed PT<br>*Paranasal sinus hypoplasia* | 10082941 |
| To SMQ | *Congenital, familial and genetic disorders (SMQ)* | | To SMQ<br>*Congenital, familial and genetic disorders (SMQ)* | 20000077 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Paranasal sinus hypoplasia to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. Hypoplasia of paranasal sinuses is a rare congenital anomaly. It can lead to problems in diagnosis, as they are commonly misdiagnosed as infections or neoplasms involving sinuses. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

**CR Number: 2019143069** **Implementation Date:** 10-Jun-19 Related CR: 2019143069

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *RPE65 gene mutation* | Approved as Requested | Proposed PT<br>*RPE65 gene mutation* | 10082888 |
| To SMQ | *Congenital, familial and genetic disorders (SMQ)* | | To SMQ<br>*Congenital, familial and genetic disorders (SMQ)* | 20000077 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT RPE65 gene mutation to Congenital, familial and genetic disorders (SMQ) as a narrow term is approved as requested. Mutations in this gene have been associated with Leber's congenital amaurosis type 2 (LCA2) and retinitis pigmentosa (RP). These abnormalities block the visual cycle, which leads to severe visual impairment beginning very early in life. This term fits the inclusion criteria for this SMQ which includes all PTs in SOC Congenital, familial and genetic disorders. All terms in this SMQ are narrow in scope.

# Supplemental Update Report

**CR Number: 2019143070** **Implementation Date:** 10-Jun-19 Related CR: 2019143070

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Kohler's disease* | Approved as Requested | Proposed PT<br>*Kohler's disease* | 10082910 |
| To SMQ | *Osteonecrosis (SMQ)* | | To SMQ<br>*Osteonecrosis (SMQ)* | 20000180 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Kohler's disease to Osteonecrosis (SMQ) as a narrow term is approved as requested. Kohler's disease is a rare bone disorder of the foot in children (usually ages 3-7) that may be related to a stress-related compression injury in the setting of underlying delayed bone ossification. As a result, foot's tarsal navicular bone temporarily develops avascular necrosis/ osteonecrosis. This term fits the inclusion criteria for narrow terms in this SMQ. Narrow PT Mueller-Weiss syndrome in this SMQ is considered as the adult-onset avascular necrosis/ osteonecrosis of the tarsal navicular bone in the foot.

**CR Number: 2019143071** **Implementation Date:** 10-Jun-19 Related CR: 2019143071

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Gelastic seizure* | Approved as Requested | Proposed PT<br>*Gelastic seizure* | 10082918 |
| To SMQ | *Convulsions (SMQ)* | | To SMQ<br>*Convulsions (SMQ)* | 20000079 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Gelastic seizure to Convulsions (SMQ) as a narrow term is approved as requested. Gelastic seizures are focal (or partial) seizures that start in an area at the base of the brain called the hypothalamus. Patients with gelastic seizures have seizure events characterized by bouts of uncontrolled laughing or giggling. Since the term represents a specific type of seizure, it will be included in the narrow search terms of this SMQ.

# Supplemental Update Report

**CR Number: 2019143072** **Implementation Date:** 10-Jun-19 Related CR: 2019143072

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Computerised tomogram pancreas abnormal* | Approved as Requested | Proposed PT<br>*Computerised tomogram pancreas abnormal* | 10082936 |
| To SMQ | *Acute pancreatitis (SMQ)* | | To SMQ<br>*Acute pancreatitis (SMQ)* | 20000022 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*B* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Computerised tomogram pancreas abnormal to Acute pancreatitis (SMQ) as a broad category B term is approved as requested. Computerised tomography is a non-invasive method of diagnosis in acute pancreatitis and is especially valuable in diagnosing the complications of the disease.

**CR Number: 2019143073** **Implementation Date:** 10-Jun-19 Related CR: 2019143073

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Bile duct reconstruction* | Approved as Requested | Proposed PT<br>*Bile duct reconstruction* | 10082921 |
| To SMQ | *Biliary tract disorders (SMQ)* | | To SMQ<br>*Biliary tract disorders (SMQ)* | 20000125 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Bile duct reconstruction to Biliary tract disorders (SMQ) as a narrow term is approved as requested. Biliary reconstruction describes a variety of surgical procedures to replace portions of the biliary (bile delivery) system that are missing at birth or damaged due to illness such as resection of biliary malignancies, benign biliary strictures, intraoperative injury, and liver transplantation.

# Supplemental Update Report

**CR Number: 2019143074** **Implementation Date:** 10-Jun-19 Related CR: 2019143074

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Biliary catheter insertion* | Approved as Requested | Proposed PT<br>*Biliary catheter insertion* | 10082920 |
| To SMQ | *Biliary tract disorders (SMQ)* | | To SMQ<br>*Biliary tract disorders (SMQ)* | 20000125 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Biliary catheter insertion to Biliary tract disorders (SMQ) as a narrow term is approved as requested. Insertion of a biliary catheter is performed for biliary drainage in cases of blockage of the bile ducts due to gallstones impacted in the ducts, narrowing in the bile ducts after previous surgery and involvement of cancer in the ducts.

**CR Number: 2019143075** **Implementation Date:** 10-Jun-19 Related CR: 2019143075

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Biliary catheter removal* | Approved as Requested | Proposed PT<br>*Biliary catheter removal* | 10081197 |
| To SMQ | *Biliary tract disorders (SMQ)* | | To SMQ<br>*Biliary tract disorders (SMQ)* | 20000125 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Biliary catheter removal to Biliary tract disorders (SMQ) as a narrow term is approved as requested. Insertion of a biliary catheter is performed for biliary drainage in cases of blockage of the bile ducts due to gallstones impacted in the ducts, narrowing in the bile ducts after previous surgery and involvement of cancer in the ducts. The posterior removal of such a catheter can help to retrieve cases of biliary tract disorder, and this term should be added to the SMQ.

# Supplemental Update Report

**CR Number: 2019143076** **Implementation Date:** 10-Jun-19 Related CR: 2019143076

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Anal eczema* | Approved as Requested | Proposed PT<br>*Anal eczema* | 10078682 |
| To SMQ | *Gastrointestinal nonspecific inflammation (SMQ)* | | To SMQ<br>*Gastrointestinal nonspecific inflammation (SMQ)* | 20000138 |
| Term scope | *Broad* | | Term scope<br>*Broad* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Anal eczema to Gastrointestinal nonspecific inflammation (SMQ) as a broad term is approved as requested. Anal and perianal eczema can develop as a form of contact dermatitis frequently attributed to appliance of topical drugs (ointments). It has also been widely reported as a mucocutaneous reaction that results from the systemic exposure to beta-lactam antibiotics and other drugs (baboon syndrome). Similarly to PT Anal inflammation, Anal eczema should be added to the broad search of this SMQ, which is meant for gathering and ordering a number of gastrointestinal non-specific conditions.

**CR Number: 2019143077** **Implementation Date:** 10-Jun-19 Related CR: 2019143077

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Anastomotic erosion* | Approved as Requested | Proposed PT<br>*Anastomotic erosion* | 10082905 |
| To SMQ | *Gastrointestinal ulceration (SMQ)* | | To SMQ<br>*Gastrointestinal ulceration (SMQ)* | 20000106 |
| Term scope | *Narrow* | | Term scope<br>*Narrow* | |
| | | | Term_category<br>*A* | |
| | | | Term_weight<br>*0* | |

MSSO Comment: The proposal to add PT Anastomotic erosion to Gastrointestinal ulceration (SMQ) as a narrow term is approved as requested. Anastomotic erosion is a complication after gastrointestinal anastomosis procedures. Gastrointestinal erosions are included in this SMQ, with only narrow terms in it.

# Supplemental Update Report

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

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

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Glycogen storage disease type IXa* | Approved as Requested | Proposed LLT | |
| To PT | *Glycogen storage disease type IX* | | *Glycogen storage disease type IXa* | 10083035 Current |
| | | | To PT | |
| | | | *Glycogen storage disease type IX* | 10083034 |

MSSO Comment:

# Supplemental Update Report

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

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Glycogen storage disease type IXb* | Approved as Requested | Proposed LLT | |
| To PT | *Glycogen storage disease type IX* | | *Glycogen storage disease type IXb* | 10083036 Current |
| | | | To PT | |
| | | | *Glycogen storage disease type IX* | 10083034 |

MSSO Comment:

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

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Trousseau's syndrome* | Approved as Requested | PT to merge | |
| To PT | *Thrombophlebitis migrans* | | *Trousseau's syndrome* | 10060905 Current |
| | | | To PT | |
| | | | *Thrombophlebitis migrans* | 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.

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

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Thrombophlebitis migrans* | Approved as Requested | Proposed PT | |
| To HLT | *Paraneoplastic syndromes NEC* | | *Thrombophlebitis migrans* | 10043581 |
| | | | To HLT | |
| | | | *Paraneoplastic syndromes NEC* | 10067229 |

MSSO Comment:

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# Supplemental Update Report

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

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| 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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| 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

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| 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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| 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

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

MSSO Comment: The proposal to 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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Uveitis immune-mediated* | 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

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Immune-mediated pancreatitis* | Approved as Requested | Proposed PT | |
| HLT primary | *Acute and chronic pancreatitis* | | *Immune-mediated pancreatitis* | 10083072 |
| SOC primary | *Gastrointestinal disorders* | | HLT primary | |
| | | | *Acute and chronic pancreatitis* | 10033646 |
| | | | SOC primary | |
| | | | *Gastrointestinal disorders* | 10017947 |
| | | | 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 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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Pancreatitis immune-mediated* | 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

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Immune-mediated myositis* | Approved as Requested | Proposed PT | |
| HLT primary | *Muscle infections and inflammations* | | *Immune-mediated myositis* | 10083073 |
| SOC primary | *Musculoskeletal and connective tissue disorders* | | HLT primary | |
| | | | *Muscle infections and inflammations* | 10021992 |
| | | | SOC primary | |
| | | | *Musculoskeletal and connective tissue disorders* | 10028395 |
| | | | 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 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

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Immune-mediated necrotising myopathy* | Approved as Requested | PT to merge | |
| To PT | *Immune-mediated myositis* | | *Immune-mediated necrotising myopathy* | 10072155 Current |
| | | | To PT | |
| | | | *Immune-mediated myositis* | 10083073 |

MSSO Comment:

# Supplemental Update Report

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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Myositis immune-mediated* | 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.

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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Immune-mediated encephalitis* | Approved as Requested | Proposed PT | |
| | | | *Immune-mediated encephalitis* | 10083074 |
| | | | HLT primary | |
| | | | *Encephalitis NEC* | 10014599 |
| | | | SOC primary | |
| | | | *Nervous system disorders* | 10029205 |
| | | | HLT secondary | |
| | | | *Immune and associated conditions NEC* | 10027682 |
| | | | SOC secondary | |
| | | | *Immune system disorders* | 10021428 |

MSSO Comment: The proposal to add a new term Immune-mediated 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.

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

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Encephalitis immune-mediated* | Rejected | | |
| HLT primary | *Encephalitis NEC* | | | |
| SOC primary | *Nervous system disorders* | | | |

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 encepalitis.

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# Supplemental Update Report

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

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Immune-mediated hypothyroidism* | Approved as Requested | Proposed PT | |
| HLT primary | *Thyroid hypofunction disorders* | | *Immune-mediated hypothyroidism* | 10083075 |
| SOC primary | *Endocrine disorders* | | HLT primary | |
| | | | *Thyroid hypofunction disorders* | 10043741 |
| | | | 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 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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Hypothyroidism immune-mediated* | 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

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Myocarditis immune-mediated* | Rejected | | |
| To PT | *Immune-mediated myocarditis* | | | |

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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Levoscoliosis* | Approved as Requested | Proposed LLT<br>*Levoscoliosis* | 10083076 Current |
| | | | To PT<br>*Scoliosis* | 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

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Intrathecal infusion pump user* | Approved as Requested | Proposed PT<br>*Intrathecal infusion pump user* | 10083063 |
| HLT primary | *Disability issues* | | HLT primary<br>*Disability issues* | 10057171 |
| SOC primary | *Social circumstances* | | SOC primary<br>*Social circumstances* | 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

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Tetraparesis* | Approved as Requested | Proposed LLT<br>*Tetraparesis* | 10083066 Current |
| To PT | *Quadriparesis* | | To PT<br>*Quadriparesis* | 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

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

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.

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

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Hypertrophied anal papillae resection* | Approved as Requested | Proposed LLT | |
| | | | *Hypertrophied anal papillae resection* | 10083064 Current |
| | | | To PT | |
| | | | *Anal skin tag excision* | 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.

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

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

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.

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# Supplemental Update Report

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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Swelling of retina* | Approved as Requested | Proposed LLT | |
| | | | *Swelling of retina* | 10083080 Current |
| | | | To PT | |
| | | | *Retinal oedema* | 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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Macular swelling* | Approved as Requested | Proposed LLT | |
| | | | *Macular swelling* | 10083081 Current |
| | | | To PT | |
| | | | *Macular oedema* | 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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Right atrial volume abnormal* | Approved as Requested | Proposed PT | |
| | | | *Right atrial volume abnormal* | 10083077 |
| | | | HLT primary | |
| | | | *Cardiac function diagnostic procedures* | 10007566 |
| | | | SOC primary | |
| | | | *Investigations* | 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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Right atrial volume increased* | Approved as Requested | Proposed PT | |
| | | | *Right atrial volume increased* | 10083079 |
| | | | HLT primary | |
| | | | *Cardiac function diagnostic procedures* | 10007566 |
| | | | SOC primary | |
| | | | *Investigations* | 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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Right atrial volume decreased* | Approved as Requested | Proposed PT | |
| | | | *Right atrial volume decreased* | 10083078 |
| | | | HLT primary | |
| | | | *Cardiac function diagnostic procedures* | 10007566 |
| | | | SOC primary | |
| | | | *Investigations* | 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

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Chest myalgia* | 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

**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.

**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 an useful plasma biomarker associated with cardiovascular disease. Lipoprotein-associated phospholipase A2 will be added as PT to HLT Tissue enzyme analyses NEC.

**CR Number: 2019148001** **Implementation Date:** 31-May-19 Related CR: 2019148001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Prolonged cytopenia* | Approved as Requested | Proposed LLT | |
| | | | *Prolonged cytopenia* | 10083092 Current |
| | | | To PT | |
| | | | *Cytopenia* | 10066274 |

MSSO Comment: The proposal to add a new LLT Prolonged cytopenia is approved as requested. The concept of prolonged cytopenia referring to the persistent decrease in the number of peripheral cells of one or more blood lineages has been traditionally used in relation to myelodysplastic syndromes (prolonged, persistent or refractory cytopenia) and other medical conditions, but also in relation to treatments for haematological malignancies. Prolonged cytopenia will be added as a sub-concept LLT to PT Cytopenia.

