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# **What's New MedDRA Version 24.1**

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**September 2021**

**000636**

### ACKNOWLEDGEMENTS

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### 1. DOCUMENT OVERVIEW

This *What's New* document contains information on the origins and types of changes made to the Medical Dictionary for Regulatory Activities (MedDRA) between Versions 24.0 and 24.1.

Section 2, Version 24.1 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 24.1, highlights changes in Version 24.1 related to change request submissions, new initiatives, information on Standardised MedDRA Queries (SMQs), and any recent updates to software tools provided by the MSSO.

Section 4, Summary of Changes, contains details on:

- The impact of this version on the terminology (in tables)
- Impact on the records in MedDRA files
- MedDRA term and SMQ counts
- LLTs in MedDRA that had a currency status change

All updated documentation associated with this version is located in the distribution file in Adobe® Portable Document Format (PDF) or, for some documents, Microsoft Excel. Please refer to the Readme.txt file for a complete listing.

The Maintenance and Support Services Organization (MSSO) Help Desk can be reached at International AT&T Toll Free at 1-877-258-8280 or [mssohelp@meddra.org](mailto:mssohelp@meddra.org).

## 2. VERSION 24.1 CHANGE REQUESTS

### 2.1 TERMINOLOGY CHANGES

Changes to MedDRA result from user change requests, from proactivity requests submitted by MedDRA users, and from internal change requests. Internal change requests result from MSSO maintenance activities and from special working group activities in which the MSSO participates.

MedDRA Version 24.1 is a simple change version which means that changes are made at the PT and LLT level only.

Change requests involve both MedDRA updates and SMQ changes. There was a total of 1,874 change requests processed for this version; 1,481 change requests were approved and implemented, and 392 change requests were not approved. There is, in addition, 1 change request suspended for further consideration and resolution beyond this version.

Information on specific changes (e.g., new terms added, LLT promotions, PT demotions, PT primary SOC changes, etc.) which occurred since the prior MedDRA release can be obtained via the Version Report included with each respective MedDRA download. In addition, users may wish to use the [MedDRA Version Analysis Tool](#) (MVAT) which is an online tool that compares any two MedDRA versions– including non-consecutive versions – to identify changes. The output of MVAT is similar to the Version Report. MVAT is provided free of charge to MedDRA users as part of their subscription.

