2 July 2026
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Information Management

Coding of indications in the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD)

Best practice for coding of indications based on section 4.1 of the Summary of Product Characteristics (SmPC) using MedDRA terminology

Background

In accordance with Article 57(2) of Regulation 726/2004, marketing authorisation holders (MAHs) are obliged to electronically submit information on all medicinal products authorised for human use in the European Union (EU) and the European Economic Area (EEA).

The International Organization for Standardization (ISO) standard 11615: 2012 on 'Data elements and structures for the unique identification and exchange of regulated medicinal product information' was published in 2012.

As part of the electronic submission of information for authorised medicinal products, the authorised therapeutic indications should be provided using the MedDRA dictionary for coding. For each indication, the following information should be provided: the MedDRA version selected for coding (AP.IND.1), the MedDRA level selected for coding (AP.IND.2), and the selected MedDRA code (AP.IND.3).

In the future, the use of ISO standards in the Product Management System (PMS) will allow the coding of further structured details related to indication, such as populations specifics (e.g.: age, age range, gender, race) and other therapy specifics (e.g. second line treatment, co-treatment) related to the approved therapeutic indication. For the time being, only co-morbidity and intended effect are included in PMS. To check the latest developments of the EU implementation of ISO IDMP please refer to the 'Implementation of the ISO IDMP standards' webpage.

This document details how the coding is currently performed in the XEVMPD. Any references to future coding practices are made for illustrative purposes only.

This document should be read in conjunction with Chapter 3.II of the XEVPRM User Guidance, section **AMP - Product indications (AP.INDs)**.

[1] Document updated to contain the most up to date information.

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Scope of this document

The aim of this document is to clarify the current selection of MedDRA codes for authorised indications using the data structure in the XEVMPD in relation to the new data structure of the ISO IDMP standard to achieve a consistent way of coding that will simplify the subsequent migration of Article 57 data into the new ISO structure used in PMS. A further aim is to reinforce the existing guidance for selecting MedDRA codes for the coding of authorised indications.

The core principle of indication coding (in the context of Art. 57 product submission) is the purpose of capturing of the most detailed and complete MedDRA LLT (low level term) code, based on the indication text in section 4.1 of the SmPC, following the principles described below. Since January 2026, indications can also be coded using MedDRA PT (preferred term) codes.

Coding principles

A set of guiding principles to be followed are listed below:

- The basis for the coding of therapeutic indications is **the SmPC as authorised by the Member State**, which means that a difference in authorised therapeutic indications across Member States is to be reflected also by the data submitted. Marketing authorisation holders should not use a single core data sheet for all authorised products unless all SmPCs are completely aligned to the core data sheet.

  Any information not listed in the section 4.1 of the SmPC should not be captured in the structured indication field; however, information in other sections of the SmPC, such as section 5.1, may be helpful to create a better understanding of the indication text.

- The MedDRA codification of an indication should be provided in the form of the **most suitable low-level terms (LLTs) or preferred terms (PTs)**. Note that the purpose is not to capture *all* the applicable LLTs for a particular concept; these are often designed as linguistic variances with the same meaning. Similarly, all medical concepts that could be covered by the indication should also not be captured. Instead, one LLT that provides the most accurate, comprehensive and detailed level of information matching to the verbatim of the indication text should be sought. If necessary, more than one LLT may be selected.

  Using internal coding based on the preferred term (PT) translated in the XEVMPD in exports of all the applicable LLT as found in the MedDRA hierarchy is also allowed.

  Combination of LLTs and PTs within one medicinal product entry is also possible.

- The basis for the selection of a MedDRA term for the indication corresponds conceptually to the **'Disease/symptoms/procedure'** described in the ISO standard, i.e. the (underlying) disease, symptom or a procedure that is the indication for treatment, including the disease or symptom part of the intended effect were stated in the indication text.

  Coded indication in current system **should not capture the 'Comorbidity/concurrent conditions'** aspect of the indication. This refers to further conditions (concurrent conditions or co-infections) that define the patient population apart from the 'Disease/symptoms/procedure' aspect of the indication. It should be noted that 'Comorbidity/concurrent conditions' is used in a broader sense than its common medical interpretation.

  Coding indication in the current system should also capture the **disease or symptom part of the 'Intended effect'**, where stated in the indication text.

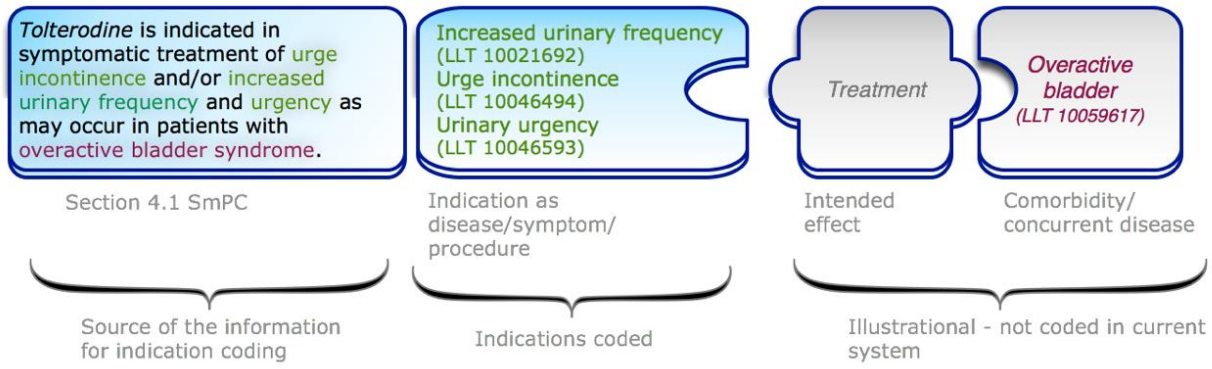
- The chosen MedDRA term should be **as specific as possible**, targeting to capture the most detailed level of information presented in the indication section. If a term can be identified, additional information should be captured; e.g.:
  - Both, the disease and its cause, as provided in the SmPC, (e.g. 'Osteoporosis steroid-induced');
  - aspects of 'Disease status specification' (e.g. 'Pancreatic adenocarcinoma metastatic');
  - details related to the target population (e.g.: 'Osteoporosis postmenopausal');
  - timing/duration (e.g.: 'Hepatitis chronic persistent').
- When the indication is for prophylaxis or prevention, and no relevant combined term (e.g. 'Constipation prophylaxis') can be identified, a term for 'Prophylaxis' or 'Prevention' needs to be added separately. While the two terms are indeed captured individually with no apparent relation between them (e.g.: 'Cardiovascular events' and 'Prophylaxis') this manner of coding is accepted as a convention until further development will be put in place. It needs to be considered whether a drug indicated for prophylaxis or prevention is also indicated for treatment. In that case, the treated symptom or disease should also be coded.

Examples

Please note that the examples are for illustrational purposes only and are not presented in any particular order. The purpose is not to indicate how to code parts of the indication that are not currently coded. It is very important to note that the information that is within the scope of the current guidance is illustrated below in green (i.e.: indication as disease/symptom/procedure) whereas the rest of information is not currently captured in the system; the manner in which this will be structured in the future remains to be established.

The examples are using terminology available in MedDRA 29.0.

Example (1): shows coding of indication as symptom for a product, where an underlying disease is mentioned as a possible cause of the symptoms treated, indicated here as comorbidity.



Low level term	LLT code	Preferred term	PT code
Increased urinary frequency	10021692	Pollakiuria	10036018
Urge incontinence	10046494	Urge incontinence	10046494
Urinary urgency	10046593	Micturition urgency	10027566

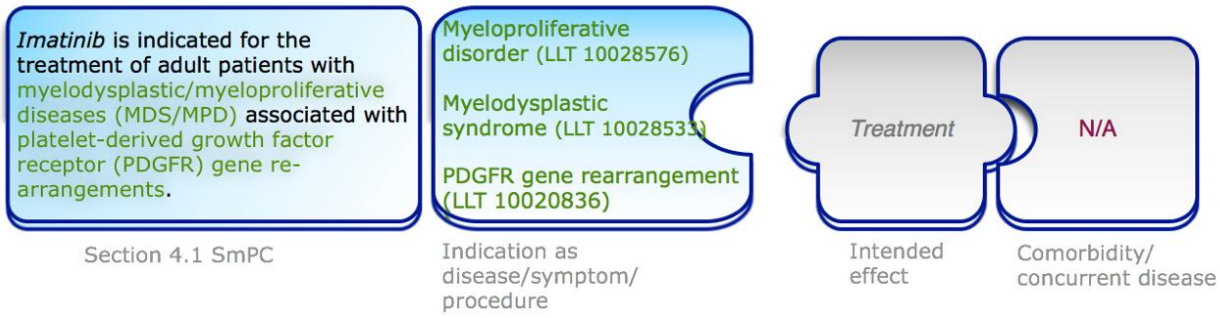
To further exemplify the separation between the therapeutic indication and the comorbidity, where the indication text states: *"Treatment of pancreatic insufficiency in patients with cystic fibrosis"*, then 'Pancreatic insufficiency' needs to be included as indication, whereas 'Cystic fibrosis' represents the 'Comorbidity/concurrent conditions' aspect of the indication and it should not be included at this stage in the indication field. This is because the treatment specifically targets the pancreatic insufficiency, and although pancreatic insufficiency is common in cystic fibrosis, many patients with cystic fibrosis do not have pancreatic insufficiency.

Careful consideration of the disease in relation to the stated therapeutic indication, as well as of the drug's mechanism of action and impact on the disease itself is required, when assessing whether the diseases mentioned in the indication text should be considered a comorbidity (and left out at this stage) or whether they constitute in fact the therapeutic indication (and need to be included). To be considered as indication, the signs or symptoms treated should not only be typical for the disease, i.e. shared by all or almost all patients with the disease, they should also represent the most important signs or symptoms for patients with the disease.

Looking at an example where the indication states: *"For the treatment of hyperglycaemia in type II diabetes",* then it needs to be considered that treatment of hyperglycaemia (i.e. achieving normoglycaemia), is the goal of all antidiabetic treatment, and type II diabetes should therefore be considered as an indication for treatment and not a concurrent disease.