# Supplemental Update Report

**CR Number: 2019148002** **Implementation Date:** 07-Jun-19 Related CR: 2019148002

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pneumatosis intestinalis* | Rejected | | |
| To SMQ | *Gastrointestinal perforation (SMQ)* | | | |
| Term scope | *Narrow* | | | |

MSSO Comment: The proposal to add PT Pneumatosis intestinalis to Gastrointestinal perforation (SMQ) as a narrow term is not approved. Pneumatosis intestinalis is not a primary gastrointestinal disease, but rather a clinical sign with multifactorial pathogenesis. It is not specific for gastrointestinal perforation, but bowel ischemia seems to be the most common cause.

**CR Number: 2019148003** **Implementation Date:** 07-Jun-19 Related CR: 2019148003

| Change Requested | Add term to SMQ | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pneumatosis intestinalis* | Approved Not as Requested | Proposed PT | |
| To SMQ | *Gastrointestinal perforation, ulcer, haemorrhage, obstruction non-specific findings/procedures (SMQ)* | | *Pneumatosis intestinalis* | 10057030 |
| Term scope | *Narrow* | | To SMQ | |
| | | | *Gastrointestinal perforation, ulcer, haemorrhage, obstruction non-specific findings/procedures (SMQ)* | 20000104 |
| | | | Term scope | |
| | | | *Broad* | |
| | | | Term_category | |
| | | | *A* | |
| | | | Term_weight | |
| | | | *0* | |

MSSO Comment: The proposal to add PT Pneumatosis intestinalis to Gastrointestinal perforation, ulcer, haemorrhage, obstruction non-specific findings/procedures (SMQ) as a narrow term is approved but not as requested. Pneumatosis intestinalis will be added as a broad scope term because it is a finding that is non-specific for perforation, ulceration, haemorrhage or obstruction. A similar term PT X-ray gastrointestinal tract abnormal is already included as a broad scope term.

# Supplemental Update Report

**CR Number: 2019148004** **Implementation Date:** 31-May-19 Related CR: 2019148004

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Septic pulmonary embolism* | Approved as Requested | Proposed PT | |
| | | | *Septic pulmonary embolism* | 10083093 |
| HLT primary | *Sepsis, bacteraemia, viraemia and fungaemia NEC* | | HLT primary | |
| | | | *Sepsis, bacteraemia, viraemia and fungaemia NEC* | 10040054 |
| SOC primary | *Infections and infestations* | | SOC primary | |
| | | | *Infections and infestations* | 10021881 |
| | | | HLT secondary | |
| | | | *Pulmonary embolism and thrombosis* | 10037379 |
| | | | SOC secondary | |
| | | | *Vascular disorders* | 10047065 |

MSSO Comment: The proposal to add a new PT Septic pulmonary embolism to primary HLT Sepsis, bacteraemia, viraemia and fungaemia NEC in SOC Infections and infestations and secondary HLT Pulmonary embolism and thrombosis in SOC Vascular disorders is approved as requested. Septic pulmonary embolism is an uncommon disease in which septic thrombi are mobilised from an infectious nidus and transported in the vascular system of the lungs. It is usually associated with tricuspid valve vegetation, septic thrombophlebitis or infected venous catheters. New PT Septic pulmonary embolism will also be linked secondary HLT Pulmonary thrombotic and embolic conditions.

**CR Number: 2019151033** **Implementation Date:** 31-May-19 Related CR: 2019148004

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Septic pulmonary embolism* | Approved as Requested | Proposed PT | |
| | | | *Septic pulmonary embolism* | 10083093 |
| To HLT | *Pulmonary thrombotic and embolic conditions* | | To HLT | |
| | | | *Pulmonary thrombotic and embolic conditions* | 10037439 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019148012** **Implementation Date:** 31-May-19 Related CR: 2019148012

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Decreased lung diffusion function* | Approved Not as Requested | Proposed PT | |
| | | | *Lung diffusion test decreased* | 10083094 |
| | | | HLT primary | |
| | | | *Pulmonary thrombotic and embolic conditions* | 10037439 |
| | | | SOC primary | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |

MSSO Comment: The proposal to add a new term Decreased lung diffusion function is approved but not as requested. Lung diffusion function test is an assessment of the diffusing capacity of the lungs for carbon monoxide (also known as carbon monoxide diffusing capacity, and transfer factor for carbon monoxide), is a clinically valuable test of lung function. It is a calculated, derived value that indirectly assesses the ability of the lungs to “transfer” oxygen to blood through the use of a test gas (namely, CO) that has a greater affinity for blood hemoglobin. Decreased lung diffusion function will be rephrased as Lung diffusion test decreased in accordance with the standard format of investigational terms, and will be added as a PT to HLT Pulmonary thrombotic and embolic conditions. In a related change, the recently added LLT Lung diffusion test abnormal will be promoted from PT Carbon monoxide diffusing capacity decreased to PT level and linked to HLT Pulmonary thrombotic and embolic conditions. Furthermore, PT Carbon monoxide diffusing capacity decreased will be merged under the new PT Lung diffusion test decreased.

**CR Number: 2019151034** **Implementation Date:** 31-May-19 Related CR: 2019148012

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Lung diffusion test abnormal* | Approved as Requested | Proposed LLT | | |
| From PT | *Carbon monoxide diffusing capacity decreased* | | *Lung diffusion test abnormal* | 10082576 | |
| HLT primary | *Pulmonary thrombotic and embolic conditions* | | From PT | | |
| | | | *Carbon monoxide diffusing capacity decreased* | 10065906 | Current |
| | | | HLT primary | | |
| | | | *Pulmonary thrombotic and embolic conditions* | 10037439 | |
| | | | SOC primary | | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 | |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019151035** **Implementation Date:** 31-May-19 Related CR: 2019148012

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Carbon monoxide diffusing capacity decreased* | Approved as Requested | PT to merge | |
| To PT | *Lung diffusion test decreased* | | *Carbon monoxide diffusing capacity decreased* | 10065906 Current |
| | | | To PT | |
| | | | *Lung diffusion test decreased* | 10083094 |

MSSO Comment:

**CR Number: 2019148013** **Implementation Date:** 31-May-19 Related CR: 2019148013

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Lung diffusion disorder* | Approved as Requested | Proposed PT | |
| | | | *Lung diffusion disorder* | 10083095 |
| | | | HLT primary | |
| | | | *Respiratory tract disorders NEC* | 10057184 |
| | | | SOC primary | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |

MSSO Comment: The proposal to add a new term Lung diffusion disorder is approved as requested. Lung diffusion disorder is a clinical description of an abnormal respiratory physiological status of a patient. Diffusing capacity of the lung is the transfer of gas from air in the lung, to the red blood cells in lung blood vessels. Lung diffusion disorder will be added as a PT to HLT Respiratory tract disorders NEC.

# Supplemental Update Report

**CR Number: 2019148021** **Implementation Date:** 31-May-19 Related CR: 2019148021

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Membranous-like glomerulopathy with masked IgG-kappa deposits (MGMID)* | Approved Not as Requested | Proposed PT | |
| | | | *Membranous-like glomerulopathy with masked IgG-kappa deposits* | 10083098 |
| | | | HLT primary | |
| | | | *Glomerulonephritis and nephrotic syndrome* | 10018365 |
| | | | 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 Membranous-like glomerulopathy with masked IgG-kappa deposits (MGMID) is approved but not as requested. Membranous-like glomerulopathy with masked IgG-kappa deposits is a distinct variant of membranous glomerulopathy and a separate clinicopathologic entity. The patients are most commonly young female individuals <40 years of age with positive autoimmune serologic study results such as ANA, although a few carry a diagnosis of any well-defined autoimmune disease such as lupus. Membranous-like glomerulopathy with masked IgG-kappa deposits, without the acronym (MGMID), will be added as a new PT to primary HLT Glomerulonephritis and nephrotic syndrome, and to secondary HLT Immune and associated conditions NEC.

**CR Number: 2019148026** **Implementation Date:** 31-May-19 Related CR: 2019148026

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Bladder ulcer* | Approved as Requested | Proposed PT | |
| | | | *Bladder ulcer* | 10083096 |
| | | | HLT primary | |
| | | | *Bladder disorders NEC* | 10005037 |
| | | | SOC primary | |
| | | | *Renal and urinary disorders* | 10038359 |

MSSO Comment: The proposal to add a new term Bladder ulcer is approved as requested. Bladder ulcers may result from a number of etiologies, such as direct chemical exposure or as secondary lesions associated with inflammation, calculi, or tumors. Bladder ulcer will be added as a PT to HLT Bladder disorders NEC.

# Supplemental Update Report

**CR Number: 2019148027** **Implementation Date:** 31-May-19 Related CR: 2019148027

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Orbital space occupying lesion* | Approved as Requested | Proposed PT | |
| | | | *Orbital space occupying lesion* | 10083097 |
| | | | HLT primary | |
| | | | *Ocular disorders NEC* | 10030032 |
| | | | SOC primary | |
| | | | *Eye disorders* | 10015919 |

MSSO Comment: The proposal to add a new term Orbital space occupying lesion is approved as requested. Orbital space occupying lesion is an unique medical concept and an important sign for several diseases such as chronic lymphocytic leukemia, ermoid cysts, cavernous hemangioma, non-Hodgkin lymphoma basal cell carcinoma, orbital metastases etc. Orbital space occupying lesion will be added as a PT to HLT Ocular disorders NEC.

**CR Number: 2019149012** **Implementation Date:** 03-Jun-19 Related CR: 2019149012

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Auricular chondritis* | Approved Not as Requested | Proposed PT | |
| To PT | *Chondritis* | | *Auricular chondritis* | 10083111 |
| | | | HLT primary | |
| | | | *External ear infections and inflammations* | 10015734 |
| | | | SOC primary | |
| | | | *Ear and labyrinth disorders* | 10013993 |
| | | | HLT secondary | |
| | | | *Cartilage disorders* | 10007709 |
| | | | SOC secondary | |
| | | | *Musculoskeletal and connective tissue disorders* | 10028395 |

MSSO Comment: The proposal to add a new LLT Auricular chondritis to PT Chondritis is approved but not as requested. Auricular chondritis, inflammation of the cartilage of the external ear, has been observed to be associated mainly with immunologic and traumatic etiologies. Auricular chondritis will be added as a PT, since it is a well described clinical entity, to primary HLT External ear infections and inflammations and to secondary HLT Cartilage disorders.

# Supplemental Update Report

**CR Number: 2019149013** **Implementation Date:** 03-Jun-19 Related CR: 2019149013

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Acute bacterial exacerbation of chronic sinusitis* | Approved as Requested | Proposed LLT | |
| To PT | *Sinusitis bacterial* | | *Acute bacterial exacerbation of chronic sinusitis* | 10083113 Current |
| | | | To PT | |
| | | | *Sinusitis bacterial* | 10060841 |

MSSO Comment: The proposal to add a new LLT Acute bacterial exacerbation of chronic sinusitis to PT Sinusitis bacterial is approved as requested. Acute exacerbation of chronic sinusitis represents a sudden worsening of baseline chronic sinusitis with either worsening or new symptoms. The microbiology of acute sinusitis is well established where the major pathogens are aerobic and facultative bacteria—Streptococcus pneumoniae, Haemophilus influenzae, and Moraxella catarrhalis.

**CR Number: 2019149014** **Implementation Date:** 03-Jun-19 Related CR: 2019149014

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Drug implant ineffective* | Approved as Requested | Proposed LLT | |
| From PT | *Device ineffective* | | *Drug implant ineffective* | 10080409 Current |
| To PT | *Therapeutic product ineffective* | | From PT | |
| | | | *Device ineffective* | 10059875 |
| | | | To PT | |
| | | | *Therapeutic product ineffective* | 10060769 |

MSSO Comment: The proposal to move the LLT Drug implant ineffective from PT Device ineffective to PT Therapeutic product ineffective is approved as requested. Because a drug implant may be comprised of a drug only, or a drug and a device, LLT Drug implant ineffective is better placed under the broader concept PT Therapeutic product ineffective.

**CR Number: 2019149015** **Implementation Date:** 03-Jun-19 Related CR: 2019149015

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Premenstrual abdominal pain* | Approved as Requested | Proposed LLT | |
| To PT | *Premenstrual pain* | | *Premenstrual abdominal pain* | 10083117 Current |
| | | | To PT | |
| | | | *Premenstrual pain* | 10065347 |

MSSO Comment: The proposal to add a new LLT Premenstrual abdominal pain to PT Premenstrual pain is approved as requested. Premenstrual pain in the lower abdomen has been described in association with both premenstrual syndrome and premenstrual dysphoric disorder. Premenstrual abdominal pain and premenstrual cramps are generally used in a synonymous manner. In a related change, PT Premenstrual cramps will be demoted under PT Premenstrual pain.

# Supplemental Update Report

**CR Number: 2019154002** **Implementation Date:** 03-Jun-19 Related CR: 2019149015

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Premenstrual cramps* | Approved as Requested | PT to merge | |
| To PT | *Premenstrual pain* | | *Premenstrual cramps* | 10065309 Current |
| | | | To PT | |
| | | | *Premenstrual pain* | 10065347 |

MSSO Comment:

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**CR Number: 2019149016** **Implementation Date:** 03-Jun-19 Related CR: 2019149016

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Premenstrual breast pain* | Approved as Requested | Proposed LLT | |
| | | | *Premenstrual breast pain* | 10083114 Current |
| | | | To PT | |
| | | | *Premenstrual pain* | 10065347 |

MSSO Comment: The proposal to add a new term Premenstrual breast pain is approved as requested. Premenstrual breast swelling and tenderness, or cyclical mastalgia, is a common symptom during the premenstrual period. Premenstrual breast pain will be added as an LLT to PT Premenstrual pain.

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**CR Number: 2019149017** **Implementation Date:** 03-Jun-19 Related CR: 2019149017

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Premenstrual back pain* | Approved as Requested | Proposed LLT | |
| To PT | *Premenstrual pain* | | *Premenstrual back pain* | 10083118 Current |
| | | | To PT | |
| | | | *Premenstrual pain* | 10065347 |

MSSO Comment: The proposal to add a new LLT Premenstrual back pain to PT Premenstrual pain is approved as requested. Premenstrual back pain is a common location of pain during the premenstrual period.

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# Supplemental Update Report

**CR Number: 2019149018** **Implementation Date:** 03-Jun-19 Related CR: 2019149018

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Premenstrual pelvic pain* | Approved as Requested | Proposed LLT | |
| To PT | *Premenstrual pain* | | *Premenstrual pelvic pain* | 10083115 Current |
| | | | To PT | |
| | | | *Premenstrual pain* | 10065347 |

MSSO Comment: The proposal to add a new LLT Premenstrual pelvic pain to PT Premenstrual pain is approved as requested. Premenstrual pelvic pain is a common location of pain during the premenstrual period.

**CR Number: 2019149019** **Implementation Date:** 03-Jun-19 Related CR: 2019149019

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Inadvertent intra-ocular air bubble* | Approved Not as Requested | Proposed LLT | |
| To PT | *Intra-ocular injection complication* | | *Inadvertent intra-ocular injection air bubble* | 10083116 Current |
| | | | To PT | |
| | | | *Intra-ocular injection complication* | 10081061 |

MSSO Comment: The proposal to add a new LLT Inadvertent intra-ocular air bubble to PT Intra-ocular injection complication is approved but not as requested. An inadvertent intra-ocular injection air bubble may result from the introduction of air into the eye as a complication of intraocular injections of therapeutic agents. The proposed term will be re-named as Inadvertent intra-ocular injection air bubble, because intra-ocular bubbles may occur from a variety of intra-ocular procedures, and will be added as a sub-concept LLT to PT Intra-ocular injection complication.