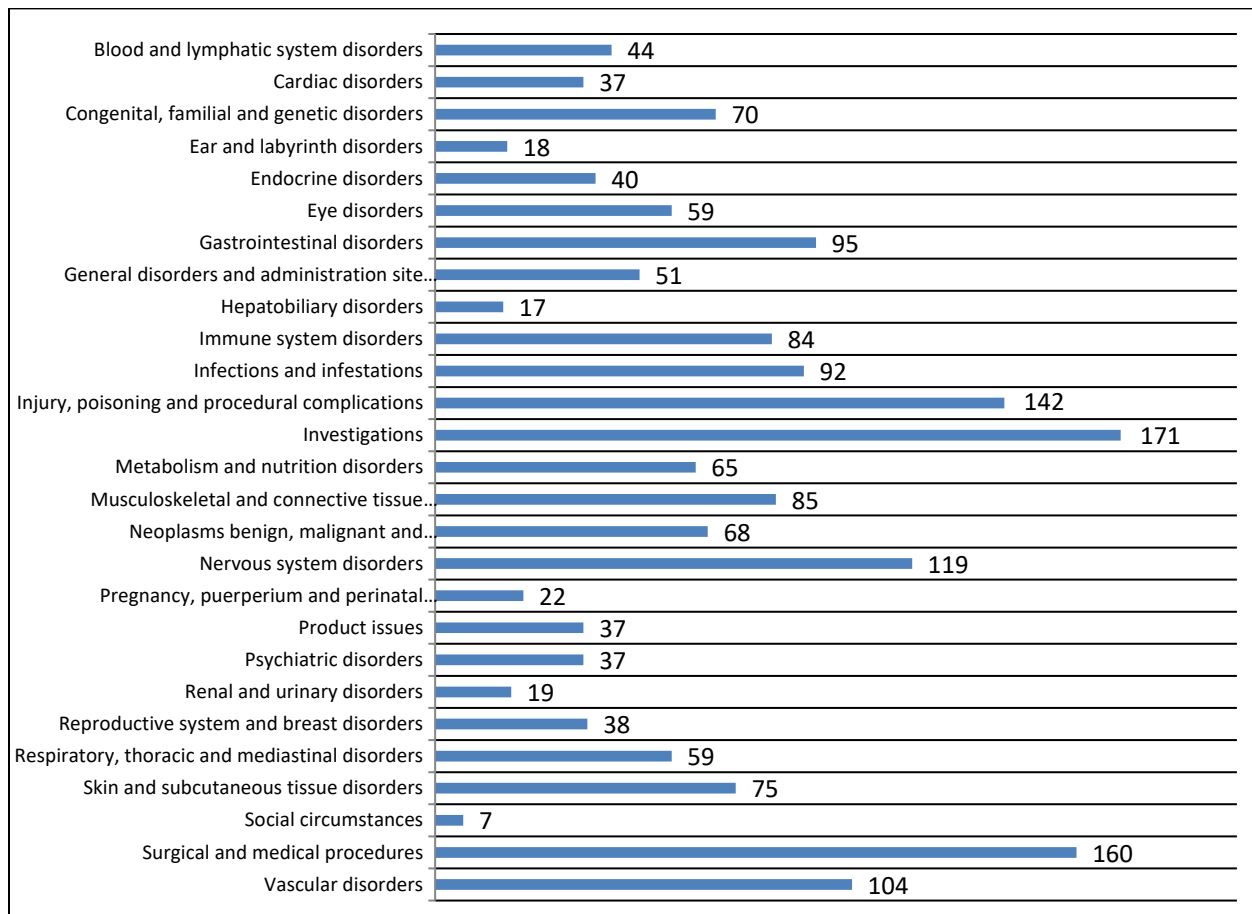
Between MedDRA releases, the MSSO makes available [weekly supplemental update](#) files, which are approved changes that will be implemented for the next MedDRA version. Additionally, supplemental changes may be viewed in MedDRA Web-Based Browser via the “supplemental view” feature. Supplemental information may be helpful for users to identify changes that will be implemented in the next release.

An explanation of all changes considered (approved and not approved) for MedDRA Version 24.1 is accessible as a cumulative Detail Report included in the MedDRA English version download. Users may review all change requests considered by the MSSO from MedDRA Version 5.1 to the present in [WebCR](#).

Figure 2-1 (shown below) summarizes all changes made per System Organ Class (SOC) and may be useful to gauge the impact of changes to a specific area of MedDRA. The data are derived from the difference in counts of primary and secondary PT/LLTs, HLTs, and HLGTS for Version 24.1 (shown in Table 4-5) and the corresponding information for Version 24.0. Additionally, LLT currency status changes are included in Figure 2-1.

Please see Section 4 for a summary of the changes in MedDRA Version 24.1.

## Version 24.1 Change Requests



**Figure 2-1 Net Changes of Terms per SOC**

### 3. NEW DEVELOPMENTS IN VERSION 24.1

#### 3.1 ADDITIONAL COVID-19 RELATED TERMS

The MSSO continued to add COVID-19 related terms in MedDRA Version 24.1 based upon MedDRA user requests. A total of 19 new COVID-19 related LLTs/PTs were added including terms related to COVID-19 vaccines. See the table below for several examples:

LLT	PT	HLT	Primary SOC
Anti-platelet factor 4 antibody positive	Anti-platelet factor 4 antibody positive	Coagulation and bleeding analyses	Investigations
Multisystem inflammatory syndrome	Multisystem inflammatory syndrome	Immune and associated conditions NEC	Immune system disorders
Multisystem inflammatory syndrome in adults	Multisystem inflammatory syndrome in adults	Immune and associated conditions NEC	Immune system disorders
Thrombosis with thrombocytopenia syndrome	Thrombosis with thrombocytopenia syndrome	Thrombocytopenias	Blood and lymphatic system disorders
Vaccination first dose	Immunisation	Immunisations	Surgical and medical procedures
Vaccination second dose	Immunisation	Immunisations	Surgical and medical procedures

**Table 3-1 COVID-19 Term Examples**

#### 3.2 STANDARDISED MedDRA QUERIES (SMQs)

One new SMQ has been added for MedDRA Version 24.1 - SMQ *Sexual dysfunction*. There are now 109 level 1 SMQs in production as of this version. In addition, there were 315 approved PT changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA Version 24.1 Version Report.