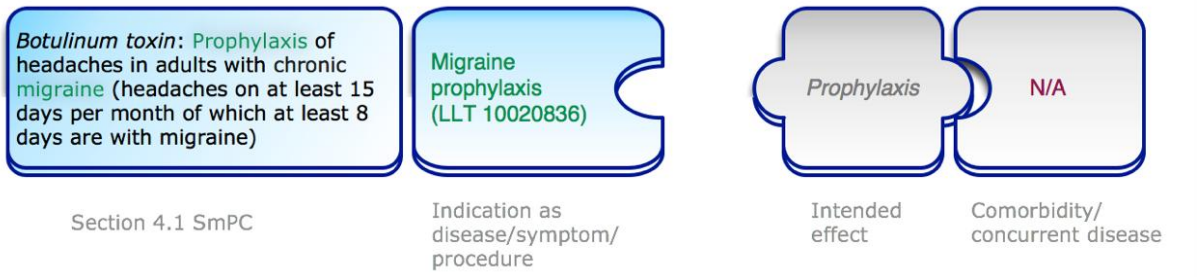
Other examples further illustrating the points presented in this document are described below.

Example (2): A case where both indications captured in SmPC are to be coded because no single code covers the entire indication:



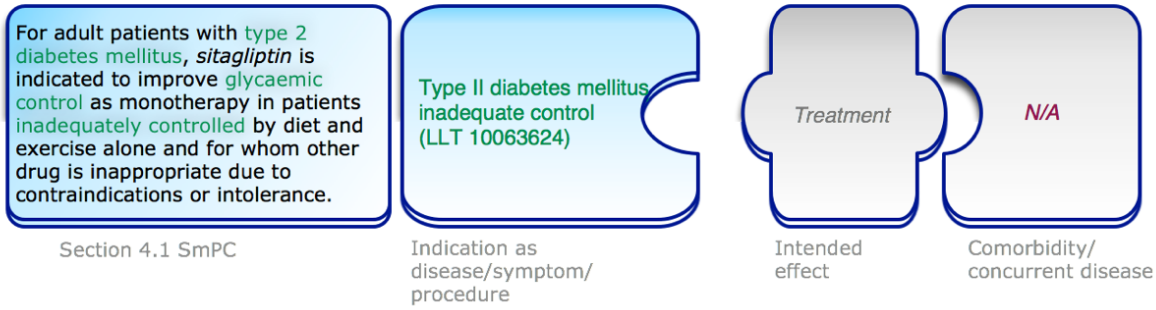
Low level term	LLT code	Preferred term	PT code
Myeloproliferative disorder	10028576	Myeloproliferative neoplasm	10077465
Myelodysplastic syndrome	10028533	Myelodysplastic syndrome	10028533
PDGFR gene rearrangement	10075678	Platelet-derived growth factor receptor gene mutation	10075655

Example (3): A case where the indication needs to be carefully considered in its context (migraine is not a concurrent condition in this case; migraine is being prevented in patients with chronic migraine). In this case the term captures both the information on prophylaxis and on the targeted event:



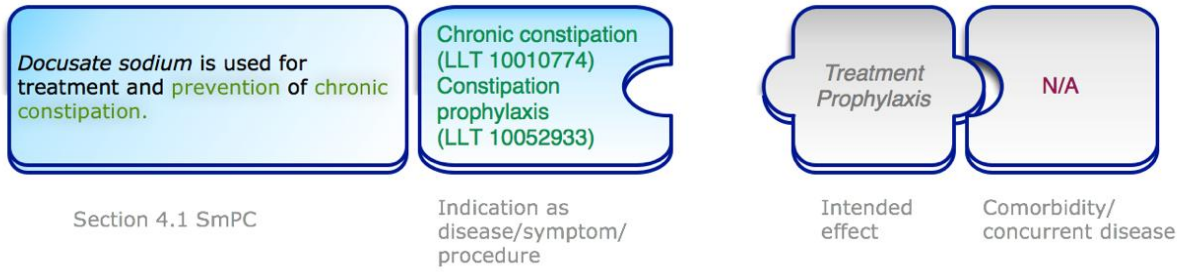
Low level term	LLT code	Preferred term	PT code
Migraine prophylaxis	10058734	Migraine prophylaxis	10058734

Example (4): A case where the most detailed level of information is used to capture the indication, as available in MedDRA terminology:



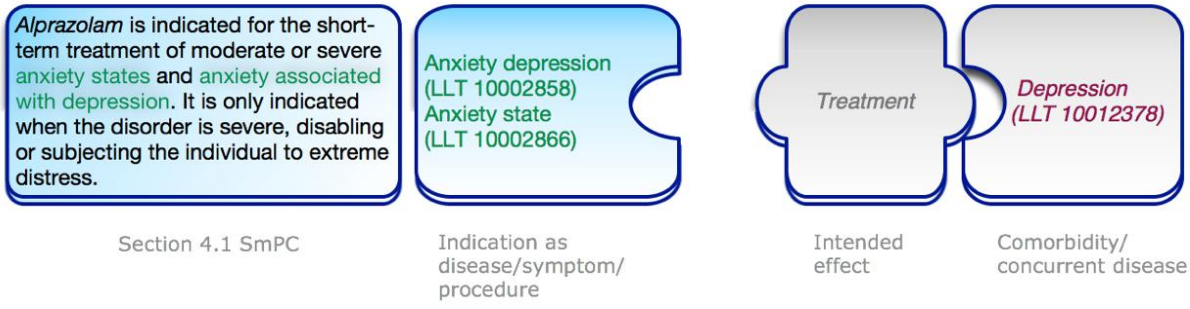
Low level term	LLT code	Preferred term	PT code
Type II diabetes mellitus inadequate control	10063624	Diabetes mellitus inadequate control	10012607

Example (5): A case where both treatment and prophylaxis are to be coded in indication section, as the medicinal product is used for both purposes:



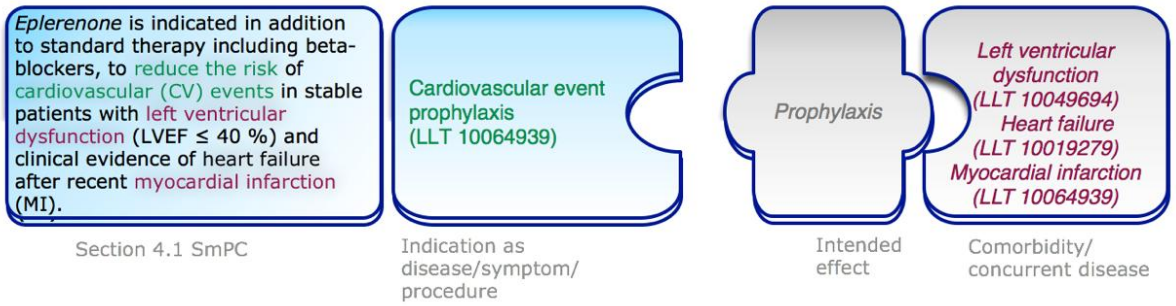
Low level term	LLT code	Preferred term	PT code
Constipation chronic	10063582	Constipation	10010774
Constipation prophylaxis	10052933	Constipation prophylaxis	10052933

Example (6): A case where most detailed information about the treated conditions is captured, showing that the indication is for anxiety both with and without depression. The code for depression might also be captured (in future system enhancements) in the comorbidity/concurrent disease part of the indication, but it does not constitute the indication of this medicine (i.e.: alprazolam is not used to treat depression, but anxiety (associated or not with depression).



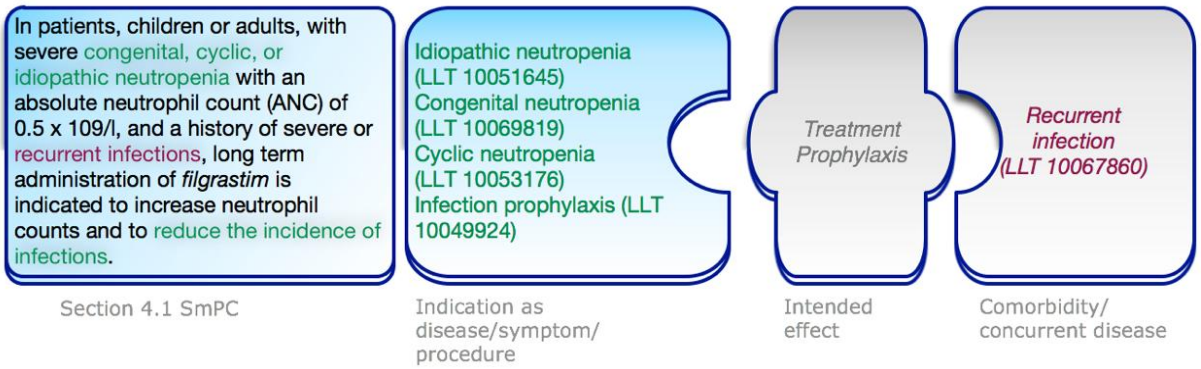
Low level term	LLT code	Preferred term	PT code
Anxiety depression	10002858	Depression	10012378
Anxiety state	10002866	Anxiety	10002855

Example (7): A case of a prophylaxis indication (*"to reduce the risk")* where an appropriate LLT is available in MedDRA (composed term that captures both the information on prophylaxis and on the targeted event):



Low level term	LLT code	Preferred term	PT code
Cardiovascular event prophylaxis	10064939	Cardiovascular event prophylaxis	10064939

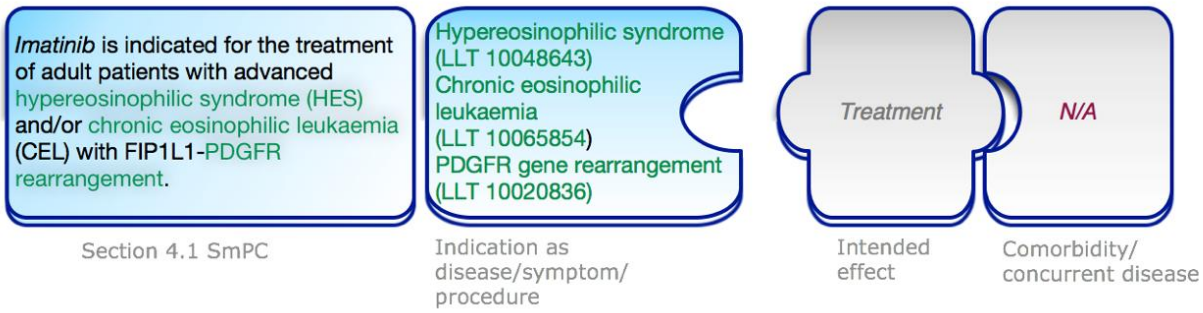
Example (8): A case where the drug is indicated for congenital, cyclic or idiopathic neutropenia for which appropriate MedDRA LLTs are available. Additional requirements are a specified absolute neutrophil count level, and a history of severe or recurrent infections. In addition, the indication text states a prophylaxis indication ('to reduce the incidence'), where an appropriate LLT is available in MedDRA (composed term that captures both the information on prophylaxis and on the targeted event):



Low level term	LLT code	Preferred term	PT code
idiopathic neutropenia	10051645	idiopathic neutropenia	10051645