**CR Number: 2019149020** **Implementation Date:** 03-Jun-19 Related CR: 2019149020

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Inadvertent intravitreal air bubble* | Approved Not as Requested | Proposed LLT | |
| To PT | *Intra-ocular injection complication* | | *Inadvertent intravitreal injection air bubble* | 10083119 Current |
| | | | To PT | |
| | | | *Intra-ocular injection complication* | 10081061 |

MSSO Comment: The proposal to add a new LLT Inadvertent intravitreal air bubble to PT Intra-ocular injection complication is approved but not as requested. An inadvertent intravitreal injection air bubble may result from the introduction of air into the eye as a complication of intraocular injections of therapeutic agents. The proposed term will be re-named as Inadvertent intravitreal injection air bubble, because intra-ocular bubbles may occur from a variety of intra-ocular procedures, and will be added as a sub-concept LLT to PT Intra-ocular injection complication.

# Supplemental Update Report

**CR Number: 2019149021** **Implementation Date:** 03-Jun-19 Related CR: 2019149021

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Vascular access site erythema* | Approved as Requested | Proposed PT | |
| | | | *Vascular access site erythema* | 10083109 |
| | | | HLT primary | |
| | | | *Cardiac and vascular procedural complications* | 10007602 |
| | | | SOC primary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |
| | | | HLT secondary | |
| | | | *Erythemas* | 10015151 |
| | | | SOC secondary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment: The proposal to add a new term Vascular access site erythema is approved as requested. Vascular access sites often entail an arteriovenous fistula, an arteriovenous graft, a peripherally inserted central catheter line, or a temporary venous catheter. Erythema may develop at the vicinity of the vascular access site from a variety of causes, including infection, an inflammatory reaction to a vascular access device or infusion agent, etc. Vascular access site erythema will be added as a new PT to primary HLT Cardiac and vascular procedural complications, to secondary HLT Erythemas, and to secondary HLT Vascular complications associated with device.

**CR Number: 2019154003** **Implementation Date:** 03-Jun-19 Related CR: 2019149021

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vascular access site erythema* | Approved as Requested | Proposed PT | |
| | | | *Vascular access site erythema* | 10083109 |
| To HLT | *Vascular complications associated with device* | | To HLT | |
| | | | *Vascular complications associated with device* | 10069789 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019149022** **Implementation Date:** 03-Jun-19 Related CR: 2019149022

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Vascular access site pruritus* | Approved as Requested | Proposed PT | |
| | | | *Vascular access site pruritus* | 10083112 |
| | | | HLT primary | |
| | | | *Cardiac and vascular procedural complications* | 10007602 |
| | | | SOC primary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |
| | | | HLT secondary | |
| | | | *Pruritus NEC* | 10049293 |
| | | | SOC secondary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment: The proposal to add a new term Vascular access site pruritus is approved as requested. Vascular access sites often entail an arteriovenous fistula, an arteriovenous graft, a peripherally inserted central catheter line, or a temporary venous catheter. Pruritus may develop at the vicinity of the vascular access site for a variety of reasons, for example, healing and scabbing following the surgical creation of the access site, irritation from an implanted device or from an infusion agent, etc. Vascular access site pruritus will be added as a new PT to primary HLT Cardiac and vascular procedural complications, to secondary HLT Pruritus NEC, and to secondary HLT Vascular complications associated with device.

**CR Number: 2019154004** **Implementation Date:** 03-Jun-19 Related CR: 2019149022

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Vascular access site pruritus* | Approved as Requested | Proposed PT | |
| To HLT | *Vascular complications associated with device* | | *Vascular access site pruritus* | 10083112 |
| | | | To HLT | |
| | | | *Vascular complications associated with device* | 10069789 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019149023** **Implementation Date:** 03-Jun-19 Related CR: 2019149023

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Postpolypectomy syndrome* | Approved as Requested | Proposed PT | |
| | | | *Postpolypectomy syndrome* | 10083110 |
| | | | HLT primary | |
| | | | *Gastrointestinal and hepatobiliary procedural complications* | 10017927 |
| | | | SOC primary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |
| | | | HLT secondary | |
| | | | *Gastrointestinal inflammatory disorders NEC* | 10017921 |
| | | | SOC secondary | |
| | | | *Gastrointestinal disorders* | 10017947 |

MSSO Comment: The proposal to add a new term Postpolypectomy syndrome is approved as requested. Postpolypectomy syndrome results from electrocoagulation injury to the colonic mucosa and the underlying muscularis layer, which causes transmural burn with concurrent inflammation of the peritoneum without evidence of colonic perforation on imaging studies. Patients with post-polypectomy electrocoagulation syndrome typically present within 12 hours following a colonoscopy with fever, tachycardia, and generalized abdominal pain. Postpolypectomy syndrome will be added to primary HLT Gastrointestinal and hepatobiliary procedural complications, and to secondary HLT Gastrointestinal inflammatory disorders NEC. In a related change, Post-polypectomy electrocoagulation syndrome will be added as a synonym LLT to new PT Postpolypectomy syndrome.

**CR Number: 2019154005** **Implementation Date:** 03-Jun-19 Related CR: 2019149023

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Post-polypectomy electrocoagulation syndrome* | Approved as Requested | Proposed LLT | |
| To PT | *Postpolypectomy syndrome* | | *Post-polypectomy electrocoagulation syndrome* | 10083120 Current |
| | | | To PT | |
| | | | *Postpolypectomy syndrome* | 10083110 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019149024** **Implementation Date:** 31-May-19 Related CR: 2019149024

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Hypotonia-Cystinuria Syndrome* | Approved Not as Requested | Proposed PT<br>*Hypotonia-cystinuria syndrome* | 10083099 |
| | | | HLT primary<br>*Inborn errors of amino acid metabolism* | 10021602 |
| | | | SOC primary<br>*Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary<br>*Inborn errors of amino acid metabolism* | 10021602 |
| | | | SOC secondary<br>*Metabolism and nutrition disorders* | 10027433 |

MSSO Comment: The proposal to add a new LLT Hypotonia-Cystinuria Syndrome is approved but not as requested. Hypotonia-Cystinuria syndrome (HCS) is a rare syndrome including neonatal and infantile hypotonia and failure to thrive, cystinuria type 1 and nephrolithiasis, growth retardation due to growth hormone deficiency, and minor facial dysmorphism. Hypotonia-cystinuria syndrome,in accordance with MedDRA capitalisation conventions, will be added as PT to primary HLT Inborn errors of amino acid metabolism, bi-axial to primary SOC Congenital, familial and genetic disorders and secondary SOC Metabolism and nutrition disorders and also linked to secondary HLT Renal lithiasis, secondary HLT Muscle tone abnormal, and secondary HLT Muscle tone abnormalities.

**CR Number: 2019151036** **Implementation Date:** 31-May-19 Related CR: 2019149024

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Hypotonia-cystinuria syndrome* | Approved as Requested | Proposed PT<br>*Hypotonia-cystinuria syndrome* | 10083099 |
| To HLT | *Renal lithiasis* | | To HLT<br>*Renal lithiasis* | 10038478 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019151037** **Implementation Date:** 31-May-19 Related CR: 2019149024

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Hypotonia-cystinuria syndrome* | Approved as Requested | Proposed PT | |
| To HLT | *Muscle tone abnormal* | | *Hypotonia-cystinuria syndrome* | 10083099 |
| | | | To HLT | |
| | | | *Muscle tone abnormal* | 10028342 |

MSSO Comment:

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**CR Number: 2019151038** **Implementation Date:** 31-May-19 Related CR: 2019149024

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Hypotonia-cystinuria syndrome* | Approved as Requested | Proposed PT | |
| To HLT | *Muscle tone abnormalities* | | *Hypotonia-cystinuria syndrome* | 10083099 |
| | | | To HLT | |
| | | | *Muscle tone abnormalities* | 10028343 |

MSSO Comment:

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**CR Number: 2019149025** **Implementation Date:** 31-May-19 Related CR: 2019149025

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Pfannenstiel incision* | Approved as Requested | Proposed LLT | |
| | | | *Pfannenstiel incision* | 10083100 Current |
| | | | To PT | |
| | | | *Laparotomy* | 10023696 |

MSSO Comment: The proposal to add a new LLT Pfannenstiel incision is approved as requested. Pfannenstiel incision, Kerr incision, is a type of abdominal surgical incision that allows access to the abdomen. It is used for gynecologic and orthopedics surgeries, and it is the most common method for performing Caesarian sections today. The surgeon cuts on a generally horizontal (slightly curved) line just above the pubic symphysis. This incision is commonly called the "bikini line incision". Pfannenstiel incision will be added as sub-concept LLT to PT Laparotomy as it represents a specific technique on how the cut of a laparatomy procedure is performed.

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# Supplemental Update Report

**CR Number: 2019149027** **Implementation Date:** 31-May-19 Related CR: 2019149027

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Tracheal collapse* | Approved Not as Requested | Proposed LLT | |
| HLT primary | *Tracheal disorders (excl infections and neoplasms)* | | *Tracheal collapse* | 10083101 Current |
| SOC primary | *Respiratory, thoracic and mediastinal disorders* | | To PT | |
| | | | *Tracheomalacia* | 10056397 |

MSSO Comment: The proposal to add a new PT Tracheal collapse to primary HLT Tracheal disorders (excl infections and neoplasms) in SOC Respiratory, thoracic and mediastinal disorders is approved but not as requested. Tracheomalacia is a rare condition that happens when the cartilage of the windpipe, or trachea, is soft, weak and floppy. This can cause the tracheal wall to collapse and block the airway, making it hard to breathe. Tracheal collapse will be added as a sub-concept LLT to PT Tracheomalacia.

**CR Number: 2019149028** **Implementation Date:** 05-Jun-19 Related CR: 2019149028

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Biloma infected* | Approved Not as Requested | Proposed PT | |
| | | | *Biloma infected* | 10083160 |
| | | | HLT primary | |
| | | | *Abdominal and gastrointestinal infections* | 10017967 |
| | | | SOC primary | |
| | | | *Infections and infestations* | 10021881 |
| | | | HLT secondary | |
| | | | *Hepatic and hepatobiliary disorders NEC* | 10027681 |
| | | | SOC secondary | |
| | | | *Hepatobiliary disorders* | 10019805 |

MSSO Comment: The proposal to add a new LLT Biloma infected is approved but not as requested. A "biloma" is a loculated collection of bile located outside of the biliary tree. It can be caused by traumatic, iatrogenic or spontaneous rupture of the biliary tree. Bilomas may become infected and may result in peritonitis. Biloma infected will be added as a PT with a primary link to HLT Abdominal and gastrointestinal infections, to secondary HLT Hepatic and hepatobiliary disorders NEC, and to secondary HLT Gastrointestinal and hepatobiliary procedural complications.

# Supplemental Update Report

**CR Number: 2019156001** **Implementation Date:** 05-Jun-19 Related CR: 2019149028

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Biloma infected* | Approved as Requested | Proposed PT | |
| To HLT | *Gastrointestinal and hepatobiliary procedural complications* | | *Biloma infected* | 10083160 |
| | | | To HLT | |
| | | | *Gastrointestinal and hepatobiliary procedural complications* | 10017927 |

MSSO Comment:

**CR Number: 2019149029** **Implementation Date:** 05-Jun-19 Related CR: 2019149029

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Secondary (reactive) thrombocytosis* | Approved Not as Requested | Proposed PT | |
| | | | *Secondary thrombocytosis* | 10083158 |
| | | | HLT primary | |
| | | | *Thrombocytoses* | 10069776 |
| | | | SOC primary | |
| | | | *Blood and lymphatic system disorders* | 10005329 |

MSSO Comment: The proposal to add a new LLT Secondary (reactive) thrombocytosis is approved but not as requested. A secondary or reactive thrombocytosis is an elevated platelet count (> 450,000/mcL) that develops secondary to another disorder. Platelet function is usually normal. Unlike in essential thrombocythemia, reactive thrombocytosis does not increase the risk of thrombotic or hemorrhagic complications unless patients have severe arterial disease or prolonged immobility. Secondary thrombocytosis will be added as a PT to HLT Thrombocytoses.

# Supplemental Update Report

**CR Number: 2019149030** **Implementation Date:** 05-Jun-19 Related CR: 2019149030

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Septic coagulopathy* | Approved Not as Requested | Proposed PT | |
| | | | *Septic coagulopathy* | 10083159 |
| | | | HLT primary | |
| | | | *Sepsis, bacteraemia, viraemia and fungaemia NEC* | 10040054 |
| | | | SOC primary | |
| | | | *Infections and infestations* | 10021881 |
| | | | HLT secondary | |
| | | | *Coagulopathies* | 10053567 |
| | | | SOC secondary | |
| | | | *Blood and lymphatic system disorders* | 10005329 |

MSSO Comment: The proposal to add a new LLT Septic coagulopathy is approved but not as requested. Sepsis always leads to deranged coagulation, ranging from mild alterations up to severe disseminated intravascular coagulation (DIC). Septic patients with severe DIC can present with manifest thromboembolic disease as purpura fulminans or clinically less apparent microvascular fibrin deposition, predominantly presenting as multiple organ dysfunction. Septic coagulopathy will be added as a PT to primary HLT Sepsis, bacteraemia, viraemia and fungaemia NEC and secondary HLT Coagulopathies.

**CR Number: 2019149031** **Implementation Date:** 05-Jun-19 Related CR: 2019149031

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Escherichia peritonitis* | Approved Not as Requested | Proposed PT | |
| | | | *Escherichia peritonitis* | 10083163 |
| | | | HLT primary | |
| | | | *Escherichia infections* | 10015295 |
| | | | SOC primary | |
| | | | *Infections and infestations* | 10021881 |
| | | | HLT secondary | |
| | | | *Peritoneal infections* | 10034668 |
| | | | SOC secondary | |
| | | | *Gastrointestinal disorders* | 10017947 |

MSSO Comment: The proposal to add a new LLT Escherichia peritonitis is approved but not as requested. Escherichia coli is one of the most common organisms that cause gram-negative peritonitis in peritoneal dialysis patients, and is associated with a high probability of mortality and technique failure. Escherichia peritonitis will be added as a PT with a primary link to HLT Escherichia infections, and a secondary link to HLT Peritoneal infections.

# Supplemental Update Report

**CR Number: 2019149032** **Implementation Date:** 05-Jun-19 Related CR: 2019149032

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Leptospira sepsis* | Approved Not as Requested | Proposed PT | |
| | | | *Leptospira sepsis* | 10083161 |
| | | | HLT primary | |
| | | | *Leptospira infections* | 10024234 |
| | | | SOC primary | |
| | | | *Infections and infestations* | 10021881 |

MSSO Comment: The proposal to add a new LLT Leptospira sepsis is approved but not as requested. Leptospira sepsis represents disseminated leptospirosis that can be differentiated from Weil's disease toxemic reaction. Leptospira sepsis will be added as a PT to HLT Leptospira infections.