Please see the MedDRA Version 24.1 SMQ Introductory Guide for detailed information on new SMQ *Sexual dysfunction*.

### 3.3 PROACTIVITY REQUESTS

The proactive maintenance process allows MedDRA users to propose general changes to MedDRA outside of the established change request process. These proactivity requests may address inconsistencies, make corrections, or suggest improvements. During the Version 24.1 change request processing period, there were no open or implemented proactivity requests. The MSSO publishes and updates a list of all proposals received and their status on the [Change Request](#) section of the MedDRA website.

The MSSO is interested in learning about any ideas that users may have about “proactive” improvements to MedDRA. Please email your ideas for “proactive” MedDRA improvements to the MSSO Help Desk. Be as specific as possible in describing your suggestion(s), and include a justification which explains why you think your proposal should be implemented.

### 3.4 MedDRA USER DOCUMENT STEAMLINING

Beginning with MedDRA Version 24.1, the MedDRA user documents have been streamlined to make them more user-friendly. The specific documents affected are:

- MedDRA Introductory Guide
- SMQ Introductory Guide
- Distribution File Format Document

The revisions retain essential information, but remove unnecessary details and term citations. A summary of these changes include:

- Section 6 of the MedDRA Introductory Guide has been rewritten into a more concise and easy to read format
- Outdated information and unnecessary term citations were removed from the SMQ Introductory Guide
- The MedDRA file record counts in the Distribution File format document have been moved to the What’s New document to consolidate redundant information

See below for an example from the MedDRA Introductory Guide.

## **6.2 CARDIAC DISORDERS**

### **6.2.1 Basis for Classification**

- The division of HLGTs within this SOC has been done partly on an anatomic basis (e.g., myocardial disorders) and partly by pathophysiology (e.g., arrhythmias)
- HLTs are grouped by pathophysiology, with the exception of valve disorders, which are grouped anatomically by the valve affected

### **6.2.2 Conventions and Exceptions**

- All congenital cardiac disorders are placed within a specific HLGT. This includes terms for certain congenital anomalies that include both cardiac and vascular components.
- Electrocardiogram (ECG) results and auscultatory abnormalities are not included in SOC *Cardiac disorders*; they are grouped within SOC *Investigations*
- For the major body systems of cardiac, hepatic, pulmonary, and renal, the terms “failure” and “insufficiency” are used synonymously. In SOC *Cardiac disorders*, the “failure” term is at the PT level and the “insufficiency” term is at the LLT level.

**Figure 3-1 MedDRA Introductory Guide Streamlined Document Example**

These updates have been applied to all 14 supported languages.

### 3.5 SNOMED CT – MedDRA MAPS

On 30 April 2021, ICH and SNOMED International announced the release of important new maps between the global medical terminologies SNOMED CT and MedDRA. The maps are intended to facilitate the exchange of data between regulatory databases (which use MedDRA) and healthcare databases/electronic health records (which use SNOMED CT). There are two independent maps (MedDRA to SNOMED CT and SNOMED CT to MedDRA) which were derived from frequently used and key pharmacovigilance MedDRA terms. See the example below. MedDRA users may obtain the maps via the download page of the MedDRA website. They will be released annually every April.

#### MedDRA to SNOMED CT (6,467 records)

	A	B	C	D
1	MedDRA Code	MedDRA LLT	SNOMED Code	SNOMED FSN
2	10000051	Abdominal aneurysm	233985008	Abdominal aortic aneurysm (disorder)
3	10000054	Abdominal aortic aneurysm	233985008	Abdominal aortic aneurysm (disorder)
4	10002338	Aneurysm of abdominal aorta	233985008	Abdominal aortic aneurysm (disorder)
5	10048746	Abdominal bloating	116289008	Abdominal bloating (finding)
6	10009881	Colic	9991008	Abdominal colic (finding)
7	10000059	Abdominal discomfort	43364001	Abdominal discomfort (finding)
8	10054209	Gastrointestinal discomfort	43364001	Abdominal discomfort (finding)
9	10000060	Abdominal distension	162068007	Abdominal distension symptom (finding)
10	10000075	Abdominal hysterectomy	116141005	Abdominal hysterectomy (procedure)