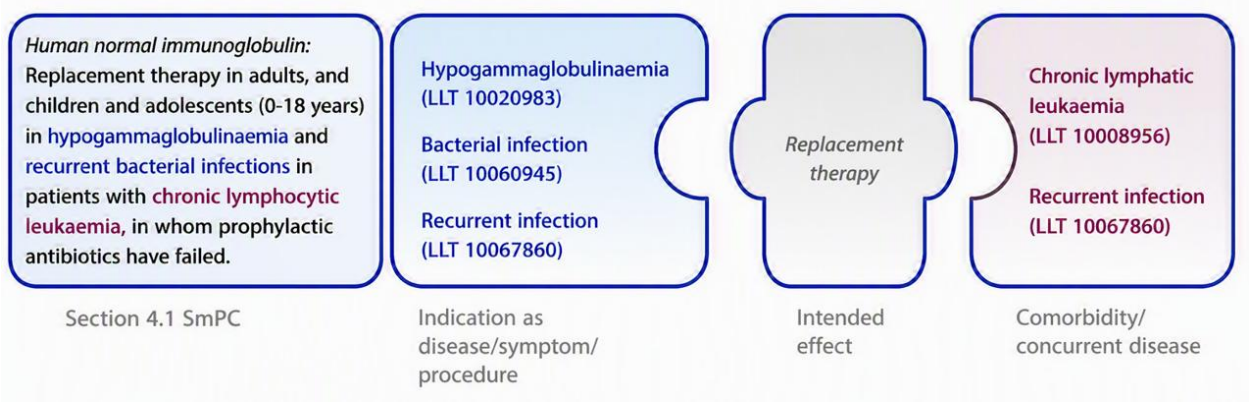
Congenital neutropenia	10069819	Infantile genetic agranulocytosis	10052210
Cyclic neutropenia	10053176	Cyclic neutropenia	10053176
Infection prophylaxis	10049924	Infection prophylaxis	10049924

Example (9): A case of coding a treatment indication:



Low level term	LLT code	Preferred term	PT code
Hypereosinophilic syndrome	10048643	Hypereosinophilic syndrome	10048643
Chronic eosinophilic leukaemia	10065854	Chronic eosinophilic leukaemia	10065854
PDGFR gene rearrangement	10075678	Platelet-derived growth factor receptor gene mutation	10075655

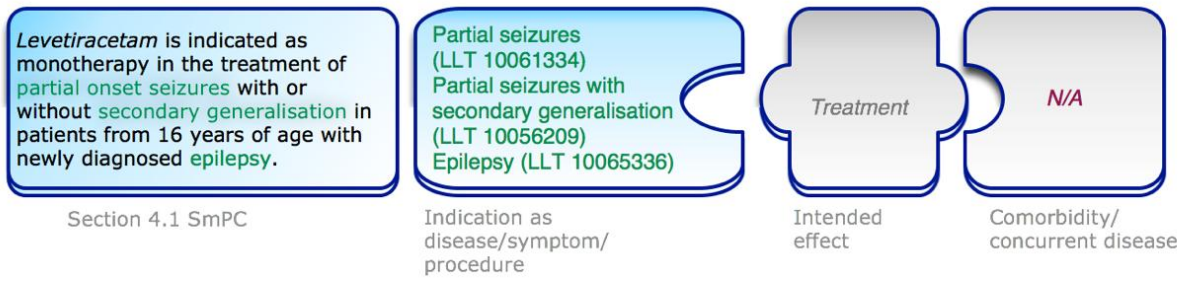
Example (10): A case where the capturing of indication of a replacement therapy is presented. The drug is a gamma globulin replacement in hypogammaglobinaemia. The patients have chronic lymphocytic leukaemia, which is not treated by the drug, and similarly, recurrent bacterial infections are encountered but not directly treated:



More granular LLT Term should be capture, Secondary acquired hypogammaglobulinaemia is not present in the text hence it should not capture:

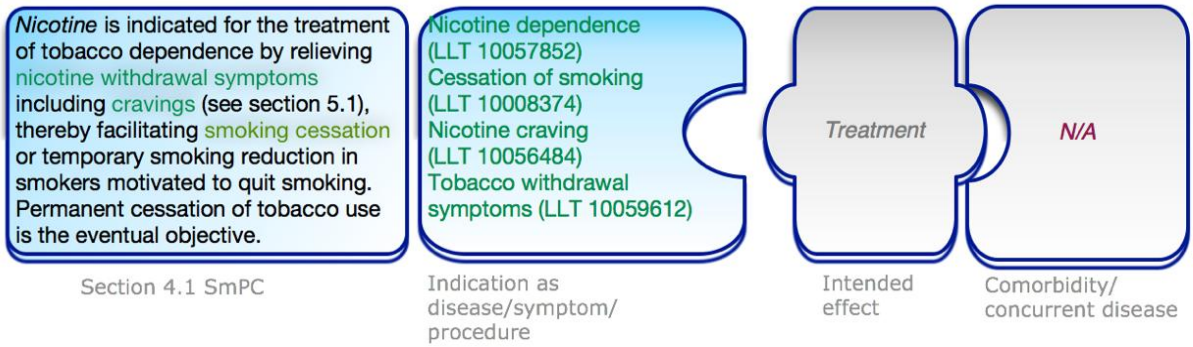
Low level term	LLT code	Preferred term	PT code
hypogammaglobulinaemia	10020983	hypogammaglobulinaemia	10020983
Bacterial infection	10060945	Bacterial infection	10060945
Recurrent infection	10067860	Infection	10021789

Example (11): A case where an antiepileptic drug is indicated for treatment of partial onset seizure type epilepsy. The most detailed information is captured. Epilepsy is also captured to reflect the disease part of the intended effect:



Low level term	LLT code	Preferred term	PT code
Partial seizures	10061334	Partial seizures	10061334
Partial seizures with secondary generalisation	10056209	Partial seizures with secondary generalisation	10056209
Epilepsy	10015037	Epilepsy	10015037

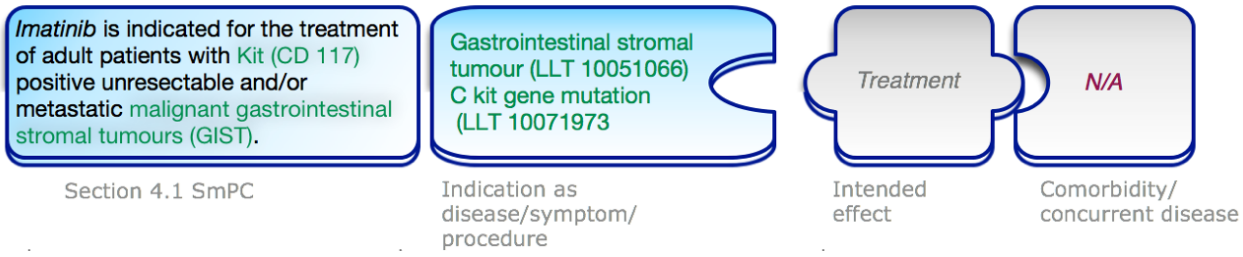
Example (12): A case where treatment is for tobacco dependence. In addition, terms representing the intended treatment effects as described in the indication text have been selected:



Low level term	LLT code	Preferred term	PT code
Nicotine dependence	10057852	Nicotine dependence	10057852

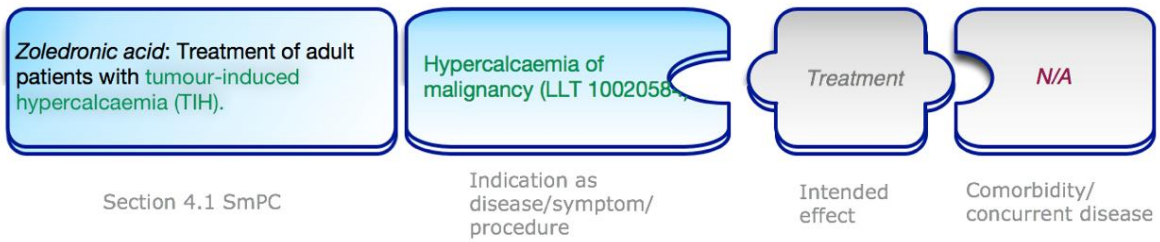
Cessation of smoking	10008374	Ex-tobacco user	10065386
Tobacco withdrawal symptoms	10059612	Tobacco withdrawal symptoms	10059612
Nicotine craving	10056484	Nicotine dependence	10057852

Example (13): A case of coding a treatment indication, where there is no term available to describe also the disease status:



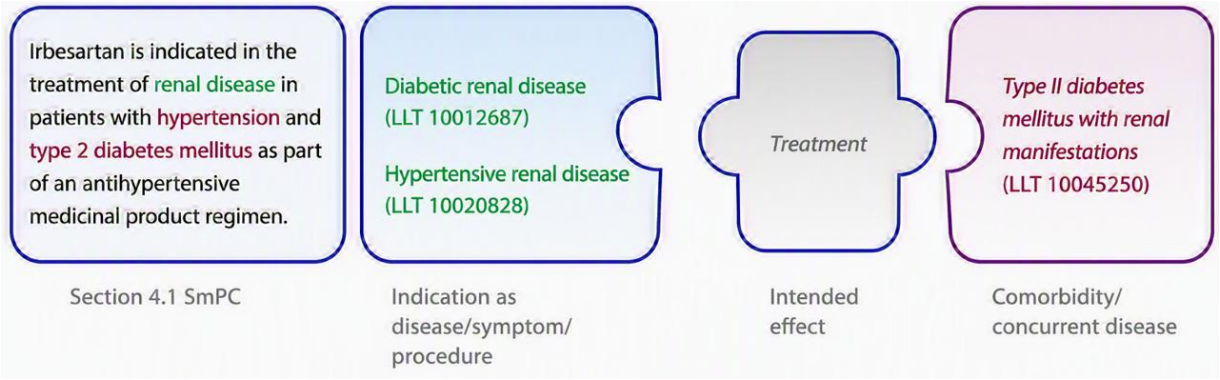
Low level term	LLT code	Preferred term	PT code
Gastrointestinal stromal tumour	10051066	Gastrointestinal stromal tumour	10051066
C-kit gene mutation	10071973	C-kit gene mutation	10071973

Example (14): A case where both the treated symptom and its cause can be coded with the same term:



Low level term	LLT code	Preferred term	PT code
Hypercalcaemia of malignancy	10020584	Hypercalcaemia of malignancy	10020584