**CR Number: 2019149033** **Implementation Date:** 05-Jun-19 Related CR: 2019149033

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Urinary tract candidiasis* | Approved Not as Requested | Proposed PT | |
| | | | *Urinary tract candidiasis* | 10083162 |
| | | | HLT primary | |
| | | | *Candida infections* | 10007134 |
| | | | SOC primary | |
| | | | *Infections and infestations* | 10021881 |
| | | | HLT secondary | |
| | | | *Genitourinary tract infections and inflammations NEC* | 10018191 |
| | | | SOC secondary | |
| | | | *Renal and urinary disorders* | 10038359 |

MSSO Comment: The proposal to add a new LLT Urinary tract candidiasis is approved but not as requested. Urinary tract candidiasis is a valuable expression for candida infections for an undetermined location in the urinary tract. Urinary tract candidiasis will be added as a PT to primary HLT Candida infections and secondary HLT Genitourinary tract infections and inflammations NEC. In a related change, PT Candiduria will be demoted to an LLT under new PT Urinary tract candidiasis as a synonym LLT.

# Supplemental Update Report

**CR Number: 2019156002** **Implementation Date:** 05-Jun-19 Related CR: 2019149033

| Change Requested | | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Demote a PT | | | | | |
| PT to merge | *Candiduria* | Approved as Requested | PT to merge | | |
| To PT | *Urinary tract candidiasis* | | *Candiduria* | 10050762 | Current |
| | | | To PT | | |
| | | | *Urinary tract candidiasis* | 10083162 | |

MSSO Comment:

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**CR Number: 2019149034** **Implementation Date:** 05-Jun-19 Related CR: 2019149034

| Change Requested | | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Add a New LLT | | | | |
| Proposed LLT | *Post procedural rectal complication* | Rejected | | |

MSSO Comment: The proposal to add a new LLT Post procedural rectal complication is not approved. The expression "rectal complication" is too broad in meaning, even when used in a given context such as a post-procedural complication. Please consider split coding such as with LLT Rectal disorder and LLT Post procedural complication for your coding needs.

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**CR Number: 2019149035** **Implementation Date:** 07-Jun-19 Related CR: 2019149035

| Change Requested | | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Add a New LLT | | | | | |
| Proposed LLT | *Metformin associated lactaemic acidosis (MALA)* | Approved Not as Requested After Suspension | Proposed LLT | | |
| | | | *Metformin associated lactic acidosis* | 10083188 | Current |
| | | | To PT | | |
| | | | *Lactic acidosis* | 10023676 | |

MSSO Comment: The proposal to add a new LLT Metformin associated lactaemic acidosis (MALA) is approved but not as requested after suspension. Lactic acidosis induced by metformin is a typical, but rare form of type B lactic acidosis. Metformin associated lactic acidosis is used when lactic acidosis is diagnosed in a patient treated with metformin, and metformin overdose is not detected. Metformin associated lactic acidosis, renamed to the most usual expression in literature and without the parenthetical abbreviation, will be added as an LLT under PT Lactic acidosis.

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# Supplemental Update Report

**CR Number: 2019149086** **Implementation Date:** 31-May-19 Related CR: 2019149086

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Lupus headaches* | Rejected | | |
| To PT | *Migraine* | | | |

MSSO Comment: The proposal to add a new LLT Lupus headaches to PT Migraine is not approved. The proposed term is a combination term and can be represented by LLT Lupus and LLT Headache. The International Classification of Headache Disorders, in its point A10.8.2 Headache attributed to other metabolic or systemic disorder states that headaches attributed to systemic disorder (such as SLE) may occur, but are not sufficiently validated.

**CR Number: 2019149437** **Implementation Date:** 31-May-19 Related CR: 2019149437

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Fluorescence angiography* | Approved as Requested | Proposed LLT | |
| | | | *Fluorescence angiography* | 10083091 Current |
| | | | To PT | |
| | | | *Fluorescence angiogram* | 10083089 |

MSSO Comment: The proposal to add a new term Fluorescence angiography is approved as requested. Fluorescein angiography, fluorescent angiography, or fundus fluorescein angiography is a technique for examining the circulation of the retina and choroid using a fluorescent dye and a specialized camera. Fluorescence angiography will be added as an LLT to PT Fluorescence angiogram. In a related change, Fluorescence angiogram will be added as a PT to HLT Vascular imaging procedures NEC. Furthermore, PT Fluorescence angiogram abnormal and PT Fluorescence angiogram normal will both be added to HLT Vascular imaging procedures NEC. In addition, LLT Fluorescein angiography abnormal will be moved from PT Angiogram abnormal to new PT Fluorescence angiogram abnormal and LLT Fluorescein angiography normal will be moved from PT Angiogram normal to new PT Fluorescence angiogram normal. Also, LLT Indocyanine green angiography will be added to PT Fluorescence angiogram.

**CR Number: 2019151024** **Implementation Date:** 31-May-19 Related CR: 2019149437

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Fluorescence angiogram* | Approved as Requested | Proposed PT | |
| HLT primary | *Vascular imaging procedures NEC* | | *Fluorescence angiogram* | 10083089 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Vascular imaging procedures NEC* | 10047078 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019151025** **Implementation Date:** 31-May-19 Related CR: 2019149437

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Fluorescence angiogram abnormal* | Approved as Requested | Proposed PT | |
| HLT primary | *Vascular imaging procedures NEC* | | *Fluorescence angiogram abnormal* | 10083087 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Vascular imaging procedures NEC* | 10047078 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment:

**CR Number: 2019151026** **Implementation Date:** 31-May-19 Related CR: 2019149437

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Fluorescence angiogram normal* | Approved as Requested | Proposed PT | |
| HLT primary | *Vascular imaging procedures NEC* | | *Fluorescence angiogram normal* | 10083088 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Vascular imaging procedures NEC* | 10047078 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment:

**CR Number: 2019151027** **Implementation Date:** 31-May-19 Related CR: 2019149437

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Fluorescein angiography abnormal* | Approved as Requested | Proposed LLT | |
| From PT | *Angiogram abnormal* | | *Fluorescein angiography abnormal* | 10016813 Current |
| To PT | *Fluorescence angiogram abnormal* | | From PT | |
| | | | *Angiogram abnormal* | 10060956 |
| | | | To PT | |
| | | | *Fluorescence angiogram abnormal* | 10083087 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019151031** **Implementation Date:** 31-May-19 Related CR: 2019149437

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Fluorescein angiography normal* | Approved as Requested | Proposed LLT | |
| From PT | *Angiogram normal* | | *Fluorescein angiography normal* | 10016814 Current |
| To PT | *Fluorescence angiogram normal* | | From PT | |
| | | | *Angiogram normal* | 10061638 |
| | | | To PT | |
| | | | *Fluorescence angiogram normal* | 10083088 |

MSSO Comment:

**CR Number: 2019151032** **Implementation Date:** 31-May-19 Related CR: 2019149437

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Indocyanine green angiography* | Approved as Requested | Proposed LLT | |
| To PT | *Fluorescence angiogram* | | *Indocyanine green angiography* | 10083090 Current |
| | | | To PT | |
| | | | *Fluorescence angiogram* | 10083089 |

MSSO Comment:

**CR Number: 2019149838** **Implementation Date:** 06-Jun-19 Related CR: 2019149838

| Change Requested | Change Status of LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| LLT to change | *Incontinence* | Rejected | | |
| Status | *non-current* | | | |

MSSO Comment: The proposal to change status of LLT Incontinence to non-current is not approved. The term is well placed in SOC Renal and urinary disorders as the primary SOC since the unqualified term, is understood to mean urinary incontinence. Any changes, regarding term status, or changing links may impact legacy data. A similar request was rejected in change request 2018320028.

# Supplemental Update Report

**CR Number: 2019149839** **Implementation Date:** 06-Jun-19 Related CR: 2019149839

| Change Requested | Change Status of LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| LLT to change | *Urge incontinence* | Rejected | | |
| Status | *non-current* | | | |

MSSO Comment: The proposal to change status of LLT Urge incontinence to non-current is not approved. Urge incontinence is a recognized concept, defined as a sudden involuntary contraction of the muscular wall of the bladder causing urinary urgency, an immediate unstoppable urge to urinate.

**CR Number: 2019149840** **Implementation Date:** 06-Jun-19 Related CR: 2019149840

| Change Requested | Change Status of LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| LLT to change | *Mixed incontinence* | Rejected | | |
| Status | *non-current* | | | |

MSSO Comment: The proposal to change status of LLT Mixed incontinence to non-current is not approved. Stress incontinence is leakage of urine caused by coughing, sneezing, or other movements that put pressure on the bladder; urge incontinence is the loss of urine after feeling a sudden need to urinate. Both stress incontinence and urge incontinence often coexist in the same patient. This combination is often referred to as mixed incontinence.

**CR Number: 2019149841** **Implementation Date:** 06-Jun-19 Related CR: 2019149841

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Terminal dribbling* | Rejected | | |
| To PT | *Post micturition dribble* | | | |

MSSO Comment: The proposal to demote the PT Terminal dribbling under PT Post micturition dribble is not approved. Terminal dribbling and Post micturition dribble are described as different urination disorders: Post micturition dribble, or after dribble, is the name given to the problem when men experience an involuntary loss of urine immediately after they have finished passing urine, usually after leaving the toilet. It is not caused by stress from exertion or due to a problem with the bladder, and it should be distinguished from terminal dribble, which occurs at the end of passing urine.

# Supplemental Update Report

**CR Number: 2019150613** **Implementation Date:** 31-May-19 Related CR: 2019150613

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *In-stent venous restenosis* | Approved as Requested | Proposed LLT | |
| | | | *In-stent venous restenosis* | 10083107 Current |
| | | | To PT | |
| | | | *Vascular stent stenosis* | 10077144 |

MSSO Comment: The proposal to add a new LLT In-stent venous restenosis is approved as requested. Stenting of the venous system has been a natural extension of arterial stent technique and technology for the treatment of venous pathologies such as thrombotic occlusions and outflow obstructions. Stent failure in the form of in-stent stenosis does occasionally occur as a complication. In-stent venous restenosis will be added as sub-concept LLT to PT Vascular stent stenosis.

**CR Number: 2019150614** **Implementation Date:** 31-May-19 Related CR: 2019150614

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Iliac venous stenosis* | Approved Not as Requested | Proposed PT | |
| | | | *Iliac vein stenosis* | 10083102 |
| | | | HLT primary | |
| | | | *Peripheral vasoconstriction, necrosis and vascular insufficiency* | 10034640 |
| | | | SOC primary | |
| | | | *Vascular disorders* | 10047065 |

MSSO Comment: The proposal to add a new LLT Iliac venous stenosis is approved but not as requested. Iliac venous stenosis, a risk of deep vein thrombosis, will be reworded and added as PT Iliac vein stenosis to HLT Peripheral vasoconstriction, necrosis and vascular insufficiency. In a related change, LLT Iliac artery stenosis will be promoted from PT Peripheral artery stenosis to PT status and linked to HLT Peripheral vasoconstriction, necrosis and vascular insufficiency. In addition, LLT Iliac artery restenosis will be promoted from PT Peripheral artery restenosis to PT level and linked to HLT Peripheral vasoconstriction, necrosis and vascular insufficiency.

# Supplemental Update Report

**CR Number: 2019151039** **Implementation Date:** 31-May-19 Related CR: 2019150614

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Iliac artery stenosis* | Approved as Requested | Proposed LLT | |
| From PT | *Peripheral artery stenosis* | | *Iliac artery stenosis* | 10053216 |
| HLT primary | *Peripheral vasoconstriction, necrosis and vascular insufficiency* | | From PT | |
| | | | *Peripheral artery stenosis* | 10072563 |
| | | | HLT primary | |
| | | | *Peripheral vasoconstriction, necrosis and vascular insufficiency* | 10034640 |
| | | | SOC primary | |
| | | | *Vascular disorders* | 10047065 |

MSSO Comment:

**CR Number: 2019151040** **Implementation Date:** 31-May-19 Related CR: 2019150614

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Iliac artery restenosis* | Approved as Requested | Proposed LLT | |
| From PT | *Peripheral artery restenosis* | | *Iliac artery restenosis* | 10082827 |
| HLT primary | *Peripheral vasoconstriction, necrosis and vascular insufficiency* | | From PT | |
| | | | *Peripheral artery restenosis* | 10072557 |
| | | | HLT primary | |
| | | | *Peripheral vasoconstriction, necrosis and vascular insufficiency* | 10034640 |
| | | | SOC primary | |
| | | | *Vascular disorders* | 10047065 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019150615** **Implementation Date:** 31-May-19 Related CR: 2019150615

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Femoral venous stenosis* | Approved Not as Requested | Proposed LLT<br>*Femoral vein stenosis* | 10083108 Current |
| | | | To PT<br>*Peripheral vein stenosis* | 10083104 |

MSSO Comment: The proposal to add a new LLT Femoral venous stenosis is approved but not as requested. Femoral venous stenosis will be reworded to Femoral vein stenosis and added as LLT to a new PT Peripheral vein stenosis. In a related change, PT Peripheral vein stenosis will be added to HLT Peripheral vasoconstriction, necrosis and vascular insufficiency.

**CR Number: 2019151041** **Implementation Date:** 31-May-19 Related CR: 2019150615

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Peripheral vein stenosis* | Approved as Requested | Proposed PT<br>*Peripheral vein stenosis* | 10083104 |
| HLT primary | *Peripheral vasoconstriction, necrosis and vascular insufficiency* | | HLT primary<br>*Peripheral vasoconstriction, necrosis and vascular insufficiency* | 10034640 |
| SOC primary | *Vascular disorders* | | SOC primary<br>*Vascular disorders* | 10047065 |

MSSO Comment:

**CR Number: 2019150616** **Implementation Date:** 31-May-19 Related CR: 2019150616

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Femoral vein occlusion* | Approved as Requested | Proposed LLT<br>*Femoral vein occlusion* | 10083106 Current |
| | | | To PT<br>*Peripheral vein occlusion* | 10083103 |

MSSO Comment: The proposal to add a new LLT Femoral vein occlusion is approved as requested. Femoral vein occlusion will be added as LLT to a new PT Peripheral vein occlusion. In a related change, Peripheral vein occlusion will be added as PT to HLT Peripheral vasoconstriction, necrosis and vascular insufficiency.

# Supplemental Update Report

**CR Number: 2019151042** **Implementation Date:** 31-May-19 Related CR: 2019150616

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Peripheral vein occlusion* | Approved as Requested | Proposed PT | |
| HLT primary | *Peripheral vasoconstriction, necrosis and vascular insufficiency* | | *Peripheral vein occlusion* | 10083103 |
| SOC primary | *Vascular disorders* | | HLT primary | |
| | | | *Peripheral vasoconstriction, necrosis and vascular insufficiency* | 10034640 |
| | | | SOC primary | |
| | | | *Vascular disorders* | 10047065 |

MSSO Comment:

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**CR Number: 2019150617** **Implementation Date:** 31-May-19 Related CR: 2019150617

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Peripheral venous stenosis* | Rejected | | |

MSSO Comment: The proposal to add a new PT Peripheral venous stenosis is not approved. Please see change request 2019150615 for the addition of new PT Peripheral vein stenosis in a related change.