#### SNOMED CT to MedDRA (3,729 records)

	A	B	C	D
1	SNOMED Code	SNOMED FSN	MedDRA Code	MedDRA LLT
2	233985008	Abdominal aortic aneurysm (disorder)	10000054	Abdominal aortic aneurysm
3	116289008	Abdominal bloating (finding)	10048746	Abdominal bloating
4	9991008	Abdominal colic (finding)	10000055	Abdominal colic
5	43364001	Abdominal discomfort (finding)	10000059	Abdominal discomfort
6	162068007	Abdominal distension symptom (finding)	10000060	Abdominal distension
7	116141005	Abdominal hysterectomy (procedure)	10000075	Abdominal hysterectomy
8	21522001	Abdominal pain (finding)	10000081	Abdominal pain
9	43478001	Abdominal tenderness (finding)	10000097	Abdominal tenderness
10	177250006	Abdominoplasty (procedure)	10053774	Abdominoplasty

Figure 3-2 SNOMED CT – MedDRA Maps example

To allow users to contribute to the maintenance of the maps, the MSSO deployed a free online mapping change request tool called [MapCR](#). MapCR allows licensed MedDRA or SNOMED CT users to submit change requests for additions or changes to maps and to search for submitted requests. For more information about the SNOMED CT to MedDRA maps and MapCR, please see the [Mapping section](#) of the MedDRA website.

In addition to the SNOMED CT to MedDRA maps, the MSSO is pursuing, with the support of the MedDRA Management Committee (MC), the development and maintenance of an ICD-10 to MedDRA mapping. The MedDRA MC has also supported

exploring with the World Health Organization (WHO) the development and maintenance of mappings between ICD-11 and MedDRA. The MSSO will be releasing more details about these mappings (e.g., timelines and formats) when they become available.

### **3.6 NEW MedDRA LANGUAGES UNDER DEVELOPMENT**

In 2020, the MedDRA MC approved additional MedDRA translations for the European Economic Area (EEA) official languages. This includes up to a total of 17 additional European languages to support the electronic product information initiative. Note that this initiative includes the translation of MedDRA terms only and does not include MedDRA user documentation.

Presently, Greek, Latvian, Maltese, Polish, and Swedish translations are in development and are expected to be completed in the first quarter of 2022. The remaining languages in the EEA region will be translated and made available between the years of 2022 to 2024. The MSSO will provide estimated release dates for the remaining languages as they become available.

Additionally, in July 2021 the MedDRA Management Committee approved an Arabic MedDRA translation. This translation is expected to begin development in 2022 and will include all MedDRA user documentation. The MSSO will provide an estimated release date for Arabic MedDRA once development of the translation is underway.

## 4. SUMMARY OF CHANGES

### 4.1 SUMMARY OF IMPACT ON THE TERMINOLOGY

The tables below (Tables 4-1 through 4-5) summarize the impact on MedDRA in Version 24.1. For detailed information on the changes to Version 24.1, please see the MedDRA Version Report in MVAT.

File Name	Number of Records in V24.0	Number of Records in V24.1	Change
hlgt.asc	337	337	0
hlgt_hlt.asc	1,755	1,755	0
hlt.asc	1,737	1,737	0
hlt_pt.asc	36,206	36,633	427
llt.asc	83,291	84,139	848
meddra_history_english.asc*	130,809	132,027	1,218
meddra_release.asc*	1	1	0
mdhier.asc	38,322	38,767	445
pt.asc	24,820	25,077	257
soc.asc	27	27	0
soc_hlgt.asc	354	354	0
intl_ord.asc	27	27	0
smq_list.asc	228	229	1
smq_content.asc	89,202	90,597	1,395

**Table 4-1 MedDRA Term File Counts**

MedDRA v24.1 is a simple change version which means changes are only made at the PT and LLT levels of the MedDRA hierarchy; hence there are no changes in the number of HLTs and HLGTS.

\* The meddra\_history\_english.asc and meddra\_release.asc files are optional files for use with the MedDRA Desktop Browser (MDB) release 3.0.2 Beta and up. These files are not part of the MedDRA schema.

The table below identifies the number of current vs. non-current terms.

### LLT Changes

Level	Currency Status	v24.0	v24.1
LLT	Current Terms	73,991	74,838
LLT	Non-current Terms	9,300	9,301*
LLT	Total LLTs <sup>1</sup>	83,291	84,139

**Table 4-2 Summary of Impact on LLTs**

<sup>1</sup>Total LLTs include PTs as they are also in the LLT distribution file.