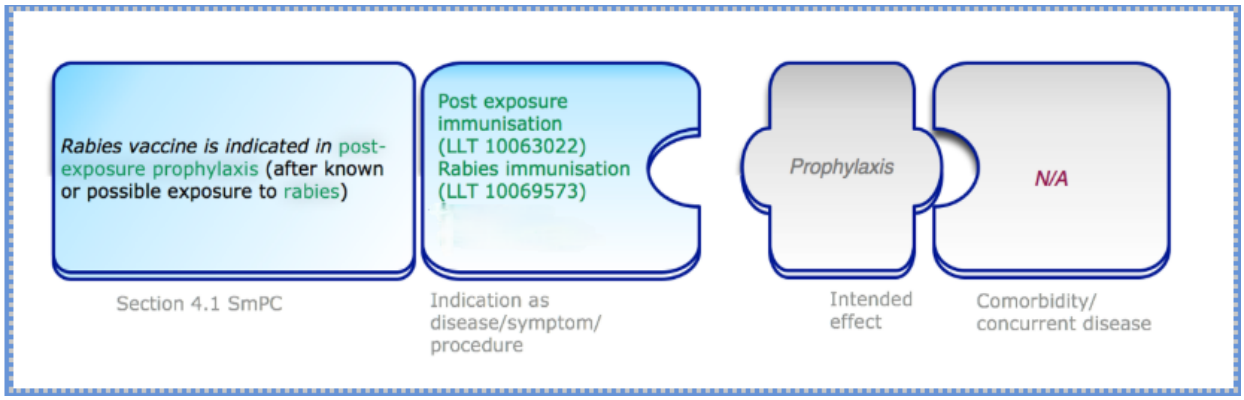
Example (15): A case where the target and effect of the medication need to be considered to discriminate between the indication as disease/symptom/procedure and the comorbidity to be included at a later stage of data submission. Hypertension is captured to reflect the disease part of the intended effect:



More granular LLT Term should be captured: Terms 'renal disease' should be replaced by 'Diabetic renal disease', and 'Hypertension' should be replaced by 'Hypertensive renal disease'.

Low level term	LLT code	Preferred term	PT code
Diabetic renal disease	10012687	Diabetic nephropathy	10061835
Hypertensive renal disease	10020828	Hypertensive nephropathy	10055171

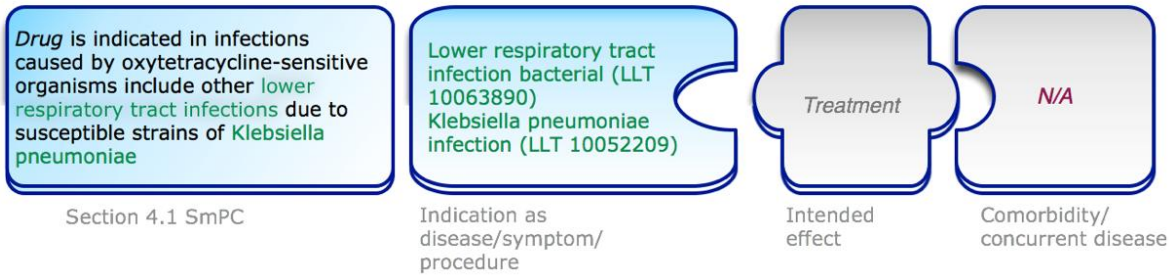
Example (16): A case of a vaccine where a separate code is added to specify that the immunisation is carried out post exposure for rabies immunization:



LLT 'Prophylaxis' should not be codded because the term 'Rabies immunisation' covers both, the prevention, as well the specific disease.

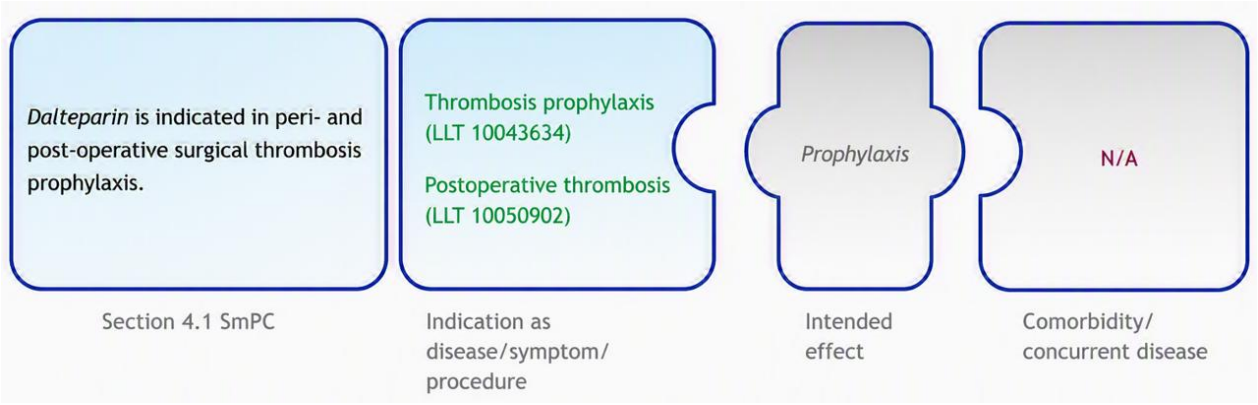
Low level term	LLT code	Preferred term	PT code
Post exposure immunisation	10063022	Immunisation	10061835
Rabies immunisation	10069573	Rabies immunisation	10069573

Example (17): A case where two codes are needed to specify both the microorganism and the location of the infection to be treated:



Low level term	LLT code	Preferred term	PT code
Lower respiratory tract infection bacterial	10063890	Lower respiratory tract infection bacterial	10063890
Klebsiella pneumoniae infection	10052209	Klebsiella infection	10061259

Example (18): Product indicated for prevention of complications/events in a patient undergoing or scheduled for medical procedure; both complications prevention and medical procedure are coded:



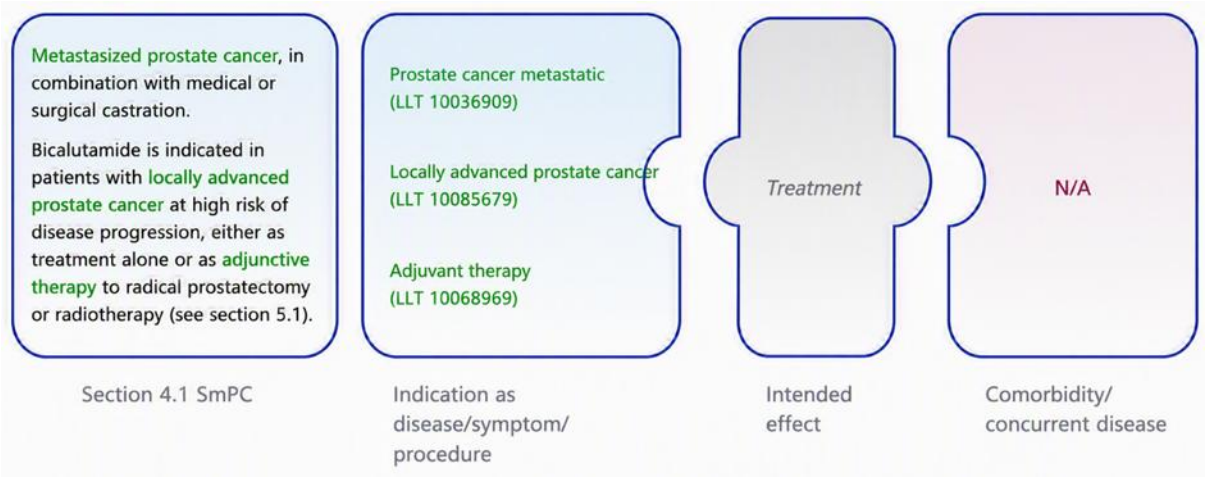
The term 'Surgical procedure' (10051332) should not be coded'; Postoperative thrombosis' (10050902), which is a more granular term, should be captured instead.

Low level term	LLT code	Preferred term	PT code
Thrombosis prophylaxis	10043634	Thrombosis prophylaxis	10043634
Postoperative thrombosis	10050902	Postoperative thrombosis	10050902

Example (19): This example applies where an authorised medicinal product is an anti-cancer drug, provided that its use as adjuvant therapy is clearly stated in section 4.1 of the SmPC. Adjuvant therapy refers to additional cancer treatment administered after the primary treatment in order to reduce the risk of cancer recurrence.

SmPC text:
"Metastasized prostate cancer, in combination with medical or surgical castration.

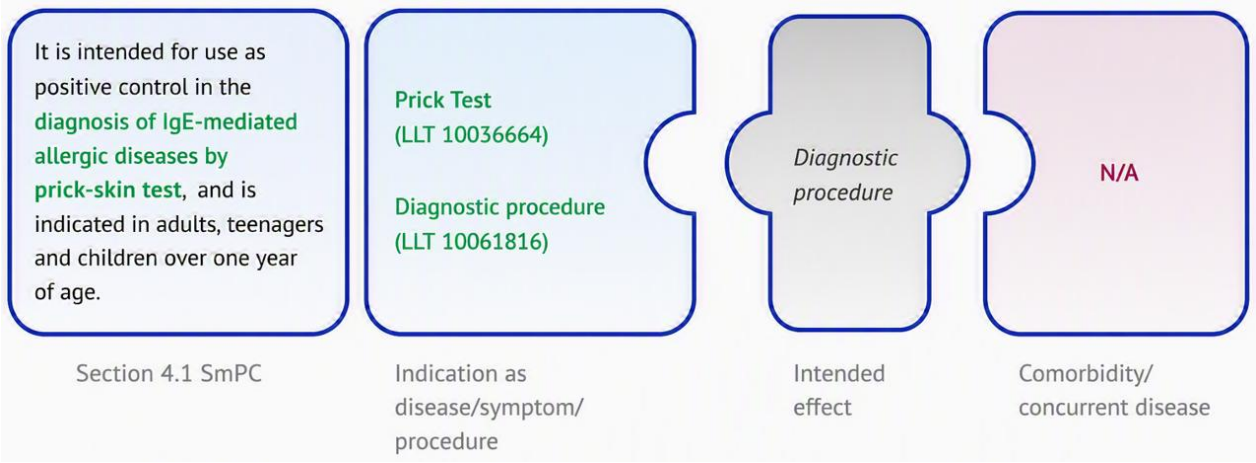
Bicalutamide is indicated in patients with locally advanced prostate cancer at high risk of disease progression, either as treatment alone or as adjunctive therapy to radical prostatectomy or radiotherapy (see section 5.1)."



Low level term	LLT code	Preferred term	PT code
Prostate cancer metastatic	10036909	Prostate cancer metastatic	10036909
Adjuvant therapy	10068969	Adjuvant therapy	10068969
Locally advanced prostate cancer	10085679	Prostate cancer	10060862

Example (20): This example applies where the medicinal product is intended exclusively for diagnostic use. In such cases, the indication should be coded as 'Diagnostic procedure'.

