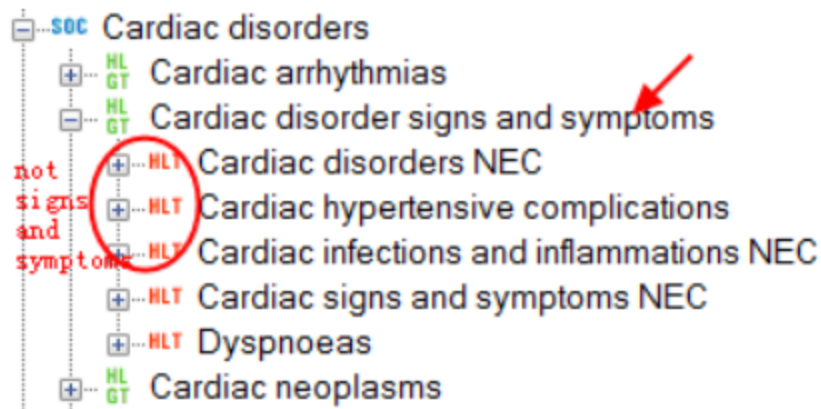


Implemented MedDRA Version 22.0 Complex Changes (October 2018)

MedDRA User Proposed Requests:

1. Move HLT *Cardiac disorders NEC* from HLGT *Cardiac disorder signs and symptoms* to new HLGT *Cardiac disorders NEC*

Submitter justification: HLGT *Cardiac disorder signs and symptoms* (10007539) should only contain terms of signs and symptoms, but actually the HLTs contain many diagnosis. That is very confusing. My suggestion is to move HLTs – HLT *Cardiac disorders NEC* (10007543), HLT *Cardiac hypertensive complications* (10007571), and HLT *Cardiac infections and inflammations NEC* (10007581) out from HLGT *Cardiac disorder signs and symptoms* (10007539) to a new HLGT named "Cardiac disorders NEC", and only keep the real signs and symptoms - HLT *Cardiac signs and symptoms NEC* (10007609) and HLT *Dyspnoeas* (10013975) under HLGT *Cardiac disorder signs and symptoms*.



Terminology Impact: Should this request be approved, HLTs - HLT *Cardiac disorders NEC*, HLT *Cardiac hypertensive complications*, and HLT *Cardiac infections and inflammations NEC* with their underlying PTs would move from HLGT *Cardiac disorder signs and symptoms* to a new HLGT *Cardiac disorders NEC*.

MSSO Note: This proposal would result in two MedDRA grouping terms having the same name which is not permitted per MedDRA rules (HLGT *Cardiac disorders NEC* and HLT *Cardiac disorders NEC*). If the proposal were to be implemented, the MSSO would need to rename one of the grouping terms to resolve this issue.

Implementation Status: This request will be approved, but not as requested. Existing HLGT *Cardiac disorder signs and symptoms* will be replaced with new HLGT *Cardiac disorders, signs and symptoms NEC* to clarify that the contents of this HLGT include miscellaneous cardiac disorders and miscellaneous signs and symptoms.

2. Replace HLGT *Vascular inflammations* with HLGT *Vascular inflammations and infections*

Submitter justification: HLGT *Vascular inflammations* contains PTs representing infections such as: PT *Aortitis Salmonella*, PT *Aortitis syphilitic*, PT *Infective aortitis*. This should be reflected in the HLGT name.

Terminology Impact: If approved, HLGT *Vascular inflammations* would be replaced by HLGT *Vascular inflammations and infections*. The underlying HLTs and PTs would move from HLGT *Vascular inflammations* to new HLGT *Vascular inflammations and infections*.

Implementation Status: This request will be approved, but not as requested. The new HLGT will reflect the fact that the HLGT contains terms for both infections and inflammations. It will be named HLGT *Vascular infections and inflammations* to be consistent with the wording used for similar grouping terms such as HLGT *Central nervous system infections and inflammations*, and HLT *Bladder infections and inflammations*. For similar reasons, underlying HLT *Aortic inflammatory disorders* will be replaced with new HLT *Aortic infections and inflammations* and HLT *Arterial inflammations* will be replaced with HLT *Arterial infections and inflammations*. HLT *Phlebitis NEC* and HLT *Vasculitidies NEC* will remain as is because, in this context, these represent broad groupings covering both inflammation concepts and infective concepts, e.g., PT *Phlebitis infective* and PT *Septic vasculitis*.