\*Note in MedDRA Version 24.1 seven LLTs changed currency status. Four LLTs changed to a status of non-current and three LLTs changed to a status of current for a net change of one for the non-current term count of 9,301. See table 4-6 for an explanation of currency changes.

### New SMQs

Level	Net Change	v24.0	v24.1
1	1	108	109
2	0	82	82
3	0	20	20
4	0	16	16
5	0	2	2

**Table 4-3 Summary of Impact on SMQs**

## 4.2 SUMMARY OF IMPACT ON RECORDS IN MedDRA FILES

The table below lists the consecutive files, associated MedDRA tables and the number of records contained in each consecutive file. A zero indicates that the file has not changed since the prior consolidated MedDRA release. The table below summarizes the impact on MedDRA in Version 24.1. Please see the MedDRA Version Report in MVAT for details.

## Summary of Changes

File Name	Number of Records in Table
hlgt.seq	0
hlgt_hlt.seq	0
hlt.seq	0
hlt_pt.seq	605
llt.seq	1,075
mdhier.seq	639
pt.seq	364
soc.seq	0
soc_hlgt.seq	0
intl_ord.seq	0

**Table 4-4 Summary of Impact on Records in MedDRA Files**

### 4.3 MedDRA TERM COUNTS BY SOC

The table below shows term counts by SOC for HLGTs, HLTs, primary and secondary PTs and LLTs, and primary PTs and LLTs. Note that the number of LLTs also includes PTs.

SOC	LLTs (Primary) <sup>1</sup>	PTs (Primary) <sup>1</sup>	LLTs (Primary and Secondary) <sup>2</sup>	PTs (Primary and Secondary) <sup>2</sup>	HLTs <sup>3</sup>	HLGTs <sup>3</sup>
<i>Blood and lymphatic system disorders</i>	1,223	313	4,498	1,099	87	17
<i>Cardiac disorders</i>	1,530	375	2,524	669	36	10
<i>Congenital, familial and genetic disorders</i>	4,223	1,677	4,223	1,677	100	19

## Summary of Changes

<b>SOC</b>	<b>LLTs (Primary)<sup>1</sup></b>	<b>PTs (Primary)<sup>1</sup></b>	<b>LLTs (Primary and Secondary)<sup>2</sup></b>	<b>PTs (Primary and Secondary)<sup>2</sup></b>	<b>HLTs<sup>3</sup></b>	<b>HLGTs<sup>3</sup></b>
<i>Ear and labyrinth disorders</i>	451	99	904	239	17	6
<i>Endocrine disorders</i>	707	201	1,935	592	38	9
<i>Eye disorders</i>	2,637	663	4,034	1,130	63	13
<i>Gastrointestinal disorders</i>	4,079	943	7,955	1,867	105	21
<i>General disorders and administration site conditions</i>	2,515	1,012	3,484	1,368	35	7
<i>Hepatobiliary disorders</i>	713	218	1,569	465	19	4
<i>Immune system disorders</i>	559	161	3,009	852	26	4
<i>Infections and infestations</i>	7,566	2,105	7,978	2,225	150	12
<i>Injury, poisoning and procedural complications</i>	7,070	1,318	10,021	2,612	78	9
<i>Investigations</i>	14,473	6,052	14,473	6,052	106	23
<i>Metabolism and nutrition disorders</i>	1,027	304	2,940	854	63	14
<i>Musculoskeletal and connective tissue disorders</i>	2,748	510	7,019	1,458	59	11

### Summary of Changes

<b>SOC</b>	<b>LLTs (Primary)<sup>1</sup></b>	<b>PTs (Primary)<sup>1</sup></b>	<b>LLTs (Primary and Secondary)<sup>2</sup></b>	<b>PTs (Primary and Secondary)<sup>2</sup></b>	<b>HLTs<sup>3</sup></b>	<b>HLGTs<sup>3</sup></b>
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	8,837	2,042	9,682	2,380	201	39
<i>Nervous system disorders</i>	3,879	1,039	7,823	2,164	108	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1,682	240	3,026	655	48	8
<i>Product issues</i>	902	178	933	192	21	2
<i>Psychiatric disorders</i>	2,451	563	3,426	856	77	23
<i>Renal and urinary disorders</i>	1,286	380	2,753	799	32	8
<i>Reproductive system and breast disorders</i>	1,831	518	4,466	1,262	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1,869	581	4,552	1,258	49	12
<i>Skin and subcutaneous tissue disorders</i>	2,256	550	5,727	1,528	56	10
<i>Social circumstances</i>	659	283	659	283	20	7
<i>Surgical and medical procedures</i>	5,543	2,416	5,543	2,416	141	19