SmPC text:
"It is intended for use as positive control in the diagnosis of IgE-mediated allergic diseases by prick-skin test, and is indicated in adults, teenagers and children over one year of age."



Low level term	LLT code	Preferred term	PT code
Prick Test	10036664	Skin test	10040929
Diagnostic procedure	10061816	Diagnostic procedure	10061816

Example (21): This example applies where an opioid analgesic is combined with another substance that is not intended to treat any disease but is included solely to counteract opioid-induced adverse effects.

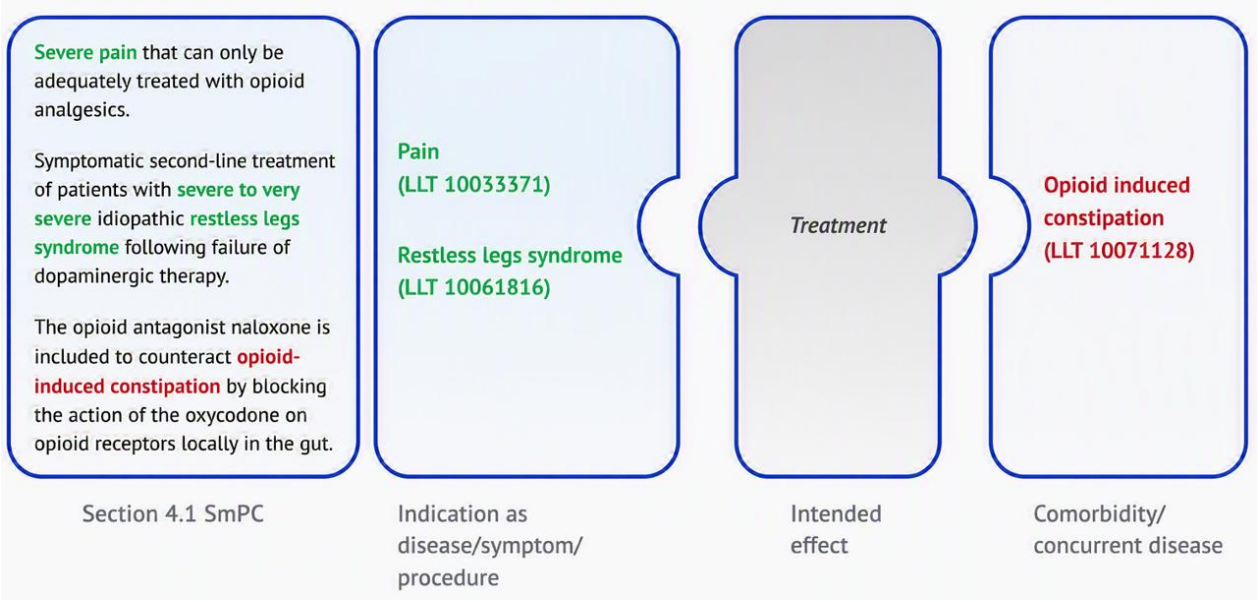
SmPC text:

"Severe pain that can only be adequately treated with opioid analgesics.

Symptomatic second-line treatment of patients with severe to very severe idiopathic restless legs syndrome following failure of dopaminergic therapy.

The opioid antagonist naloxone is included to counteract opioid-induced constipation by blocking the action of the oxycodone on opioid receptors locally in the gut."

In this case, the indications to be coded are the therapeutic indications of the opioid analgesic (e.g. pain, restless legs syndrome). Substances included solely to mitigate adverse effects (e.g. naloxone to counteract opioid-induced constipation) must not be coded as separate indications, as they do not represent an authorised therapeutic use.



Low level term	LLT code	Preferred term	PT code
Pain	10033371	Pain	10033371
Restless legs syndrome	10061816	Restless legs syndrome	10058920

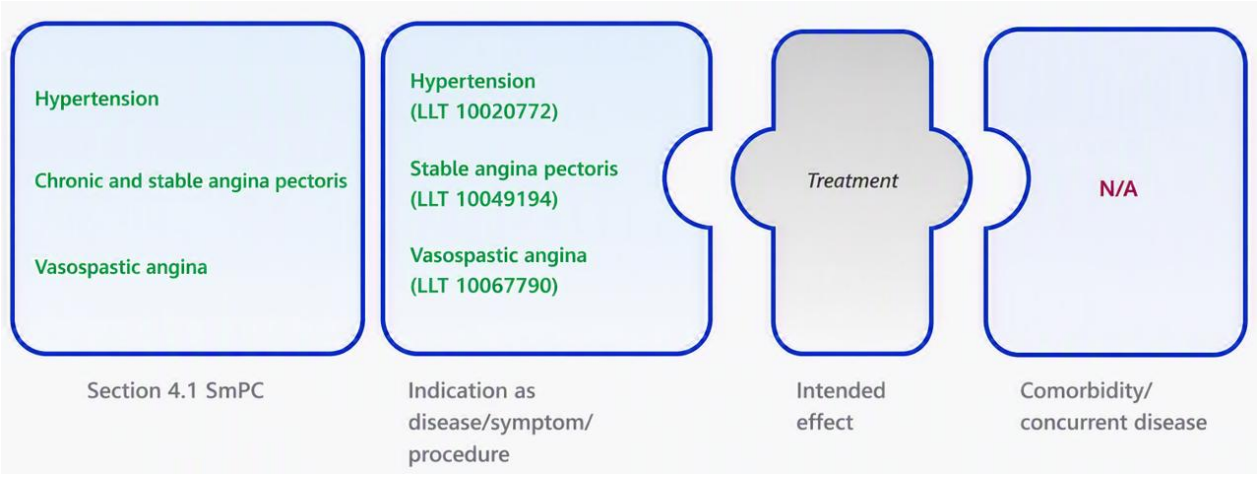
Example (22): This example illustrates a case where synonymous clinical terms are used in the SmPC. Where different terms describe the same medical concept, the indication should be coded using the appropriate MedDRA Term to ensure consistency and standardisation.

SmPC text:

"Hypertension

Chronic and stable angina pectoris

Vasospastic angina"

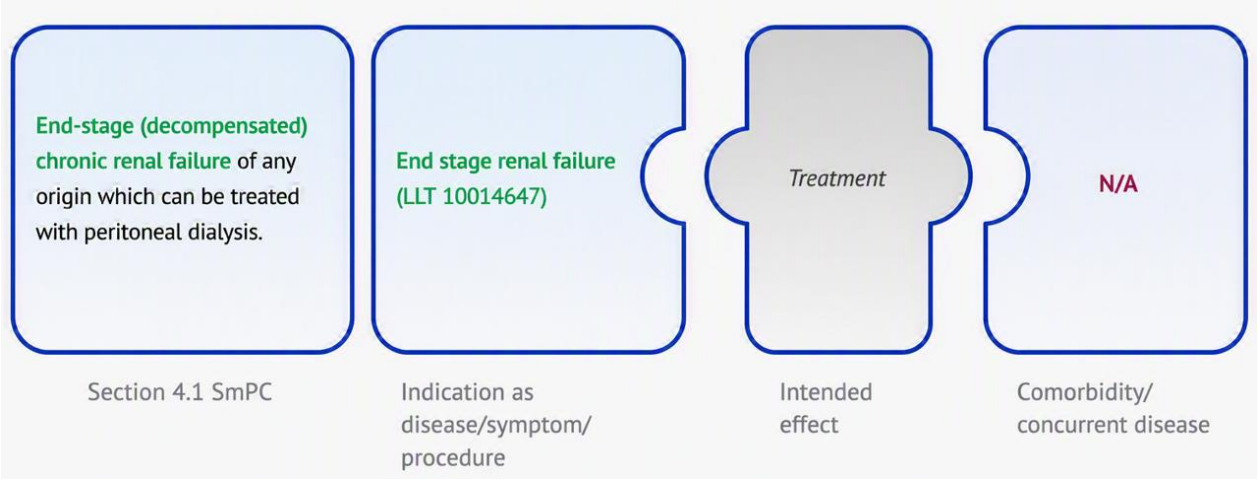


Low level term	LLT code	Preferred term	PT code
Hypertension	10020772	Hypertension	10020772
Stable angina pectoris	10049194	Angina pectoris	10002383
Vasospastic angina	10067790	Prinzmetal angina	10036759

Note: 'Vasospastic angina' and 'Prinzmetal angina' are synonymous terms in MedDRA. Therefore, either term may be selected at LLT level.

Example (23): This example applies where text of the SmPC explicitly describes the stage of a disease. In such cases, the indication should be coded using a MedDRA term that reflects both the disease and its stage, rather than coding only the general disease.

SmPC Text:
"End-stage (decompensated) chronic renal failure of any origin which can be treated with peritoneal dialysis."



Low level term	LLT code	Preferred term	PT code
End stage renal failure	10014647	End stage renal disease	10077512