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**CR Number: 2019150618** **Implementation Date:** 31-May-19 Related CR: 2019150618

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *In-stent venous stenosis* | Approved as Requested | Proposed LLT | |
| | | | *In-stent venous stenosis* | 10083105 Current |
| | | | To PT | |
| | | | *Vascular stent stenosis* | 10077144 |

MSSO Comment: The proposal to add a new LLT In-stent venous stenosis is approved as requested. In-stent venous stenosis, a complication after stent placement in the lower extremity venous outflow tract, will be added as an LLT to PT Vascular stent stenosis.

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# Supplemental Update Report

**CR Number: 2019150619** **Implementation Date:** 31-May-19 Related CR: 2019150619

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Peripheral venous occlusion* | Rejected | | |

MSSO Comment: The proposal to add a new PT Peripheral venous occlusion is not approved. Please see change request 2019150616 for the addition of PT Peripheral vein occlusion in a related change.

**CR Number: 2019150623** **Implementation Date:** 07-Jun-19 Related CR: 2019150623

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Suspected illegal product* | Rejected After Suspension | | |
| HLT primary | *Counterfeit, falsified and substandard products* | | | |
| SOC primary | *Product issues* | | | |

MSSO Comment: The proposal to add a new PT Suspected illegal product to primary HLT Counterfeit, falsified and substandard products in SOC Product issues is not approved after suspension. Illegal is too broad a term and can refer to falsified products as well as other products that are illegal such as recreational drugs. Also, what is illegal in one country may not be in another country. MedDRA generally refrains from adding these concepts.

**CR Number: 2019150624** **Implementation Date:** 05-Jun-19 Related CR: 2019150624

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *TEN-SJS overlap* | Approved Not as Requested | Proposed PT | |
| HLT primary | *Bullous conditions* | | *SJS-TEN overlap* | 10083164 |
| SOC primary | *Skin and subcutaneous tissue disorders* | | HLT primary | |
| | | | *Bullous conditions* | 10006555 |
| | | | SOC primary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |
| | | | HLT secondary | |
| | | | *Allergies to foods, food additives, drugs and other chemicals* | 10001737 |
| | | | SOC secondary | |
| | | | *Immune system disorders* | 10021428 |

MSSO Comment: The proposal to add a new PT TEN-SJS overlap to primary HLT Bullous conditions in SOC Skin and subcutaneous tissue disorders is approved but not as requested. Stevens–Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) are clinically similar except for their distribution. Changes affect < 10% of body surface area in SJS and > 30% of body surface area in TEN; involvement of 10 to 30% of body surface area is considered SJS-TEN overlap. SJS-TEN overlap will be added as a new PT to primary HLT Bullous conditions, to secondary HLT Allergies to foods, food additives, drugs and other chemicals, to secondary HLT Inflammatory disorders following infection, and to secondary HLT Poisoning and toxicity.

# Supplemental Update Report

**CR Number: 2019156003** **Implementation Date:** 05-Jun-19 Related CR: 2019150624

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *SJS-TEN overlap* | Approved as Requested | Proposed PT | |
| To HLT | *Inflammatory disorders following infection* | | *SJS-TEN overlap* | 10083164 |
| | | | To HLT | |
| | | | *Inflammatory disorders following infection* | 10021982 |

MSSO Comment:

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**CR Number: 2019156004** **Implementation Date:** 05-Jun-19 Related CR: 2019150624

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *SJS-TEN overlap* | Approved as Requested | Proposed PT | |
| To HLT | *Poisoning and toxicity* | | *SJS-TEN overlap* | 10083164 |
| | | | To HLT | |
| | | | *Poisoning and toxicity* | 10035777 |

MSSO Comment:

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**CR Number: 2019150680** **Implementation Date:** 05-Jun-19 Related CR: 2019150680

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Homocysteinemia* | Approved Not as Requested | Proposed LLT | |
| To PT | *Hyperhomocysteinemia* | | *Homocysteinemia* | 10083166 Current |
| | | | To PT | |
| | | | *Hyperhomocysteinaemia* | 10051286 |

MSSO Comment: The proposal to add a new LLT Homocysteinemia to PT Hyperhomocysteinemia is approved but not as requested. Hyperhomocysteinaemia is a medical condition characterized by an abnormally high level of homocysteine in the blood. Etiologies include, for example, genetic defects in 5-MTHF reductase, deficiencies in B vitamins, and excessive alcohol intake. Homocysteinemia, a synonym of hyperhomocysteinaemia, will be added as an LLT to the British English spelled PT Hyperhomocysteinaemia.

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# Supplemental Update Report

**CR Number: 2019150681** **Implementation Date:** 05-Jun-19 Related CR: 2019150681

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Solitary rectal ulcer syndrome* | Approved as Requested | Proposed PT | |
| | | | *Solitary rectal ulcer syndrome* | 10083165 |
| | | | HLT primary | |
| | | | *Anal and rectal disorders NEC* | 10002113 |
| | | | SOC primary | |
| | | | *Gastrointestinal disorders* | 10017947 |

MSSO Comment: The proposal to add a new term Solitary rectal ulcer syndrome is approved as requested. Solitary rectal ulcer syndrome is a rare disorder that often has been associated with straining during defecation, a sense of incomplete evacuation, and sometimes passage of blood and mucus by rectum. It thought to be caused by localized ischemic injury or prolapse of the distal rectal mucosa. The name of the syndrome is misleading because associated lesions may be solitary or multiple, and ulcerated or nonulcerated; they range from mucosal erythema to ulcers to small polypoid lesions. Solitary rectal ulcer syndrome will be added as a PT to HLT Anal and rectal disorders NEC.

**CR Number: 2019150682** **Implementation Date:** 05-Jun-19 Related CR: 2019150682

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Mucosal prolapse syndrome* | Approved as Requested | Proposed LLT | |
| | | | *Mucosal prolapse syndrome* | 10083167 Current |
| | | | To PT | |
| | | | *Solitary rectal ulcer syndrome* | 10083165 |

MSSO Comment: The proposal to add a new term Mucosal prolapse syndrome is approved as requested. Mucosal prolapse syndrome (MPS) is thought to occur because of chronic mechanical stimulation; is often recognized in prolapsing colostomies or prolapsing hemorrhoid at the site of the rectum; and can present as polypoid lesions, ulcerations or erythema at the anterior wall of the rectum. The aetiology of MPS remains unproven but there is now considerable evidence that a combination of mucosal prolapse, trauma and ischemia, caused by excessive straining at stool may be important factors. Mucosal prolapse syndrome will be added as a sub-concept LLT to PT Solitary rectal ulcer syndrome added in change request 2019150681.

**CR Number: 2019150683** **Implementation Date:** 03-Jun-19 Related CR: 2019150683

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Prothetic perivalvular leak* | Rejected | | |

MSSO Comment: The proposal to add a new term Prothetic perivalvular leak is not approved. The proposed concept can be represented by existing LLT Paravalvular leak or LLT Prosthetic cardiac valve leakage.

# Supplemental Update Report

**CR Number: 2019150684** **Implementation Date:** 04-Jun-19 Related CR: 2019150684

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Immune-mediated dermatitis* | Approved as Requested | Proposed PT | |
| | | | *Immune-mediated dermatitis* | 10083156 |
| | | | HLT primary | |
| | | | *Dermatitis and eczema* | 10012435 |
| | | | SOC primary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |
| | | | HLT secondary | |
| | | | *Immune and associated conditions NEC* | 10027682 |
| | | | SOC secondary | |
| | | | *Immune system disorders* | 10021428 |

MSSO Comment: The proposal to add a new term Immune-mediated dermatitis 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 are not exclusively so. PT Immune-mediated dermatitis will be linked to primary HLT Dermatitis and eczema and to secondary HLT Immune and associated conditions NEC.

**CR Number: 2019150685** **Implementation Date:** 04-Jun-19 Related CR: 2019150685

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Immune-mediated arthritis* | Approved as Requested | Proposed PT | |
| | | | *Immune-mediated arthritis* | 10083155 |
| | | | HLT primary | |
| | | | *Arthropathies NEC* | 10003284 |
| | | | SOC primary | |
| | | | *Musculoskeletal and connective tissue disorders* | 10028395 |
| | | | HLT secondary | |
| | | | *Immune and associated conditions NEC* | 10027682 |
| | | | SOC secondary | |
| | | | *Immune system disorders* | 10021428 |

MSSO Comment: The proposal to add a new term Immune-mediated arthritis 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 are not exclusively so. PT Immune-mediated arthritis will be linked to primary HLT Arthropathies NEC and to secondary HLT Immune and associated conditions NEC.

# Supplemental Update Report

**CR Number: 2019150686** **Implementation Date:** 05-Jun-19 Related CR: 2019150686

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Mammary tuberculosis* | Approved as Requested | Proposed PT | |
| HLT primary | *Tuberculous infections* | | *Mammary tuberculosis* | 10083169 |
| SOC primary | *Infections and infestations* | | HLT primary | |
| | | | *Tuberculous infections* | 10044756 |
| | | | SOC primary | |
| | | | *Infections and infestations* | 10021881 |
| | | | HLT secondary | |
| | | | *Breast infections and inflammations* | 10021883 |
| | | | SOC secondary | |
| | | | *Reproductive system and breast disorders* | 10038604 |

MSSO Comment: The proposal to add a new PT Mammary tuberculosis to primary HLT Tuberculous infections in SOC Infections and infestations is approved as requested. Mammary tuberculosis, a rare manifestation of extra-pulmonary localization, will also be linked to secondary HLT Breast infections and inflammations.

**CR Number: 2019150687** **Implementation Date:** 05-Jun-19 Related CR: 2019150687

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Corneal thickness measurement* | Approved Not as Requested | Proposed LLT | |
| HLT primary | *Ophthalmic function diagnostic procedures* | | *Corneal thickness measurement* | 10083170 Current |
| SOC primary | *Investigations* | | To PT | |
| | | | *Corneal pachymetry* | 10083168 |

MSSO Comment: The proposal to add a new PT Corneal thickness measurement to primary HLT Ophthalmic function diagnostic procedures in SOC Investigations is approved but not as requested. Corneal thickness is measured usually with either ultrasonic or optical instruments. Corneal thickness measurement will be added as an LLT to PT Corneal pachymetry. In a related change, Corneal pachymetry, the measurement of the thickness of the cornea, will be added to HLT Ophthalmic function diagnostic procedures.

# Supplemental Update Report

**CR Number: 2019156005** **Implementation Date:** 05-Jun-19 Related CR: 2019150687

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Corneal pachymetry* | Approved as Requested | Proposed PT | |
| HLT primary | *Ophthalmic function diagnostic procedures* | | *Corneal pachymetry* | 10083168 |
| SOC primary | *Investigations* | | HLT primary | |
| | | | *Ophthalmic function diagnostic procedures* | 10030864 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment:

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**CR Number: 2019150688** **Implementation Date:** 04-Jun-19 Related CR: 2019150688

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *High ligation of hernial sac* | Approved as Requested | Proposed LLT | |
| | | | *High ligation of hernial sac* | 10083153 Current |
| | | | To PT | |
| | | | *Inguinal hernia repair* | 10022020 |

MSSO Comment: The proposal to add a new term High ligation of hernial sac is approved as requested. High ligation of hernial sac, a standard procedure in inguinal hernia repair, will be added as a sub-concept LLT to PT Inguinal hernia repair.

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**CR Number: 2019150689** **Implementation Date:** 04-Jun-19 Related CR: 2019150689

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *ANTRAL DEFOMITY* | Approved Not as Requested | Proposed LLT | |
| | | | *Antral deformity* | 10083154 Current |
| | | | To PT | |
| | | | *Prepyloric stenosis* | 10050173 |

MSSO Comment: The proposal to add a new LLT ANTRAL DEFOMITY is approved but not as requested. Antral or pyloric deformities, due to benign or malignant gastric lesions or as a complication seen after endoscopic submucosal dissection are risk factors for pyloric strictures. Antral deformity, is corrected in accordance with MedDRA capitalisation conventions and corrected for spelling. Antral deformity will be added as a sub-concept LLT to PT Prepyloric stenosis.

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# Supplemental Update Report

**CR Number: 2019151001** **Implementation Date:** 07-Jun-19 Related CR: 2019151001

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Mannose-binding lectin deficiency* | Approved as Requested | Proposed PT | |
| HLT primary | *Immune system abnormalities congenital* | | *Mannose-binding lectin deficiency* | 10083190 |
| SOC primary | *Congenital, familial and genetic disorders* | | HLT primary | |
| | | | *Immune system abnormalities congenital* | 10021424 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary | |
| | | | *Primary immunodeficiency syndromes* | 10036700 |
| | | | SOC secondary | |
| | | | *Immune system disorders* | 10021428 |

MSSO Comment: The proposal to add a new PT Mannose-binding lectin deficiency to primary HLT Immune system abnormalities congenital in SOC Congenital, familial and genetic disorders is approved as requested. Mannose-binding lectin (MBL) deficiency results in a decreased amount of a specific protein (mannan-binding protein) involved in the immune system. MBL deficiency is more likely to be associated with infections in toddlers and those who have a weakened immune system (immunocompromised), including those with an underlying medical condition, cancer patients undergoing chemotherapy, and organ-transplant patients. Some studies have also suggested an association between severe MBL deficiency and recurrent infections. Mannose-binding lectin deficiency will be added as a PT to primary HLT Immune system abnormalities congenital and to secondary HLT Primary immunodeficiency syndromes. In a related change, MBL deficiency will be added as a synonym LLT to new PT Mannose-binding lectin deficiency.

**CR Number: 2019157001** **Implementation Date:** 07-Jun-19 Related CR: 2019151001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *MBL deficiency* | Approved as Requested | Proposed LLT | |
| To PT | *Mannose-binding lectin deficiency* | | *MBL deficiency* | 10083191 Current |
| | | | To PT | |
| | | | *Mannose-binding lectin deficiency* | 10083190 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019151002** **Implementation Date:** 07-Jun-19 Related CR: 2019151002

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Aicardi's syndrome* | Rejected | | |
| To HLT | *Neurological disorders congenital NEC* | | | |

MSSO Comment: The proposal to link the PT Aicardi's syndrome to the HLT Neurological disorders congenital NEC is not approved. PT Aicardi's syndrome is already linked to HLT Neurological disorders congenital NEC. Aicardi's syndrome is an extremely rare genetic disorder. Almost all people with Aicardi's syndrome are females. Individuals with Aicardi's syndrome have agenesis of the corpus callosum, chorioretinal lacunae, and infantile spasms. Aicardi's syndrome is distinct from Aicardi-Goutieres syndrome, which is an inherited encephalopathy that affects newborn infants and characterized in its most severe form by cerebral atrophy, leukodystrophy, and intracranial calcifications. However, in a related change, for better hierarchical placement of PT Aicardi's syndrome, it will be unlinked from secondary HLT Leukodystrophies, and linked to secondary HLT Seizures and seizure disorders NEC. In addition, PT Aicardi's syndrome will be secondarily linked to HLT Retinal structural change, deposit and degeneration.