3. Add a New HLT *Subacute polyneuropathies* to HLT *Peripheral neuropathies*

Submitter justification: We have Acute and Chronic polyneuropathies as HLTs but none of these will be able to accommodate the PT “Subacute inflammatory demyelinating polyneuropathy” which is “a definite entity bridging the gap between Guillain–Barré syndrome and chronic inflammatory demyelinating polyneuropathy” - definition (<http://n.neurology.org/content/61/11/1507>). Adding new HLT *Subacute polyneuropathies* can open doors for adding PTs like SIDP.

Terminology Impact: If approved, PT *Subacute inflammatory demyelinating polyneuropathy* would be moved from HLT *Acute polyneuropathies* to new HLT *Subacute polyneuropathies* in SOC *Nervous system disorders*. The MSSO would determine if any additional existing terms or new terms added for MedDRA Version 22.0 would need to be placed in new HLT *Subacute polyneuropathies*.

Implementation Status: This request will not be implemented. The current placement PT *Subacute inflammatory demyelinating polyneuropathy* under HLT *Acute polyneuropathies* is acceptable since subacute polyneuropathy is a sub-concept of acute polyneuropathy.

4. Add a New HLT *Severity of illness scale*

Submitter justification: SCORTEN score and other severity of illness scales could be collected in this HLT.

Terminology Impact: If approved, the MSSO would identify appropriate PTs such as PT *APACHE II score* and PT *Disability assessment scale* to move to HLT *Severity of illness scale*.

Implementation Status: This request will not be implemented. Severity of illness scales are appropriately placed in the relevant anatomical and physiological groupings in SOC *Investigations* to facilitate coding and retrieval. The few more general scales such as the disability assessment scale that do not pertain to any particular anatomical location or physiological system are also appropriately grouped under HLT *Investigations NEC*.

5. Proactivity request to consider replacing HLT *Paraesthesias and dysaesthesias* with an improved name to better describe the underlying terms

Submitter justification: Below is a proactivity proposal to review the placement of anaesthesia terms, and also perhaps consider the naming of the *Paraesthesias and dysaesthesias* HLT. Anaesthesia terms in MedDRA are split between the HLT *Paraesthesias and dysaesthesias* and HLT *Sensory abnormalities NEC*. For instance:

<i>Paraesthesias and dysaesthesias</i> HLT	<i>Sensory abnormalities NEC</i> HLT
<i>Administration site anaesthesia</i> (PT)	<i>Anaesthesia</i> (PT)
<i>Anesthesia mouth</i> (LLT)	<i>Thermoanaesthesia</i> (PT)

There should be consistency of mapping of anaesthesia terms to the same HLT, particularly “site” (e.g. injection) anaesthesia and Anaesthesia.

Also, some anaesthesia terms are found at the PT level, whilst others exist only at the LLT level, e.g. Application site anaesthesia is a PT, but Oral mucosal anaesthesia is an LLT in the Hypoesthesia oral PT. Anaesthesia could be considered on a continuum of hypoesthesia, so justifying its sublimation as a sub-concept LLT; however a contrary opinion could be taken too.

Finally, should all the anaesthesia terms be moved to the *Paraesthesias and dysaesthesias* HLT, you could consider renaming the HLT to include the phrase anaesthesia – this one depends on whether the term “dysaesthesia” is assumed to cover conditions such as hypoesthesia and anaesthesia.

Terminology Impact: If HLT *Paraesthesias and dysaesthesias* was replaced with a new HLT, the MSSO would move the appropriate PTs under the new HLT. Additionally, based on the submitter’s request and regardless of whether a complex change is implemented, the MSSO would consider modifying the position of underlying anaesthesia PTs and LLTs for better and consistent placement in MedDRA.