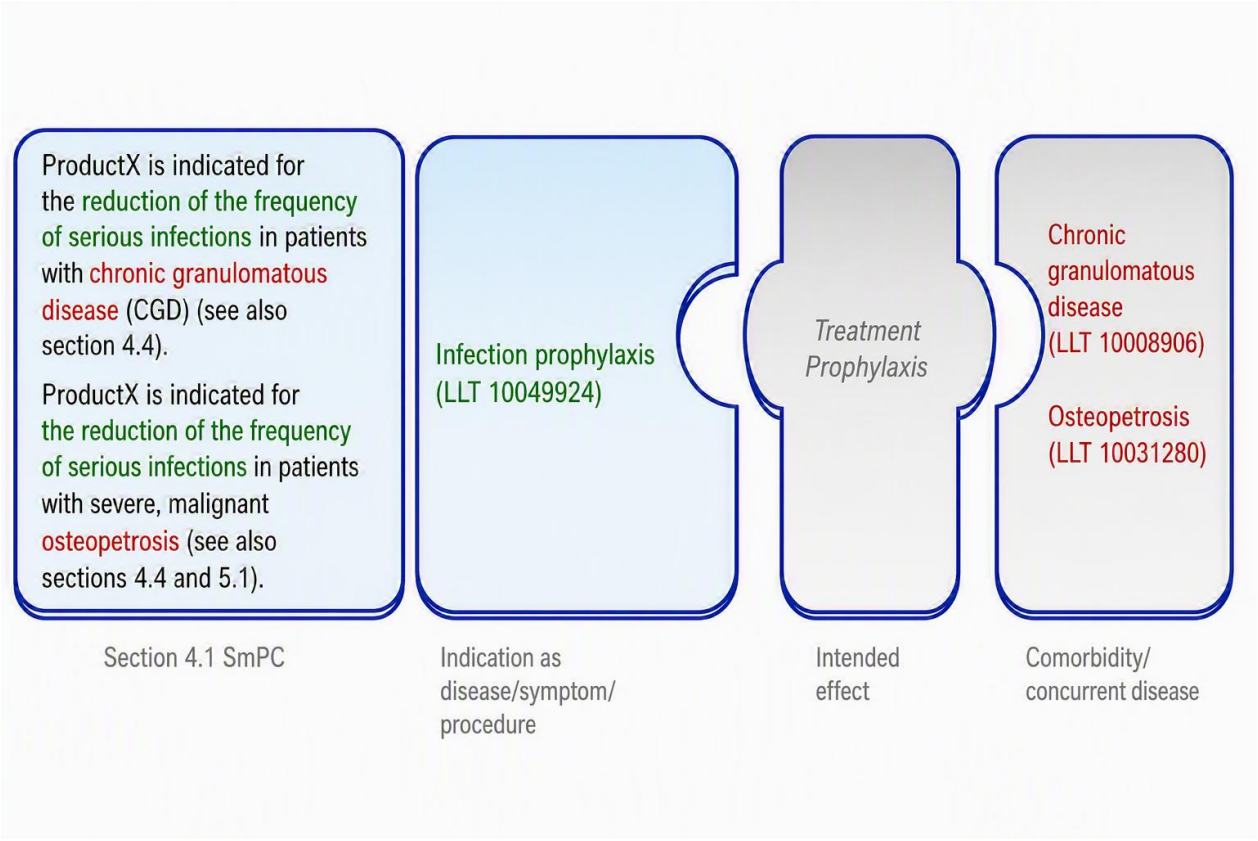
Note: An exact LLT is not available in MedDRA for 'end-stage (decompensated) chronic renal failure'. In this context, the LLT 'End stage renal failure' represents the most appropriate and granular term, as end-stage renal failure, also referred to as end-stage renal disease (ESRD), corresponds to the final and irreversible stage of chronic kidney disease.

Example (24): This example applies where section 4.1 of the SmPC describes the use of a medicinal product to reduce the frequency of infections, irrespective of the underlying disease responsible for increased susceptibility.

SmPC Text:

"ProductX is indicated for the reduction of the frequency of serious infections in patients with chronic granulomatous disease (CGD) (see also section 4.4).

ProductX is indicated for the reduction of the frequency of serious infections in patients with severe, malignant osteopetrosis (see also sections 4.4 and 5.1)."



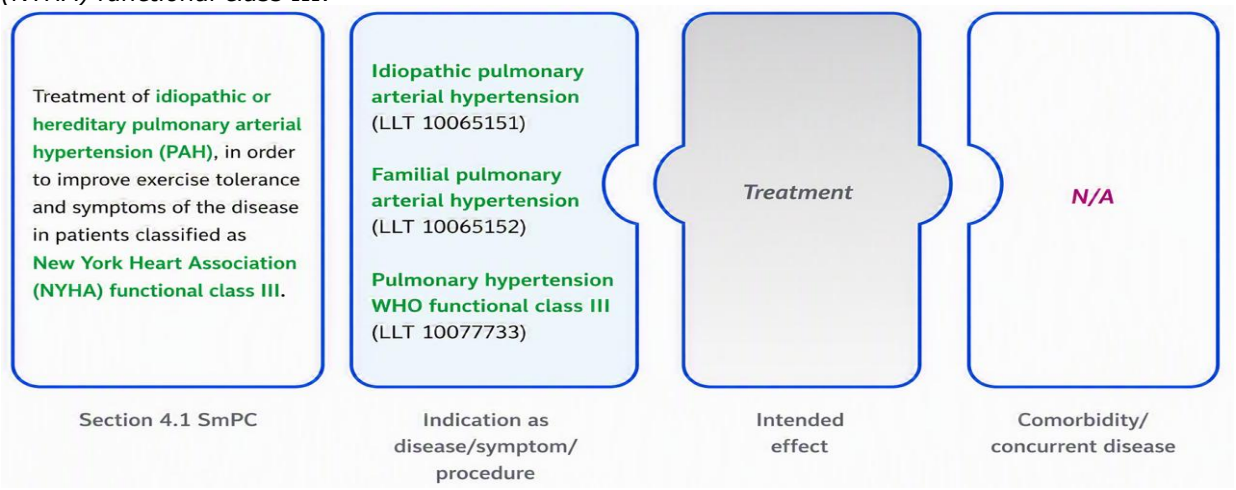
Low level term	LLT code	Preferred term	PT code
Infection prophylaxis	10049924	Infection prophylaxis	10049924

Note: The LLTs 'Chronic granulomatous disease (10008906)' and 'Osteopetrosis (10031280)' should not be captured as they considered 'Comorbidity/concurrent conditions' aspect of the indication. Hence, only one LLT 'Infection prophylaxis (10049924)' would be sufficient for the mentioned text.

Example (25): This example applies where test of the SmPC describes disease and further specifies a functional classification, which defines a sub-population of patients for whom the medicinal product is indicated.

SmPC Text:

"Treatment of idiopathic or hereditary pulmonary arterial hypertension (PAH), in order to improve exercise tolerance and symptoms of the disease in patients classified as New York Heart Association (NYHA) functional class III."



Low Level Term (LLT)	LLT Code	Preferred Term (PT)	PT Code
Idiopathic pulmonary arterial hypertension	10065151	Pulmonary arterial hypertension	10064911
Familial pulmonary arterial hypertension	10065152	Heritable pulmonary arterial hypertension	10085244
Pulmonary hypertension WHO functional class III	10077733	Pulmonary hypertension	10037400

Note: Idiopathic and hereditary pulmonary arterial hypertension represent the primary disease indications. The specification of NYHA/WHO functional class III describes a defined patient subgroup within these conditions for whom the treatment is authorised.

Therefore, the indication 'Pulmonary hypertension WHO functional class III' should be captured in addition to the disease-specific indications.

Example (26) This example applies where the SmPC describes multiple related disease indications that may occur independently or together. In such cases, all relevant LLTs representing the individual conditions as well as their combined form should be captured.

SmPC Text:

"4.1. Therapeutic indications: Omeprazole is indicated for

Adults

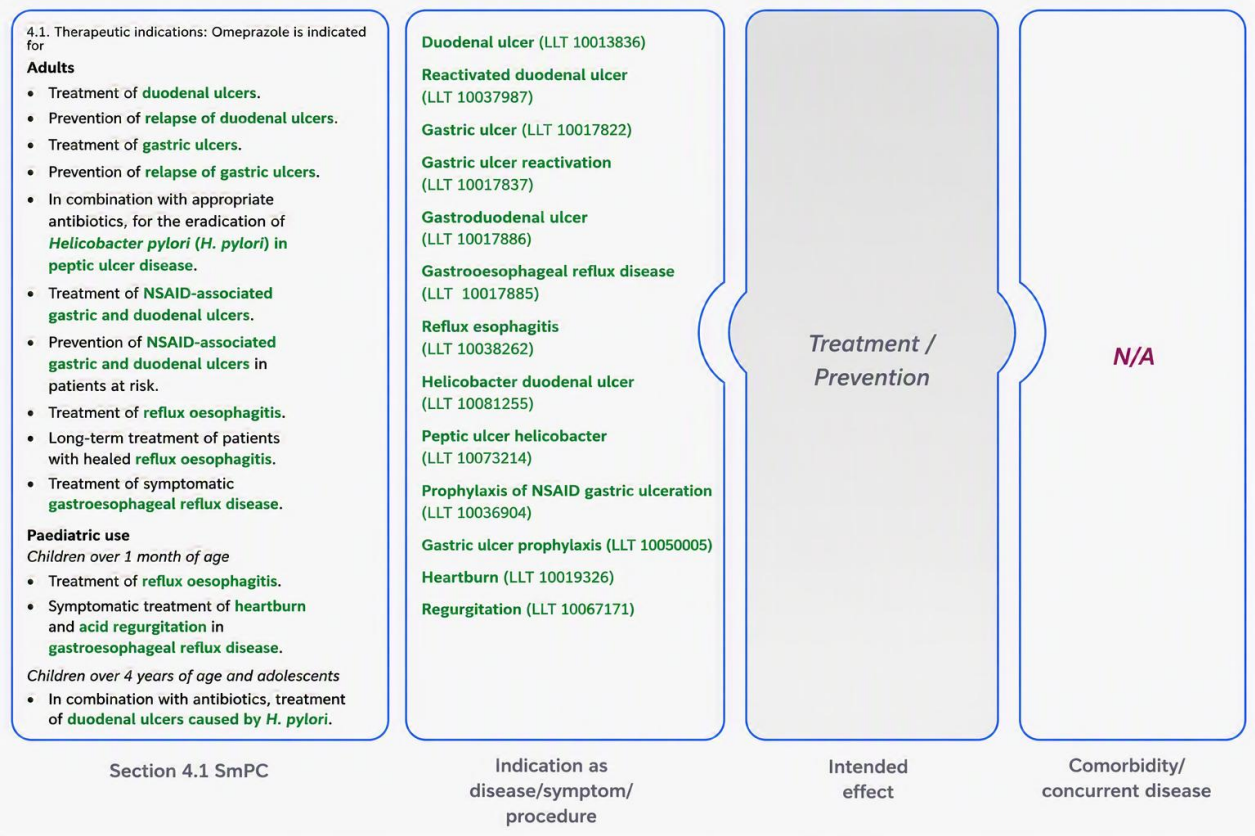
- *Treatment of duodenal ulcers.*
- *Prevention of relapse of duodenal ulcers.*
- *Treatment of gastric ulcers.*
- *Prevention of relapse of gastric ulcers.*
- *In combination with appropriate antibiotics, for the eradication of Helicobacter pylori (H. pylori) in peptic ulcer disease.*
- *Treatment of NSAID-associated gastric and duodenal ulcers.*
- *Prevention of NSAID-associated gastric and duodenal ulcers in patients at risk.*
- *Treatment of reflux oesophagitis.*
- *Long-term treatment of patients with healed reflux oesophagitis.*
- *Treatment of symptomatic gastroesophageal reflux disease.*
  Paediatric use

Children over 1 month of age

- *Treatment of reflux oesophagitis.*
- *Symptomatic treatment of heartburn and acid regurgitation in gastroesophageal reflux disease.*

Children over 4 years of age and adolescents

- In combination with antibiotics, treatment of duodenal ulcers caused by H. pylori."