**CR Number: 2019157002** **Implementation Date:** 07-Jun-19 Related CR: 2019151002

| Change Requested | Unlink a PT from a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Aicardi's syndrome* | Approved as Requested | Proposed PT | |
| From HLT | *Leukodystrophies* | | *Aicardi's syndrome* | 10054935 |
| | | | From HLT | |
| | | | *Leukodystrophies* | 10068202 |

MSSO Comment:

**CR Number: 2019157003** **Implementation Date:** 07-Jun-19 Related CR: 2019151002

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Aicardi's syndrome* | Approved as Requested | Proposed PT | |
| To HLT | *Retinal structural change, deposit and degeneration* | | *Aicardi's syndrome* | 10054935 |
| | | | To HLT | |
| | | | *Retinal structural change, deposit and degeneration* | 10038896 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019157004** **Implementation Date:** 07-Jun-19 Related CR: 2019151002

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Aicardi's syndrome* | Approved as Requested | Proposed PT | |
| To HLT | *Seizures and seizure disorders NEC* | | *Aicardi's syndrome* | 10054935 |
| | | | To HLT | |
| | | | *Seizures and seizure disorders NEC* | 10039912 |

MSSO Comment:

**CR Number: 2019151003** **Implementation Date:** 07-Jun-19 Related CR: 2019151003

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Aicardi-Goutieres syndrome* | Approved as Requested | Proposed PT | |
| HLT primary | *Neurological disorders congenital NEC* | | *Aicardi-Goutieres syndrome* | 10083189 |
| SOC primary | *Congenital, familial and genetic disorders* | | HLT primary | |
| | | | *Neurological disorders congenital NEC* | 10029300 |
| | | | SOC primary | |
| | | | *Congenital, familial and genetic disorders* | 10010331 |
| | | | HLT secondary | |
| | | | *Leukodystrophies* | 10068202 |
| | | | SOC secondary | |
| | | | *Nervous system disorders* | 10029205 |

MSSO Comment: The proposal to add a new PT Aicardi-Goutieres syndrome to primary HLT Neurological disorders congenital NEC in SOC Congenital, familial and genetic disorders and secondary HLT Leukodystrophies in SOC Nervous system disorders is approved as requested. Aicardi-Goutieres syndrome is a genetically heterogeneous encephalopathy. It is characterized in its most severe form by cerebral atrophy, leukodystrophy, and intracranial calcifications. Severe neurologic dysfunction becomes clinically apparent in infancy, and manifests as progressive microcephaly, spasticity, dystonic posturing, profound psychomotor retardation, and often death in early childhood.

**CR Number: 2019151004** **Implementation Date:** 04-Jun-19 Related CR: 2019151004

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Rhinoconjunctivitis* | Rejected | | |
| From PT | *Conjunctivitis* | | | |

MSSO Comment: The proposal to promote the LLT Rhinoconjunctivitis from PT Conjunctivitis is not approved. The promotion of LLT Rhinoconjunctivitis would present a situation similar to the current placement, where primary the HLT must be assigned either to HLT Eye and eyelid infections, or to HLT Upper respiratory tract infections. Furthermore, Rhinoconjunctivitis has been an LLT to PT Conjunctivitis since Version 2.1, and a promotion of the term at this time could potentially affect legacy data and adverse event profiles of existing products.

# Supplemental Update Report

**CR Number: 2019151005** **Implementation Date:** 04-Jun-19 Related CR: 2019151005

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Allergic rhinoconjunctivitis* | Rejected | | |
| From PT | *Conjunctivitis allergic* | | | |

MSSO Comment: The proposal to promote the LLT Allergic rhinoconjunctivitis from PT Conjunctivitis allergic is not approved. The promotion of LLT Allergic rhinoconjunctivitis would present a situation similar to the current mapping, where the primary HLT must be assigned either to HLT Conjunctival infections, irritations and inflammations, or to HLT Nasal congestion and inflammations. Furthermore, Allergic rhinoconjunctivitis has been an LLT to PT Conjunctivitis allergic since Version 2.1, and a promotion of the term at this time could potentially affect legacy data and adverse event profiles of existing products.

**CR Number: 2019151006** **Implementation Date:** 04-Jun-19 Related CR: 2019151006

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| PT to merge | *Device used for unapproved schedule* | Approved as Requested | PT to merge | | |
| | | | *Device used for unapproved schedule* | 10079135 | Current |
| To PT | *Device use issue* | | To PT | | |
| | | | *Device use issue* | 10077812 | |

MSSO Comment: The proposal to demote the PT Device used for unapproved schedule under PT Device use issue is approved as requested. This demotion of PT Device used for unapproved schedule places the term in a similar manner as LLT Drug use for unapproved schedule under PT Product use issue.

**CR Number: 2019151007** **Implementation Date:** 04-Jun-19 Related CR: 2019151007

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Delivery device component difficult to push down* | Approved Not as Requested | Proposed LLT | | |
| | | | *Delivery device component difficult to use* | 10083150 | Current |
| To PT | *Device difficult to use* | | To PT | | |
| | | | *Device difficult to use* | 10069853 | |

MSSO Comment: The proposal to add a new LLT Delivery device component difficult to push down to PT Device difficult to use is approved but not as requested. The requested term will be modified to Delivery device component difficult to use, to more generally represent many possible difficulties pertaining to therapeutic delivery devices. MedDRA cannot accommodate a unique term for every specific type of device use difficulty. Accordingly, Delivery device component difficult to use will be added as a sub-concept LLT to PT Device difficult to use.

# Supplemental Update Report

**CR Number: 2019151008** **Implementation Date:** 04-Jun-19 Related CR: 2019151008

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Duplicate therapy with same active substance* | Approved as Requested | Proposed LLT<br>*Duplicate therapy with same active substance* | 10083149 | Current |
| | | | To PT<br>*Duplicate therapy error* | 10080422 | |

MSSO Comment: The proposal to add a new LLT Duplicate therapy with same active substance is approved as requested. Duplicate therapy with same active substance will be added as a sub-concept LLT to PT Duplicate therapy error.

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**CR Number: 2019151009** **Implementation Date:** 04-Jun-19 Related CR: 2019151009

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # | |
|---|---|---|---|---|---|
| Proposed LLT | *Dose counter confusion* | Approved as Requested | Proposed LLT<br>*Dose counter confusion* | 10083157 | Current |
| | | | To PT<br>*Device use confusion* | 10083151 | |

MSSO Comment: The proposal to add a new LLT Dose counter confusion is approved as requested. Device use confusion represents a lack of understanding or uncertainty in one or more aspects of the intended use of a medical device. Dose counter confusion will be added as a sub-concept LLT to PT Device use confusion. In a related change, new PT Device use confusion will be added to HLT Product confusion errors and issues.

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**CR Number: 2019155002** **Implementation Date:** 04-Jun-19 Related CR: 2019151009

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Device use confusion* | Approved as Requested | Proposed PT<br>*Device use confusion* | 10083151 |
| HLT primary | *Product confusion errors and issues* | | HLT primary<br>*Product confusion errors and issues* | 10079148 |
| SOC primary | *Injury, poisoning and procedural complications* | | SOC primary<br>*Injury, poisoning and procedural complications* | 10022117 |

MSSO Comment:

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# Supplemental Update Report

**CR Number: 2019151010** **Implementation Date:** 04-Jun-19 Related CR: 2019151010

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Expiration date format confusion* | Approved as Requested | Proposed LLT<br>*Expiration date format confusion*<br>To PT<br>*Product label confusion* | <br>10083147 Current<br><br>10069273 |

MSSO Comment: The proposal to add a new LLT Expiration date format confusion is approved as requested. The numerical representation format of a product expiration date may potentially result in difficulty with its interpretation. Expiration date format confusion will be added as a sub-concept LLT to PT Product label confusion.

**CR Number: 2019151011** **Implementation Date:** 04-Jun-19 Related CR: 2019151011

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Product used prior to being brought to room temperature* | Approved Not as Requested | Proposed LLT<br>*Product used prior to being brought to recommended temperature*<br>To PT<br>*Product preparation error* | <br>10083148 Current<br><br>10076869 |

MSSO Comment: The proposal to add a new LLT Product used prior to being brought to room temperature is approved but not as requested. The requested term will be modified to Product used prior to being brought to recommended temperature to represent a broader term concept that is not specific for a particular incorrect product temperature. MedDRA cannot accommodate a unique term for every appropriate temperature level for product use. Accordingly, Product used prior to being brought to recommended temperature will be added as a sub-concept LLT to PT Product preparation error.

**CR Number: 2019151012** **Implementation Date:** 04-Jun-19 Related CR: 2019151012

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Tongue abnormal feeling of* | Rejected | | |
| From PT | *Paraesthesia oral* | | | |
| To PT | *Oral dysaesthesia* | | | |

MSSO Comment: The proposal to move the LLT Tongue abnormal feeling of from PT Paraesthesia oral to PT Oral dysaesthesia is not approved. As with any lay expression, the precise meaning of the term "Tongue abnormal feeling of" is difficult to define. However it looks closer to the definition of paresthesia (abnormal touch sensation often in absence of stimulus) than the one of dysesthesia, which implies distortion of a sense, often with an unpleasant sensation under normal stimuli. Therefore, even if not optimal, current placement of the LLT Tongue abnormal feeling of is considered adequate.

# Supplemental Update Report

**CR Number: 2019151014** **Implementation Date:** 04-Jun-19 Related CR: 2019151014

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Cosmetic dermatitis* | Approved as Requested | Proposed LLT | |
| To PT | *Dermatitis contact* | | *Cosmetic dermatitis* | 10083145 Current |
| | | | To PT | |
| | | | *Dermatitis contact* | 10012442 |

MSSO Comment: The proposal to add a new LLT Cosmetic dermatitis to PT Dermatitis contact is approved as requested. Cosmetic dermatitis is defined as an allergic contact dermatitis caused by an ingredient of a cosmetic preparation, and therefore will be added as a sub-element LLT of Dermatitis contact.

**CR Number: 2019151015** **Implementation Date:** 04-Jun-19 Related CR: 2019151015

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Bags under eyes* | Approved as Requested | Proposed LLT | |
| From PT | *Eye swelling* | | *Bags under eyes* | 10078395 Current |
| To PT | *Periorbital swelling* | | From PT | |
| | | | *Eye swelling* | 10015967 |
| | | | To PT | |
| | | | *Periorbital swelling* | 10056647 |

MSSO Comment: The proposal to move the LLT Bags under eyes from PT Eye swelling to PT Periorbital swelling is approved as requested. Swelling around the eyes, is the appearance of a swelling in the periorbital tissues. It is due to multiple causes, including fluid buildup and normal aging of the periocular tissues. Thus, the LLT Bags under eyes is better represented under PT Periorbital swelling. In an associated change, and for the same reason, the LLT Puffy eyes will also be moved from PT Eye swelling and demoted under PT Periorbital swelling.

**CR Number: 2019155001** **Implementation Date:** 04-Jun-19 Related CR: 2019151015

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Puffy eyes* | Approved as Requested | Proposed LLT | |
| From PT | *Eye swelling* | | *Puffy eyes* | 10082020 Current |
| To PT | *Periorbital swelling* | | From PT | |
| | | | *Eye swelling* | 10015967 |
| | | | To PT | |
| | | | *Periorbital swelling* | 10056647 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019151016** **Implementation Date:** 04-Jun-19 Related CR: 2019151016

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Malar mound* | Approved as Requested | Proposed LLT | |
| From PT | *Eye swelling* | | *Malar mound* | 10078396 Current |
| To PT | *Periorbital swelling* | | From PT | |
| | | | *Eye swelling* | 10015967 |
| | | | To PT | |
| | | | *Periorbital swelling* | 10056647 |

MSSO Comment: The proposal to move the LLT Malar mound from PT Eye swelling to PT Periorbital swelling is approved as requested. Malar mounds describe skin folds caused by swelling of the lower eyelid and cheek. They form as a result of various causes including aging, sun damage and forces under the skin caused by contracting muscle action, as in certain expressions. Therefore, the LLT Malar mound will be better represented under PT Periorbital swelling.

**CR Number: 2019151017** **Implementation Date:** 04-Jun-19 Related CR: 2019151017

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Pustule* | Approved as Requested | Proposed LLT | |
| From PT | *Rash pustular* | | *Pustule* | 10037578 |
| HLT primary | *Skin structures and soft tissue infections* | | From PT | |
| | | | *Rash pustular* | 10037888 |
| | | | HLT primary | |
| | | | *Skin structures and soft tissue infections* | 10040786 |
| | | | SOC primary | |
| | | | *Infections and infestations* | 10021881 |
| | | | HLT secondary | |
| | | | *Pustular conditions* | 10037573 |
| | | | SOC secondary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment: The proposal to promote the LLT Pustule from PT Rash pustular to primary HLT Skin structures and soft tissue infections in SOC Infections and infestations and secondary HLT Pustular conditions in SOC Skin and subcutaneous tissue disorders is approved as requested. A pustule is a visible collection of pus within or beneath the epidermis which warrants independent representation at the PT level without the current subordination to a rash term.

# Supplemental Update Report

**CR Number:** **2019151018** **Implementation Date:** 04-Jun-19 Related CR: 2019151018

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Scratch* | Rejected | | |
| To PT | *Skin laceration* | | | |

MSSO Comment: The proposal to demote the PT Scratch under PT Skin laceration is not approved. A scratch is usually a marking on the surface with a sharp or pointed object. Whereas laceration entails a deeper and continuous injury over a skin area.

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**CR Number:** **2019151019** **Implementation Date:** 04-Jun-19 Related CR: 2019151019

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Skin oozing* | Approved as Requested | Proposed LLT | |
| | | | *Skin oozing* | 10083146 Current |
| | | | To PT | |
| | | | *Skin weeping* | 10080560 |

MSSO Comment: The proposal to add a new term Skin oozing is approved as requested. Skin oozing usually refers to the exudation of serum over a denuded injured skin, and is synonymous with skin weeping. As a result, Skin oozing will be added as an LLT under PT Skin weeping.

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**CR Number:** **2019151020** **Implementation Date:** 04-Jun-19 Related CR: 2019151020

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Skin discharge* | Approved as Requested | Proposed PT | |
| | | | *Skin discharge* | 10083144 |
| | | | HLT primary | |
| | | | *Skin and subcutaneous conditions NEC* | 10042356 |
| | | | SOC primary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment: The proposal to add a new term Skin discharge is approved as requested. As result of different pathologies, skin may exhibit different types of discharge, such as serum (weeping, oozing), purulent or caseum material, etc. Consequently, the new term Skin discharge warrants PT level and will be placed as such under HLT Skin and subcutaneous conditions NEC.