## Summary of Changes

SOC	LLTs (Primary) <sup>1</sup>	PTs (Primary) <sup>1</sup>	LLTs (Primary and Secondary) <sup>2</sup>	PTs (Primary and Secondary) <sup>2</sup>	HLTs <sup>3</sup>	HLGTs <sup>3</sup>
<i>Vascular disorders</i>	1,423	336	7,257	1,815	68	11
<b>Total</b>	<b>84,139</b>	<b>25,077</b>				

**Table 4-5 MedDRA Term Counts by SOC**

<sup>1</sup>Primary count only includes the number of terms that are primarily linked to the designated SOC at either the LLT level or the PT level. The sums of primary LLTs and PTs match those in Tables 4-1 and 4-2.

<sup>2</sup>Total count includes the number of terms that are both primarily and secondarily linked to the designated SOC at either the LLT level or the PT level. Therefore, the sums of total LLTs and PTs are greater than those in Tables 4-1 and 4-2.

<sup>3</sup>The HLT and HLGT counts are not necessarily unique values given MedDRA's multi-axiality (see Section 2.2 of the Introductory Guide for a discussion of multi-axiality). There are some HLTs that are counted in more than one SOC. For example, HLT *Connective tissue disorders congenital* and HLGT *Musculoskeletal and connective tissue disorders congenital* are counted in both SOC *Congenital, familial and genetic disorders* and SOC *Musculoskeletal and connective tissue disorders*. The sums of HLTs and HLGTs are greater than those found in Table 4-1.

## 4.4 LLT CURRENCY STATUS CHANGES

The following table reflects seven terms at the LLT level in MedDRA Version 24.1 that had a change in currency status along with the rationale for the change.

Lowest Level Term	Currency Status Changed to	Rationale
Ear, nose and throat infection	Current	Ear, nose and throat infection is a valid medical concept and is frequently reported as an indication as well as an adverse event. Note that in MedDRA Version 24.1, LLT <i>Ear, nose and throat infection</i> was promoted from under PT <i>Upper respiratory tract infection</i> to the PT level, to allow appropriate linkage to primary HLT <i>Infections NEC</i> and secondary HLTs - HLT <i>Ear disorders NEC</i> and HLT <i>Upper respiratory tract infections NEC</i> .

## Summary of Changes

Lowest Level Term	Currency Status Changed to	Rationale
Hurler's disease	Current	LLT <i>Hurler's disease</i> is a valid synonym of existing PT <i>Mucopolysaccharidosis</i> . Therefore, the term was changed to a status of current.
MGUS undetermined	Current	LLT <i>MGUS undetermined</i> was changed to a status of current because it is a valid acronym of Monoclonal gammopathy of undetermined significance.
Airway patency oesophageal device	Non-Current	Following a demotion under existing PT <i>Airway patency device insertion</i> , LLT <i>Airway patency oesophageal device</i> was changed to a status of non-current as it does not include the word "insertion" to distinguish it as a procedure from the device itself. This procedural concept is already represented by LLT <i>Pharyngotracheal lumen airway insertion</i> .
Airway patency esophageal device	Non-Current	LLT <i>Airway patency esophageal device</i> was changed to a status of non-current, as it does not include the word "insertion" to distinguish it as a procedure from the device itself. This procedural concept is already represented by LLT <i>Pharyngotracheal lumen airway insertion</i> .
Hydropic decompensation	Non-current	The currency status of LLT <i>Hydropic decompensation</i> was changed to non-current as it is an ambiguous term that could refer to cardiac or hepatic decompensation.
Myocardial strain	Non-Current	PT <i>Myocardial strain</i> was demoted to an LLT under the new PT <i>Myocardial strain imaging</i> and its status was changed to non-current because of its ambiguity.

**Table 4-6 LLT Currency Changes**