Low Level Term (LLT)	LLT Code	Preferred Term (PT)	PT Code
Reactivated duodenal ulcer	10037987	Duodenal ulcer	10013836
Duodenal ulcer	10013836		
Heartburn	10019326	Dyspepsia	10013946
Gastric ulcer	10017822	Gastric ulcer	10017822
Gastric ulcer reactivation	10017837		
Gastroduodenal ulcer	10017886	Gastroduodenal ulcer	10017886
Gastrooesophageal reflux disease	10017885	Gastrooesophageal reflux disease	10017885

Reflux esophagitis	10038262		
Helicobacter duodenal ulcer	10081255	Helicobacter duodenal ulcer	10081255
Peptic ulcer helicobacter	10073214	Peptic ulcer helicobacter	10073214
Prevention	10036654	Prophylaxis	10036898
Prophylaxis of NSAID gastric ulceration	10036904	Prophylaxis against gastrointestinal ulcer	10054981
Gastric ulcer prophylaxis	10050005		
Regurgitation	10067171	Regurgitation	10067171

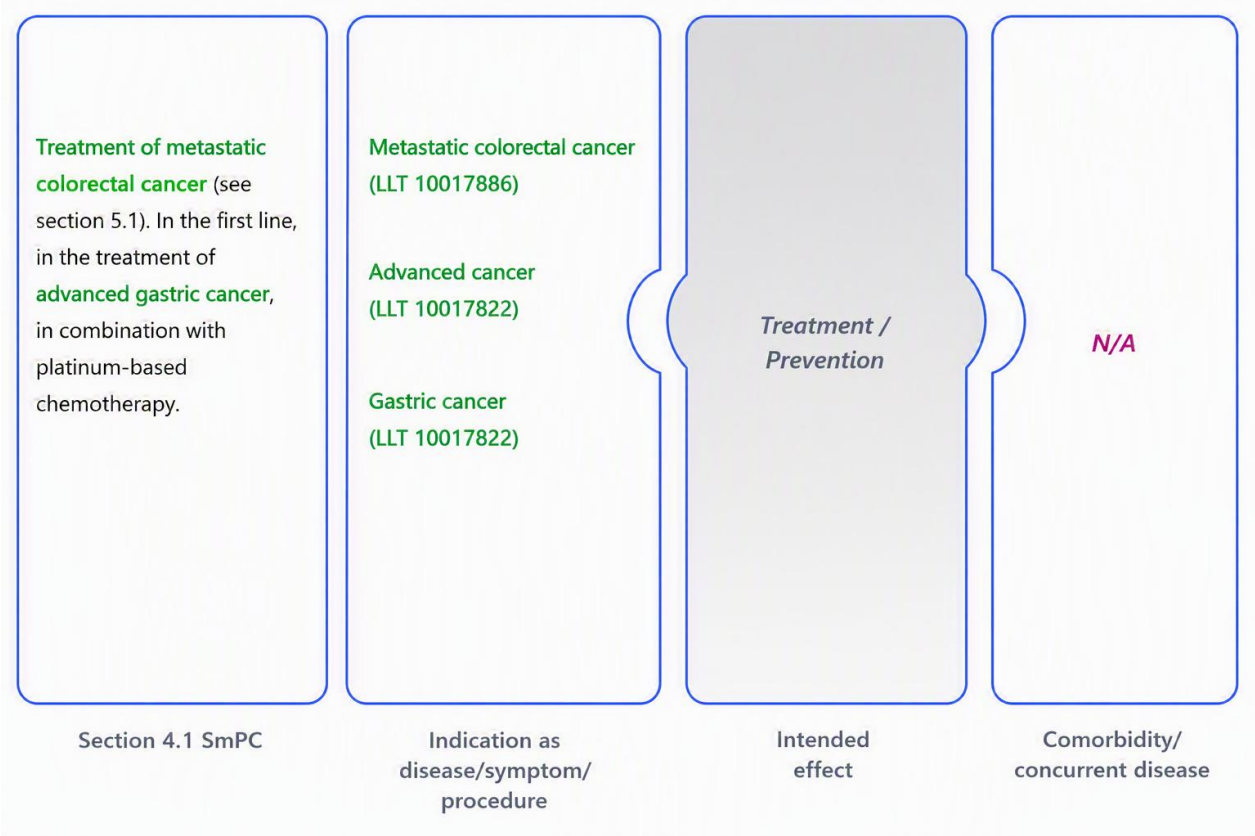
Note: 'Gastric ulcer' and 'duodenal ulcer' represent distinct disease conditions for which the medicinal product is indicated. However, the SmPC wording also allows for use in patients who may have both conditions concurrently.

Therefore, the combined condition 'Gastroduodenal ulcer' should also be captured in addition to the individual indications 'Gastric ulcer' and 'Duodenal ulcer'.

Example (27): This example applies where the SmPC includes a disease with a stage descriptor. In such cases, where the disease and its stage do not have single term then it should be captured separately to ensure clarity and completeness of coding.

SmPC Text:

"Treatment of metastatic colorectal cancer (see section 5.1). In the first line, in the treatment of advanced gastric cancer, in combination with platinum-based chemotherapy."



Low Level Term (LLT)	LLT Code	Preferred Term (PT)	PT Code
Metastatic colorectal cancer	10017886	Colorectal cancer metastatic	10052358
Advanced cancer	10017822	Neoplasm malignant	10028997
Gastric cancer	10017822	Gastric ulcer	10017822

Note: 'Metastatic colorectal cancer' represents a distinct indication and should be captured accordingly.

For the indication 'advanced gastric cancer' the term combines both a disease ('gastric cancer') and a stage descriptor ('advanced'). To ensure accurate and comprehensive coding, both components should be captured separately.

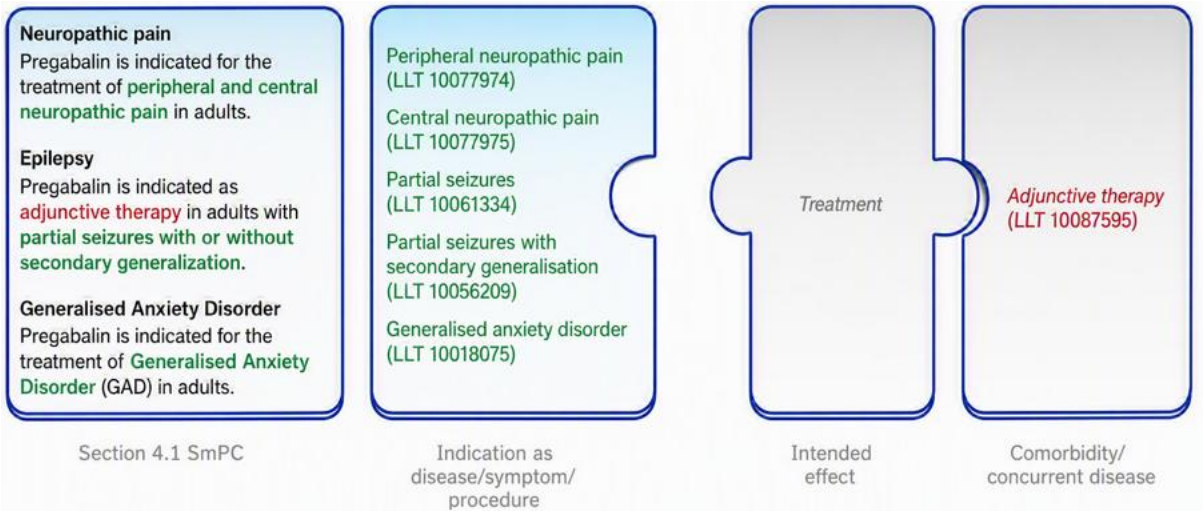
Example (28): This example applies where the SmPC describes multiple indications and includes wording such as 'adjunctive therapy' however the drug is not an anticancer drug; in this case 'adjunctive therapy' should not be captured as an LLT.

SmPC Text:

"Neuropathic pain
Pregabalin is indicated for the treatment of peripheral and central neuropathic pain in adults.

Epilepsy
Pregabalin is indicated as adjunctive therapy in adults with partial seizures with or without secondary generalization.

Generalised Anxiety Disorder
Pregabalin is indicated for the treatment of Generalised Anxiety Disorder (GAD) in adults."



Low Level Term (LLT)	LLT Code	Preferred Term (PT)	PT Code
Peripheral neuropathic pain	10077974	Neuralgia	10029223
Central neuropathic pain	10077975	Central pain syndrome	10064012
Partial seizures	10061334	Partial seizures	10061334
Partial seizures with secondary generalisation	10056209	Partial seizures with secondary generalisation	10056209
Generalised anxiety disorder	10018075	Generalised anxiety disorder	10018075

Note: The indications 'neuropathic pain', "'partial seizures' and 'generalised anxiety disorder' represent valid medical conditions and should be captured accordingly.

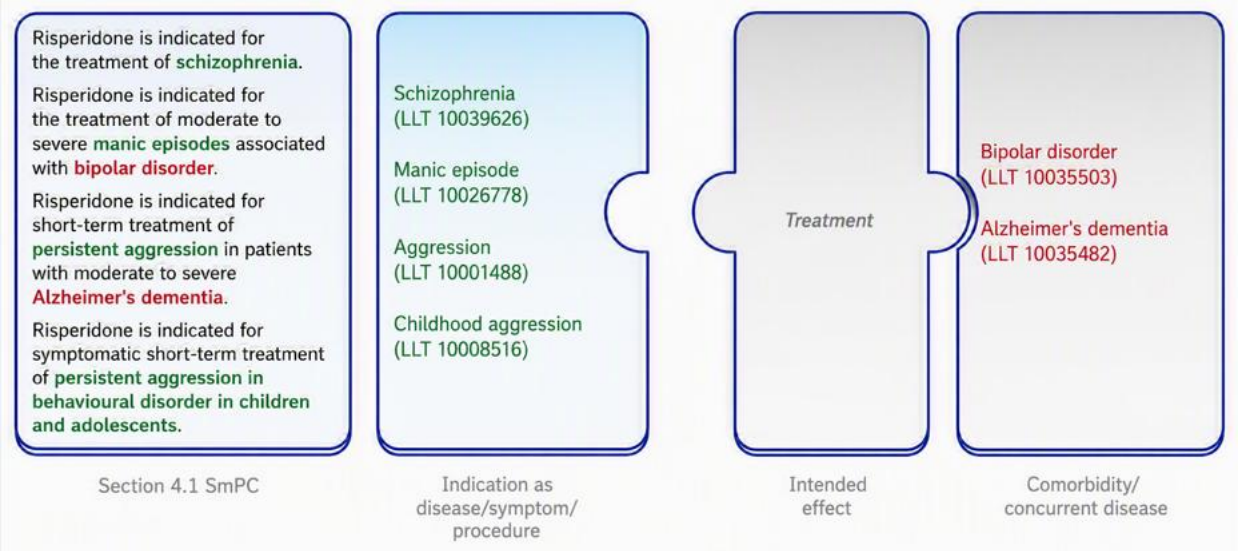
The term 'adjunctive therapy' is generally associated with treatment strategies in oncology, where it refers to additional therapy administered after primary treatment to reduce the risk of disease recurrence. Such therapies may include chemotherapy, radiotherapy, hormone therapy, targeted therapy, or biological therapy.