Implementation Status: This request to add a new HLT will not be implemented. Dysesthesias is a broad concept considered to cover hyperesthesia, hypoesthesia, and anesthesia. However, for consistency of placement, the following PTs will be moved from HLT *Sensory abnormalities NEC* to HLT *Paraesthesias and dysaesthesias*:

- PT *Anaesthesia dolorosa*
- PT *Anaesthesia*
- PT *Hemianaesthesia*
- PT *Thermoanaesthesia*

MSSO Proposed Requests:

1. Add a New HLT *Thoracic spinal cord and nerve root disorders* to HLT *Spinal cord and nerve root disorders*

MSSO Rationale: The proposal for new HLT *Thoracic spinal cord and nerve root disorders* is to complement existing HLT *Cervical spinal cord and nerve root disorders* and HLT *Lumbar spinal cord and nerve root disorders* in HLT *Spinal cord and nerve root disorders*.

Terminology Impact: If approved, PT *Thoracic spinal stenosis* and PT *Thoracic radiculopathy* would be moved from HLT *Spinal cord and nerve root disorders NEC* to new HLT *Thoracic spinal cord and nerve root disorders*.

Implementation Status: This request will be approved as requested.

2. Merge HLT *Gingival pains* with existing HLT *Oral soft tissue pain and paraesthesia*

MSSO Rationale: HLT *Gingival pains* contains only one PT – PT *Gingival pain*. Merging HLT *Gingival pains* with existing HLT *Oral soft tissue pain and paraesthesia* would group PT *Gingival pain* together with other oral soft tissue pain and paraesthesia concepts such as PT *Oral pain* and PT *Lip pain*.

Terminology Impact: PT *Gingival pain* would be moved under existing HLT *Oral soft tissue pain and paraesthesia*. HLT *Gingival pains* would be removed from MedDRA.

Implementation Status: This request will be approved, but not as requested. Based on feedback, the MSSO will add a new HLT *Gingival disorders, signs and symptoms NEC* and merge existing HLTs - HLT *Gingival disorders NEC*, HLT *Gingival pains*, HLT *Gingival discolourations* under the new HLT. Rather than grouping the gingival terms with oral soft tissue concepts, new HLT *Gingival disorders, signs and symptoms NEC* groups miscellaneous gingival disorders and signs and symptoms together to facilitate coding and retrieval. The following PTs will be moved to new HLT *Gingival disorders, signs and symptoms NEC*:

PT *Gingival blister*
PT *Gingival discomfort*
PT *Gingival pruritus*

PT *Gingival oedema*
PT *Gingival swelling*
PT *Lineal gingival erythema*

3. **Add new HLT *Hallucinations (excl sleep-related)* to HLGT *Disturbances in thinking and perception***

Add new HLT *Perception disturbances NEC* to HLGT *Disturbances in thinking and perception*

Merge existing HLT *Perception disturbances* to new HLT *Perception disturbances NEC*

MSSO Rationale: These changes were recommended by the CIOMS SMQ Implementation Working Group to facilitate the retrieval of potential cases of hallucinations in lieu of a dedicated SMQ for hallucinations. The existing HLT Perception disturbances currently groups hallucination terms together with other disturbances in perception such as PT *Deja vu* and PT *Time perception altered*. These changes will group the specific terms for hallucinations together while separating out the other miscellaneous perception disturbances. Sleep-related hallucination concepts are not included in new HLT *Hallucinations (excl sleep-related)*; PT *Hypnagogic hallucination* and PT *Hypnopompic hallucination* remain in HLT *Narcolepsy and associated conditions*.

Terminology Impact: The following PTs would move from HLT *Perception disturbances* to new HLT *Hallucinations (excl sleep-related)*:

PT *Charles Bonnet syndrome*
PT *Formication*
PT *Hallucination*
PT *Hallucination, auditory*
PT *Hallucination, gustatory*
PT *Hallucination, olfactory*
PT *Hallucination, synaesthetic*
PT *Hallucination, tactile*
PT *Hallucination, visual*
PT *Hallucinations, mixed*
PT *Paroxysmal perceptual alteration*
PT *Somatic hallucination*

Implementation Status: This request will be approved as requested.