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# Supplemental Update Report

**CR Number: 2019151021** **Implementation Date:** 04-Jun-19 Related CR: 2019151021

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Purulent skin discharge* | Rejected | | |

MSSO Comment: The proposal to add a new term Purulent skin discharge is not approved. The proposed term can be represented by split coding with PT Skin discharge or PT Purulent discharge.

**CR Number: 2019151043** **Implementation Date:** 04-Jun-19 Related CR: 2019151043

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Syringe markings confusion* | Approved Not as Requested | Proposed LLT | |
| To PT | *Product design confusion* | | *Syringe markings confusion* | 10083152 Current |
| | | | To PT | |
| | | | *Device use confusion* | 10083151 |

MSSO Comment: The proposal to add a new LLT Syringe markings confusion to PT Product design confusion is approved but not as requested. Device use confusion represents a lack of understanding or uncertainty in one or more aspects of the intended use of a medical device. Confusion in the proper use of a device does not necessarily signify a design issue with the device. Syringe markings confusion will be added as a sub-concept LLT to PT Device use confusion added in change request 2019151009.

**CR Number: 2019151044** **Implementation Date:** 06-Jun-19 Related CR: 2019151044

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Hepatic venous pressure gradient increased* | Approved as Requested | Proposed PT | |
| | | | *Hepatic venous pressure gradient increased* | 10083171 |
| | | | HLT primary | |
| | | | *Liver function analyses* | 10024689 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new term Hepatic venous pressure gradient increased is approved as requested. Hepatic venous pressure gradient measurement is a preferred method to evaluate the presence and severity of portal hypertension. It is a clinical measurement of the pressure gradient between the wedge hepatic venous pressure and the free hepatic venous pressures, and thus is an estimate of the pressure gradient between the portal vein and the inferior vena cava. Hepatic venous pressure gradient increased will be added as a PT to HLT Liver function analyses.

# Supplemental Update Report

**CR Number: 2019151045** **Implementation Date:** 06-Jun-19 Related CR: 2019151045

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Hepatic venous pressure gradient abnormal* | Approved as Requested | Proposed PT | |
| | | | *Hepatic venous pressure gradient abnormal* | 10083172 |
| | | | HLT primary | |
| | | | *Liver function analyses* | 10024689 |
| | | | SOC primary | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to add a new term Hepatic venous pressure gradient abnormal is approved as requested. Hepatic venous pressure gradient measurement is a preferred method to evaluate the presence and severity of portal hypertension. It is a clinical measurement of the pressure gradient between the wedge hepatic venous pressure and the free hepatic venous pressures, and thus is an estimate of the pressure gradient between the portal vein and the inferior vena cava. Hepatic venous pressure gradient abnormal will be added as a PT to HLT Liver function analyses.

**CR Number: 2019151046** **Implementation Date:** 06-Jun-19 Related CR: 2019151046

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Jejunal interposition* | Approved Not as Requested | Proposed LLT | |
| | | | *Jejunal esophageal interposition* | 10083173 Current |
| | | | To PT | |
| | | | *Oesophagoplasty* | 10061985 |

MSSO Comment: The proposal to add a new term Jejunal interposition is approved but not as requested. Jejunal esophageal interposition is a procedure in which a missing section of an esophagus is replaced with a section of the jejunum. Jejunal esophageal interposition will be added as a sub-concept LLT to PT Oesophagoplasty. In a related change LLT Oesophagoplasty will be promoted from PT Oesophageal operation to PT level and linked to HLT Oesophageal therapeutic procedures. In addition, PT Colon-patch oesophagoplasty will be demoted as a sub-concept LLT to new PT Oesophagoplasty.

# Supplemental Update Report

**CR Number: 2019157006** **Implementation Date:** 06-Jun-19 Related CR: 2019151046

| Change Requested | Promote an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Oesophagoplasty* | Approved as Requested | Proposed LLT<br>*Oesophagoplasty* | 10061985 |
| From PT | *Oesophageal operation* | | From PT<br>*Oesophageal operation* | 10061319 |
| HLT primary | *Oesophageal therapeutic procedures* | | HLT primary<br>*Oesophageal therapeutic procedures* | 10030179 |
| | | | SOC primary<br>*Surgical and medical procedures* | 10042613 |

MSSO Comment:

**CR Number: 2019157007** **Implementation Date:** 06-Jun-19 Related CR: 2019151046

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Colon-patch oesophagoplasty* | Approved as Requested | PT to merge<br>*Colon-patch oesophagoplasty* | 10080592 Current |
| To PT | *Oesophagoplasty* | | To PT<br>*Oesophagoplasty* | 10061985 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019152001** **Implementation Date:** 06-Jun-19 Related CR: 2019152001

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Liver transplant failure* | Approved as Requested | Proposed PT | |
| | | | *Liver transplant failure* | 10083175 |
| | | | HLT primary | |
| | | | *Transplantation complications* | 10074474 |
| | | | SOC primary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |
| | | | HLT secondary | |
| | | | *Transplant rejections* | 10052779 |
| | | | SOC secondary | |
| | | | *Immune system disorders* | 10021428 |

MSSO Comment: The proposal to add a new term Liver transplant failure is approved as requested. Liver transplant failure can occur due to acute or chronic rejection, recurrent hepatitis, arterial thrombosis/stenosis, recurrent malignancy or other less frequent causes. Liver transplant failure will be placed as PT to primary HLT Transplantation complications and with secondary links to HLT Transplant rejections and HLT Hepatic and hepatobiliary disorders NEC. In a related change, the existing synonym PT Liver graft loss will be demoted under the new PT Liver transplant failure.

**CR Number: 2019157008** **Implementation Date:** 06-Jun-19 Related CR: 2019152001

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Liver transplant failure* | Approved as Requested | Proposed PT | |
| To HLT | *Hepatic and hepatobiliary disorders NEC* | | *Liver transplant failure* | 10083175 |
| | | | To HLT | |
| | | | *Hepatic and hepatobiliary disorders NEC* | 10027681 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019157009** **Implementation Date:** 06-Jun-19 Related CR: 2019152001

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Liver graft loss* | Approved as Requested | PT to merge | |
| To PT | *Liver transplant failure* | | *Liver graft loss* | 10049478 Current |
| | | | To PT | |
| | | | *Liver transplant failure* | 10083175 |

MSSO Comment:

**CR Number: 2019152002** **Implementation Date:** 06-Jun-19 Related CR: 2019152002

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Infantile acropustulosis* | Approved as Requested | Proposed PT | |
| | | | *Infantile acropustulosis* | 10083179 |
| | | | HLT primary | |
| | | | *Pustular conditions* | 10037573 |
| | | | SOC primary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |
| | | | HLT secondary | |
| | | | *Newborn complications NEC* | 10010168 |
| | | | SOC secondary | |
| | | | *Pregnancy, puerperium and perinatal conditions* | 10036585 |

MSSO Comment: The proposal to add a new term Infantile acropustulosis is approved as requested. Infantile acropustulosis occurs at birth or during infancy. Crops of intensely pruritic vesicles and pustules occur on the soles, palms, and dorsal surfaces of acral sites. The lesions will resolve within a few days, leaving a hyperpigmented macule that can be more difficult to discern in pigmented skin. History of preceding scabies infestation is common but not present in all cases. Infantile acropustulosis will be added as PT with a primary link to HLT Pustular conditions and secondary links to HLT Newborn complications NEC and HLT Inflammatory disorders following infection.

# Supplemental Update Report

**CR Number: 2019157010** **Implementation Date:** 06-Jun-19 Related CR: 2019152002

| Change Requested | | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Link a PT to a HLT | | | | |
| Proposed PT | *Infantile acropustulosis* | Approved as Requested | Proposed PT | |
| To HLT | *Inflammatory disorders following infection* | | *Infantile acropustulosis* | 10083179 |
| | | | To HLT | |
| | | | *Inflammatory disorders following infection* | 10021982 |

MSSO Comment:

**CR Number: 2019152003** **Implementation Date:** 06-Jun-19 Related CR: 2019152003

| Change Requested | | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Add a New LLT | | | | |
| Proposed LLT | *Itching papule* | Approved as Requested | Proposed LLT | |
| To PT | *Papule* | | *Itching papule* | 10083183 Current |
| | | | To PT | |
| | | | *Papule* | 10033733 |

MSSO Comment: The proposal to add a new LLT Itching papule to PT Papule is approved as requested. Pruritic or itchy papules are the constituent of several dermatosis, such as papular urticaria, lichen planus, atopic dermatitis and other pruritic rashes and eczemas or in daily situation like the bite of an insect.

# Supplemental Update Report

**CR Number: 2019152004** **Implementation Date:** 06-Jun-19 Related CR: 2019152004

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pharyngeal contusion* | Approved Not as Requested | Proposed PT | |
| HLT primary | *Oral soft tissue signs and symptoms* | | *Pharyngeal contusion* | 10083176 |
| SOC primary | *Gastrointestinal disorders* | | HLT primary | |
| | | | *Site specific injuries NEC* | 10040759 |
| | | | SOC primary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |
| | | | HLT secondary | |
| | | | *Pharyngeal disorders (excl infections and neoplasms)* | 10034823 |
| | | | SOC secondary | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |

MSSO Comment: The proposal to add a new PT Pharyngeal contusion to primary HLT Oral soft tissue signs and symptoms in SOC Gastrointestinal disorders and secondary HLT Site specific injuries NEC in SOC Injury, poisoning and procedural complications is approved but not as requested. Pharyngeal contusion is common and ranges from minor contusions to severe trauma of the head and neck. It can be caused by multiple traumatic events, such as sudden movement while having a foreign object in the mouth, falls or collisions causing external blunt trauma, or even diagnostic or therapeutic procedures. Pharyngeal contusion will be added as a PT linked to primary HLT Site specific injuries NEC to secondary link to HLT Pharyngeal disorders (excl infections and neoplasms). In a related change, the related PT Pharyngeal haematoma will be secondarily linked to HLT Site specific injuries NEC. Furthermore, the primary SOC for PT Oral contusion will be changed from SOC Gastrointestinal disorders to SOC Injury, poisoning and procedural complications.

**CR Number: 2019157011** **Implementation Date:** 06-Jun-19 Related CR: 2019152004

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Pharyngeal haematoma* | Approved as Requested | Proposed PT | |
| To HLT | *Site specific injuries NEC* | | *Pharyngeal haematoma* | 10068121 |
| | | | To HLT | |
| | | | *Site specific injuries NEC* | 10040759 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019157012** **Implementation Date:** 06-Jun-19 Related CR: 2019152004

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Oral contusion* | Approved as Requested | Proposed PT | |
| Old Primary SOC | *Gastrointestinal disorders* | | *Oral contusion* | 10078170 |
| New Primary SOC | *Injury, poisoning and procedural complications* | | Old Primary SOC | |
| | | | *Gastrointestinal disorders* | 10017947 |
| | | | New Primary SOC | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |

MSSO Comment:

**CR Number: 2019152005** **Implementation Date:** 06-Jun-19 Related CR: 2019152005

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Throat bruising* | Approved as Requested | Proposed LLT | |
| To PT | *Pharyngeal contusion* | | *Throat bruising* | 10083185 Current |
| | | | To PT | |
| | | | *Pharyngeal contusion* | 10083176 |

MSSO Comment: The proposal to add a new LLT Throat bruising to PT Pharyngeal contusion is approved as requested. Throat bruising is a frequently used synonym of the new PT Pharyngeal contusion.

**CR Number: 2019152006** **Implementation Date:** 06-Jun-19 Related CR: 2019152006

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Portomesenteric vein thrombosis* | Approved as Requested | Proposed LLT | |
| To PT | *Portosplenomesenteric venous thrombosis* | | *Portomesenteric vein thrombosis* | 10083184 Current |
| | | | To PT | |
| | | | *Portosplenomesenteric venous thrombosis* | 10077623 |

MSSO Comment: The proposal to add a new LLT Portomesenteric vein thrombosis to PT Portosplenomesenteric venous thrombosis is approved as requested. Portomesenteric venous thrombosis is an unusual cause of acute or chronic mesenteric ischemia. Because of its rarity and nonspecific presentation, radiologic imaging plays a key role in the diagnosis. Medical management with anticoagulation is the mainstay of therapy, with surgery reserved for patients suspected of having peritonitis or bowel infarction.

# Supplemental Update Report

**CR Number: 2019152007** **Implementation Date:** 06-Jun-19 Related CR: 2019152007

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Premature device expansion* | Approved as Requested | Proposed LLT | |
| To PT | *Device malfunction* | | *Premature device expansion* | 10083186 Current |
| | | | To PT | |
| | | | *Device malfunction* | 10063829 |

MSSO Comment: The proposal to add a new LLT Premature device expansion to PT Device malfunction is approved as requested. Premature device expansion represents a form of device malfunction of an expandable device, which is not imputable to an incorrect device handling by operator, and can cause problems during the insertion process.

**CR Number: 2019152008** **Implementation Date:** 06-Jun-19 Related CR: 2019152008

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Testicular varicose vein* | Rejected | | |
| To PT | *Varicocele* | | | |

MSSO Comment: The proposal to add a new LLT Testicular varicose vein to PT Varicocele is not approved. Testicular varicose vein is an explanatory expression seldom used in medical literature. It can also be misleading, since a varicocele is a scrotal condition, and the word "testicular", in the standalone use of the requested term, may suggest a different anatomical location in the male reproductive system. However, in a related change, PT Scrotal varicose veins, which is an explanatory expression of varicocele, will be demoted under to PT Varicocele.

**CR Number: 2019157013** **Implementation Date:** 06-Jun-19 Related CR: 2019152008

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *Scrotal varicose veins* | Approved as Requested | PT to merge | |
| To PT | *Varicocele* | | *Scrotal varicose veins* | 10039762 Current |
| | | | To PT | |
| | | | *Varicocele* | 10046986 |

MSSO Comment:

# Supplemental Update Report

**CR Number: 2019152009** **Implementation Date:** 07-Jun-19 Related CR: 2019152009

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Serous retinopathy* | Approved After Suspension | Proposed PT | |
| HLT primary | *Retinopathies NEC* | | *Serous retinopathy* | 10083187 |
| SOC primary | *Eye disorders* | | HLT primary | |
| | | | *Retinopathies NEC* | 10038932 |
| | | | SOC primary | |
| | | | *Eye disorders* | 10015919 |

MSSO Comment: The proposal to add a new PT Serous retinopathy to primary HLT Retinopathies NEC in SOC Eye disorders is approved as requested after suspension. Serous retinopathy is a condition in which a serous detachment of the neurosensory retina occurs over an area of leakage from the choriocapillaris through the retinal pigment epithelium. In related change, serous retinopathy has been observed in association with biological targeted therapies, PT MEK inhibitor-associated serous retinopathy will be demoted as a sub-concept LLT to the new PT Serous retinopathy.

**CR Number: 2019158129** **Implementation Date:** 07-Jun-19 Related CR: 2019152009

| Change Requested | Demote a PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| PT to merge | *MEK inhibitor-associated serous retinopathy* | Approved as Requested | PT to merge | |
| To PT | *Serous retinopathy* | | *MEK inhibitor-associated serous retinopathy* | 10078376 Current |
| | | | To PT | |
| | | | *Serous retinopathy* | 10083187 |

MSSO Comment:

**CR Number: 2019152010** **Implementation Date:** 06-Jun-19 Related CR: 2019152010

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Partial anosmia* | Approved Not as Requested | Proposed LLT | |
| To PT | *Anosmia* | | *Preferential anosmia* | 10083181 Current |
| | | | To PT | |
| | | | *Anosmia* | 10002653 |

MSSO Comment: The proposal to add a new LLT Partial anosmia to PT Anosmia is approved but not as requested. Preferential anosmia the inability to smell certain odors. The condition is often caused by psychological factors concerning either a particular smell or the situation in which the smell occurs. Preferential anosmia is preferred to the proposed term Partial anosmia, which may be taken as a severity descriptor and understood as a diminished sense of smell, or hyposmia. Preferential anosmia will be added as an LLT to PT Anosmia.

# Supplemental Update Report

**CR Number: 2019152011** **Implementation Date:** 06-Jun-19 Related CR: 2019152011

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Fallopian tube congestion* | Approved as Requested | Proposed PT | |
| | | | *Fallopian tube congestion* | 10083177 |
| | | | HLT primary | |
| | | | *Ovarian and fallopian tube disorders NEC* | 10013342 |
| | | | SOC primary | |
| | | | *Reproductive system and breast disorders* | 10038604 |

MSSO Comment: The proposal to add a new term Fallopian tube congestion is approved as requested. Fallopian tubes can become swollen, edematous, and congested in conditions involving infection and inflammation, such as pelvic inflammatory disease, fallopian tube torsion or pyosalpinx. Fallopian tube congestion will be added as PT under HLT Ovarian and fallopian tube disorders NEC.

**CR Number: 2019152012** **Implementation Date:** 06-Jun-19 Related CR: 2019152012

| Change Requested | Add a New Term | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed Term | *Hemidysesthesia* | Approved as Requested | Proposed LLT | |
| | | | *Hemidysesthesia* | 10083182 Current |
| | | | To PT | |
| | | | *Hemidysaesthesia* | 10083174 |

MSSO Comment: The proposal to add a new term Hemidysesthesia is approved as requested. Hemidysesthesia is defined as the distortion of any sense, especially of that of touch, often with an unpleasant abnormal sensation produced by normal stimuli, which affects one side of the body only. Hemidysesthesia will be added as an LLT under a new PT Hemidysaesthesia representing the British spelling of the term. In a related change, Hemidysaesthesia will be added as a PT to primary HLT Paraesthesias and dysaesthesias and secondary HLT Dermal and epidermal conditions NEC.

# Supplemental Update Report

**CR Number: 2019157014** **Implementation Date:** 06-Jun-19 Related CR: 2019152012

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Hemidysaesthesia* | Approved as Requested | Proposed PT | |
| HLT primary | *Paraesthesias and dysaesthesias* | | *Hemidysaesthesia* | 10083174 |
| SOC primary | *Nervous system disorders* | | HLT primary | |
| | | | *Paraesthesias and dysaesthesias* | 10033788 |
| | | | SOC primary | |
| | | | *Nervous system disorders* | 10029205 |
| | | | HLT secondary | |
| | | | *Dermal and epidermal conditions NEC* | 10012424 |
| | | | SOC secondary | |
| | | | *Skin and subcutaneous tissue disorders* | 10040785 |

MSSO Comment:

**CR Number: 2019152013** **Implementation Date:** 06-Jun-19 Related CR: 2019152013

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Bronchial scarring* | Approved Not as Requested | Proposed PT | |
| HLT primary | *Bronchospasm and obstruction* | | *Bronchial scarring* | 10083178 |
| SOC primary | *Respiratory, thoracic and mediastinal disorders* | | HLT primary | |
| | | | *Bronchial conditions NEC* | 10006429 |
| | | | SOC primary | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |

MSSO Comment: The proposal to add a new PT Bronchial scarring to primary HLT Bronchospasm and obstruction in SOC Respiratory, thoracic and mediastinal disorders is approved but not as requested. Infections and inflammations of the bronchial tree may lead to the appearance of scars when the inflammatory lesions heal. In occasions, this scarring leads to obstruction of the lumen, but some other times it is associated to a dilatation and bronchiectasis. Bronchial scarring will be added as a new PT under Bronchial conditions NEC, which is a non compromising HLT encompassing both the obstructive or dilatation evolution of the condition.

# Supplemental Update Report

**CR Number: 2019152014** **Implementation Date:** 06-Jun-19 Related CR: 2019152014

| Change Requested | Add a New PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Tracheal scarring* | Approved as Requested | Proposed PT | |
| HLT primary | *Tracheal disorders (excl infections and neoplasms)* | | *Tracheal scarring* | 10083180 |
| SOC primary | *Respiratory, thoracic and mediastinal disorders* | | HLT primary | |
| | | | *Tracheal disorders (excl infections and neoplasms)* | 10044288 |
| | | | SOC primary | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |
| | | | HLT secondary | |
| | | | *Respiratory tract and thoracic cavity procedural complications* | 10052823 |
| | | | SOC secondary | |
| | | | *Injury, poisoning and procedural complications* | 10022117 |

MSSO Comment: The proposal to add a new PT Tracheal scarring to primary HLT Tracheal disorders (excl infections and neoplasms) in SOC Respiratory, thoracic and mediastinal disorders is approved as requested. Inflammatory and ulcerative proceses of the trachea may lead to scar formation, often with subsequent tracheal stenosis. Tracheal scarring can also be the consequence of treatment interventions such as endoscopy or tracheal resection and reconstruction. Tracheal scarring will also be secondarily linked to HLT Respiratory tract and thoracic cavity procedural complications.

**CR Number: 2019161001** **Implementation Date:** 11-Jun-19 Related CR: 2019161001

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Jejunal oesophageal interposition* | Approved as Requested | Proposed LLT | |
| To PT | *Oesophagoplasty* | | *Jejunal oesophageal interposition* | 10083195 Current |
| | | | To PT | |
| | | | *Oesophagoplasty* | 10061985 |

MSSO Comment: The proposal to add a new LLT Jejunal oesophageal interposition to PT Oesophagoplasty is approved as requested. LLT Jejunal oesophageal interposition is the spelling British equivalent for the newly added LLT Jejunal esophageal interposition.

# Supplemental Update Report

**CR Number: 2019161002** **Implementation Date:** 11-Jun-19 Related CR: 2019161002

| Change Requested | Link (move) an LLT to another PT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Esophagoplasty* | Approved as Requested | Proposed LLT | |
| From PT | *Oesophageal operation* | | *Esophagoplasty* | 10062057 Current |
| To PT | *Oesophagoplasty* | | From PT | |
| | | | *Oesophageal operation* | 10061319 |
| | | | To PT | |
| | | | *Oesophagoplasty* | 10061985 |

MSSO Comment: The proposal to move the LLT Esophagoplasty from PT Oesophageal operation to PT Oesophagoplasty is approved as requested. LLT Oesophagoplasty was promoted to the PT level and therefore, the U.S. English spelling LLT Esophagoplasty must be moved to the promoted PT Oesophagoplasty.

**CR Number: 2019161003** **Implementation Date:** 11-Jun-19 Related CR: 2019161003

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Homocysteinaemia* | Approved as Requested | Proposed LLT | |
| To PT | *Hyperhomocysteinaemia* | | *Homocysteinaemia* | 10083193 Current |
| | | | To PT | |
| | | | *Hyperhomocysteinaemia* | 10051286 |

MSSO Comment: The proposal to add a new LLT Homocysteinaemia to PT Hyperhomocysteinaemia is approved as requested. This term is the British English spelling equivalent for the newly added LLT Homocysteinemia.

**CR Number: 2019161004** **Implementation Date:** 11-Jun-19 Related CR: 2019161004

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Dacryocystocoele* | Approved as Requested | Proposed LLT | |
| To PT | *Dacryocystocele* | | *Dacryocystocoele* | 10083192 |
| | | | To PT | |
| | | | *Dacryocystocele* | 10082947 Current |

MSSO Comment: The proposal to add a new LLT Dacryocystocoele to PT Dacryocystocele is approved as requested. This term is the British English spelling equivalent for the newly added PT Dacryocystocele.

# Supplemental Update Report

**CR Number: 2019161005** **Implementation Date:** 11-Jun-19 Related CR: 2019161005

| Change Requested | Add a New LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed LLT | *Dacryocystocoele acquired* | Approved as Requested | Proposed LLT | |
| To PT | *Dacryocystocele acquired* | | *Dacryocystocoele acquired* | 10083194 |
| | | | To PT | |
| | | | *Dacryocystocele acquired* | 10082948 Current |

MSSO Comment: The proposal to add a new LLT Dacryocystocoele acquired to PT Dacryocystocele acquired is approved as requested. This term is the British English spelling equivalent for the newly added PT Dacryocystocele acquired.

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**CR Number: 2019161006** **Implementation Date:** 11-Jun-19 Related CR: 2019161006

| Change Requested | Swap a PT with an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Dacryocystocele* | Approved as Requested | Proposed PT | |
| With LLT | *Dacryocystocoele* | | *Dacryocystocele* | 10082947 Current |
| | | | With LLT | |
| | | | *Dacryocystocoele* | 10083192 |

MSSO Comment: The proposal to swap the PT Dacryocystocele with the LLT Dacryocystocoele is approved as requested. Per MedDRA convention, terms with British spellings reside at the PT level and above.

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**CR Number: 2019161007** **Implementation Date:** 11-Jun-19 Related CR: 2019161007

| Change Requested | Swap a PT with an LLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Dacryocystocele acquired* | Approved as Requested | Proposed PT | |
| With LLT | *Dacryocystocoele acquired* | | *Dacryocystocele acquired* | 10082948 Current |
| | | | With LLT | |
| | | | *Dacryocystocoele acquired* | 10083194 |

MSSO Comment: The proposal to swap the PT Dacryocystocele acquired with the LLT Dacryocystocoele acquired is approved as requested. Per MedDRA convention, terms with British spellings reside at the PT level and above.

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# Supplemental Update Report

**CR Number: 2019162072** **Implementation Date:** 12-Jun-19 Related CR: 2019162072

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Lung diffusion test abnormal* | Approved as Requested | Proposed PT | |
| To HLT | *Respiratory and pulmonary function diagnostic procedures* | | *Lung diffusion test abnormal* | 10082576 |
| | | | To HLT | |
| | | | *Respiratory and pulmonary function diagnostic procedures* | 10037385 |

MSSO Comment: The proposal to link the PT Lung diffusion test abnormal to the HLT Respiratory and pulmonary function diagnostic procedures is approved as requested. Lung diffusion test abnormal is an investigation concept which has been incorrectly linked to an HLT in SOC Respiratory, thoracic and mediastinal disorders. This change links the concept to the correct HLT in SOC Investigations.

**CR Number: 2019162073** **Implementation Date:** 12-Jun-19 Related CR: 2019162073

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Lung diffusion test abnormal* | Approved as Requested | Proposed PT | |
| Old Primary SOC | *Respiratory, thoracic and mediastinal disorders* | | *Lung diffusion test abnormal* | 10082576 |
| | | | Old Primary SOC | |
| New Primary SOC | *Investigations* | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |
| | | | New Primary SOC | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to reassign the primary SOC of PT Lung diffusion test abnormal from current SOC Respiratory, thoracic and mediastinal disorders to SOC Investigations is approved as requested. Lung diffusion test abnormal is an investigation concept which has been incorrectly linked to an HLT in SOC Respiratory, thoracic and mediastinal disorders. This change switches the primary SOC of the concept to SOC Investigations.

**CR Number: 2019162074** **Implementation Date:** 12-Jun-19 Related CR: 2019162074

| Change Requested | Unlink a PT from a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Lung diffusion test abnormal* | Approved as Requested | Proposed PT | |
| From HLT | *Pulmonary thrombotic and embolic conditions* | | *Lung diffusion test abnormal* | 10082576 |
| | | | From HLT | |
| | | | *Pulmonary thrombotic and embolic conditions* | 10037439 |

MSSO Comment: The proposal to unlink the PT Lung diffusion test abnormal from the HLT Pulmonary thrombotic and embolic conditions is approved as requested. Lung diffusion test abnormal is an investigation concept which has been incorrectly linked to an HLT in SOC Respiratory, thoracic and mediastinal disorders. This change removes the link to SOC Respiratory, thoracic and mediastinal disorders.

# Supplemental Update Report

**CR Number: 2019162075** **Implementation Date:** 12-Jun-19 Related CR: 2019162075

| Change Requested | Link a PT to a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Lung diffusion test decreased* | Approved as Requested | Proposed PT | |
| | | | *Lung diffusion test decreased* | 10083094 |
| To HLT | *Respiratory and pulmonary function diagnostic procedures* | | To HLT | |
| | | | *Respiratory and pulmonary function diagnostic procedures* | 10037385 |

MSSO Comment: The proposal to link the PT Lung diffusion test decreased to the HLT Respiratory and pulmonary function diagnostic procedures is approved as requested. Lung diffusion test decreased is an investigation concept which has been incorrectly linked to an HLT in SOC Respiratory, thoracic and mediastinal disorders. This change links the concept to the correct HLT in SOC Investigations.

**CR Number: 2019162076** **Implementation Date:** 12-Jun-19 Related CR: 2019162076

| Change Requested | Reassign Primary SOC | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Lung diffusion test decreased* | Approved as Requested | Proposed PT | |
| | | | *Lung diffusion test decreased* | 10083094 |
| Old Primary SOC | *Respiratory, thoracic and mediastinal disorders* | | Old Primary SOC | |
| | | | *Respiratory, thoracic and mediastinal disorders* | 10038738 |
| New Primary SOC | *Investigations* | | New Primary SOC | |
| | | | *Investigations* | 10022891 |

MSSO Comment: The proposal to reassign the primary SOC of PT Lung diffusion test decreased from current SOC Respiratory, thoracic and mediastinal disorders to SOC Investigations is approved as requested. Lung diffusion test decreased is an investigation concept which has been incorrectly linked to an HLT in SOC Respiratory, thoracic and mediastinal disorders. This change switches the primary SOC of the concept to SOC Investigations.

**CR Number: 2019162077** **Implementation Date:** 12-Jun-19 Related CR: 2019162077

| Change Requested | Unlink a PT from a HLT | Final Disposition | Final Placement | MedDRA Code # |
|---|---|---|---|---|
| Proposed PT | *Lung diffusion test decreased* | Approved as Requested | Proposed PT | |
| | | | *Lung diffusion test decreased* | 10083094 |
| From HLT | *Pulmonary thrombotic and embolic conditions* | | From HLT | |
| | | | *Pulmonary thrombotic and embolic conditions* | 10037439 |

MSSO Comment: The proposal to unlink the PT Lung diffusion test decreased from the HLT Pulmonary thrombotic and embolic conditions is approved as requested. Lung diffusion test decreased is an investigation concept which has been incorrectly linked to an HLT in SOC Respiratory, thoracic and mediastinal disorders. This change removes the link to SOC Respiratory, thoracic and mediastinal disorders.