As the product in this case does not fall within these categories, the term 'adjunctive therapy' is not applicable to its pharmacological classification or therapeutic indication. Therefore, it should not be captured as an LLT.

Example (29): This example applies where the SmPC includes age-specific subpopulations. In such cases, age-specific indications should be captured in addition to the general condition, where applicable.

SmPC Text:

"Risperidone is indicated for the treatment of schizophrenia.
Risperidone is indicated for the treatment of moderate to severe manic episodes associated with bipolar disorder.
Risperidone is indicated for short-term treatment of persistent aggression in patients with moderate to severe Alzheimer's dementia.
Risperidone is indicated for symptomatic short-term treatment of persistent aggression in behavioural disorder in children and adolescents."



Low Level Term (LLT)	LLT Code	Preferred Term (PT)	PT Code
Schizophrenia	10039626	Schizophrenia	10039626
Manic episode	10026778	Mania	10026749
Aggression	10001488	Aggression	10001488
Childhood aggression	10008516	Aggression	10001488

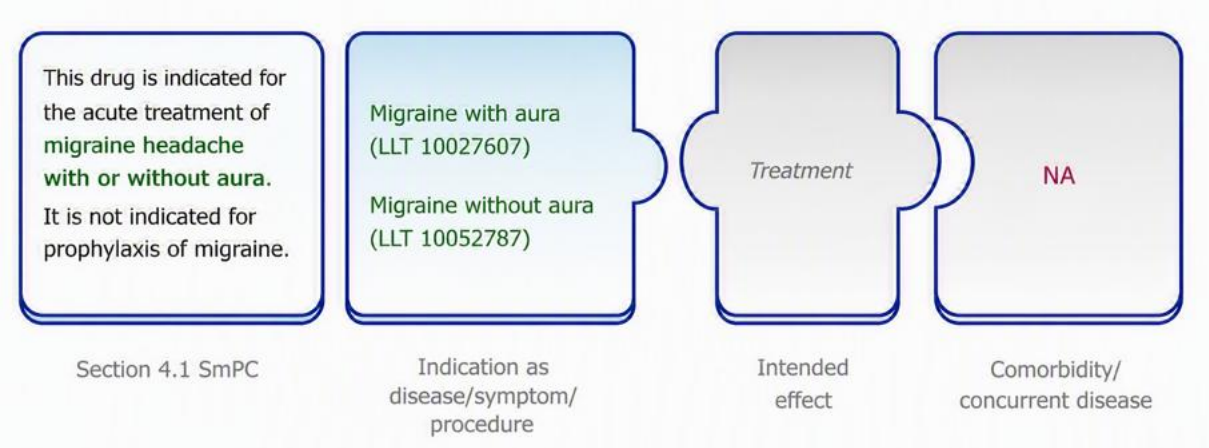
Note: 'Schizophrenia' and 'Manic episodes" represent primary disease indications and should be captured accordingly.

The term 'aggression' is described in both adult and paediatric populations ('behavioural disorders'). Therefore, both 'Aggression', and 'Childhood aggression' should be captured to reflect the overall condition and the specific paediatric context.

Example (30): This example applies where the SmPC describes a condition with alternative clinical presentations (e.g., *"with or without aura"*). In such cases, each presentation should be captured separately to ensure complete representation of the indication.

SmPC Text:

"This drug is indicated for the acute treatment of migraine headache with or without aura. It is not indicated for prophylaxis of migraine."



Low Level Term (LLT)	LLT Code	Preferred Term (PT)	PT Code
Migraine with aura	10027607	Migraine with aura	10027607
Migraine without aura	10052787	Migraine without aura	10052787

Note: The indication specifies *"migraine headache with or without aura",* which represents two distinct clinical presentations of migraine.

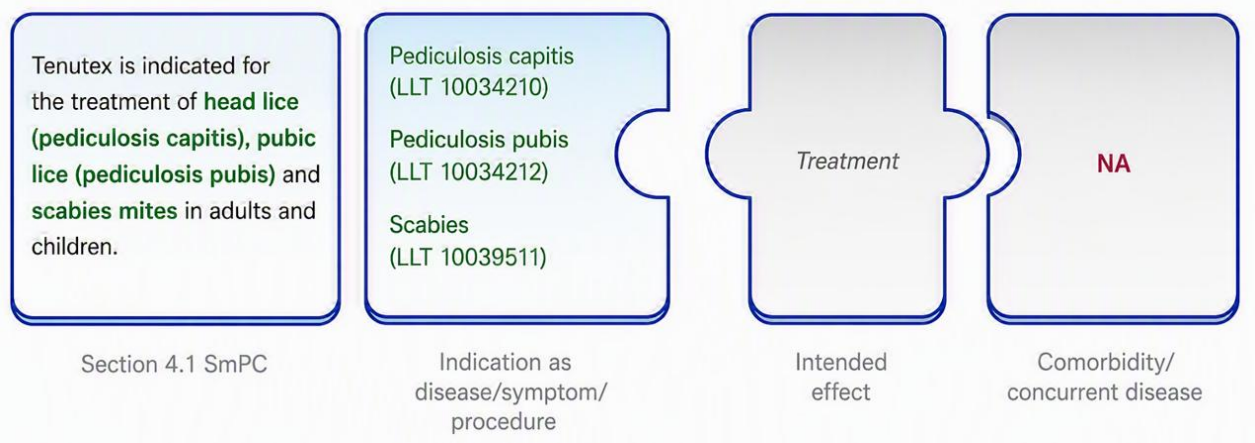
Therefore, both 'Migraine with aura' and 'Migraine without aura' should be captured to ensure complete and accurate coding of the indication.

The statement *"not indicated for prophylaxis of migraine"* represents a limitation of use rather than an indication and should not be captured as an LLT.

Example (31): This example applies where the SmPC describes multiple distinct parasitic infestations. In such cases, each specific infestation should be captured separately to ensure complete representation of the authorised indication. The age group ("adults and children") should not be coded as an indication.

SmPC Text:

"Tenutex is indicated for the treatment of head lice (pediculosis capitis), pubic lice (pediculosis pubis) and scabies mites in adults and children."



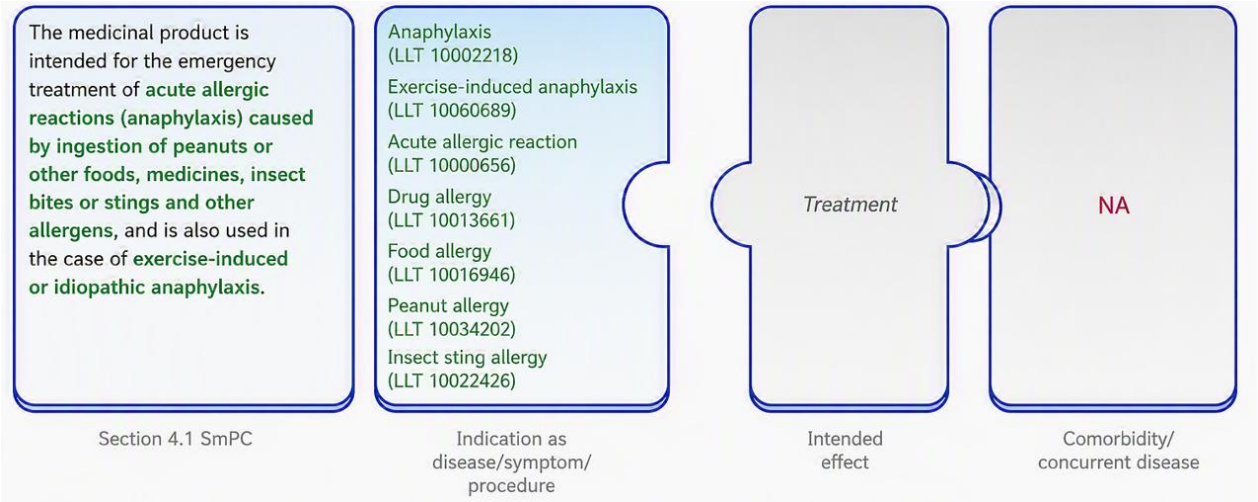
Low Level Term (LLT)	LLT Code	Preferred Term (PT)	PT Code
Pediculosis capitis	10034210	Lice infestation	10024424
Pediculosis pubis	10034212		
Scabies	10039511	Scabies	10039511

Note: The indication includes three distinct parasitic infestations: pediculosis capitis, pediculosis pubis, and scabies. Therefore, all three conditions should be captured at LLT level to ensure complete representation of the authorised indication.

Example (32): This example applies where the SmPC describes anaphylaxis and multiple specific allergen-related triggers, including food, peanut, drug, and insect sting allergies, as well as distinct clinical presentations of anaphylaxis. In such cases, each specific condition and presentation should be captured separately to ensure complete representation of the authorised indication.

SmPC Text:

"The medicinal product is intended for the emergency treatment of acute allergic reactions (anaphylaxis) caused by ingestion of peanuts or other foods, medicines, insect bites or stings and other allergens, and is also used in the case of exercise-induced or idiopathic anaphylaxis."



Low Level Term (LLT)	LLT Code	Preferred Term (PT)	PT Code
Anaphylaxis	10002218	Anaphylactic reaction	10002198
Exercise-induced anaphylaxis	10060689		

Acute allergic reaction	10000656	Hypersensitivity	10020751
Drug allergy	10013661	Drug hypersensitivity	10013700
Food allergy	10016946	Food allergy	10016946
Peanut allergy	10034202		
Insect sting allergy	10022426	Allergy to arthropod sting	10058284

Note: The indication describes both the primary condition (anaphylaxis) and several specific allergen-related causes and clinical presentations. Therefore, the following should be captured:

- Anaphylaxis and Exercise-induced anaphylaxis to represent the general and specific forms of anaphylaxis.
- Acute allergic reaction to reflect the emergency treatment of allergic reactions.
- Drug allergy, Food allergy, Peanut allergy, and Insect sting allergy to represent the specific allergen categories explicitly described in the SmPC.

Example (33): This example applies where the SmPC describes the same disease with multiple disease phases, genetic characteristics, and age-specific subpopulations. In such cases, each distinct presentation should be captured separately to ensure complete representation of the authorised indication.

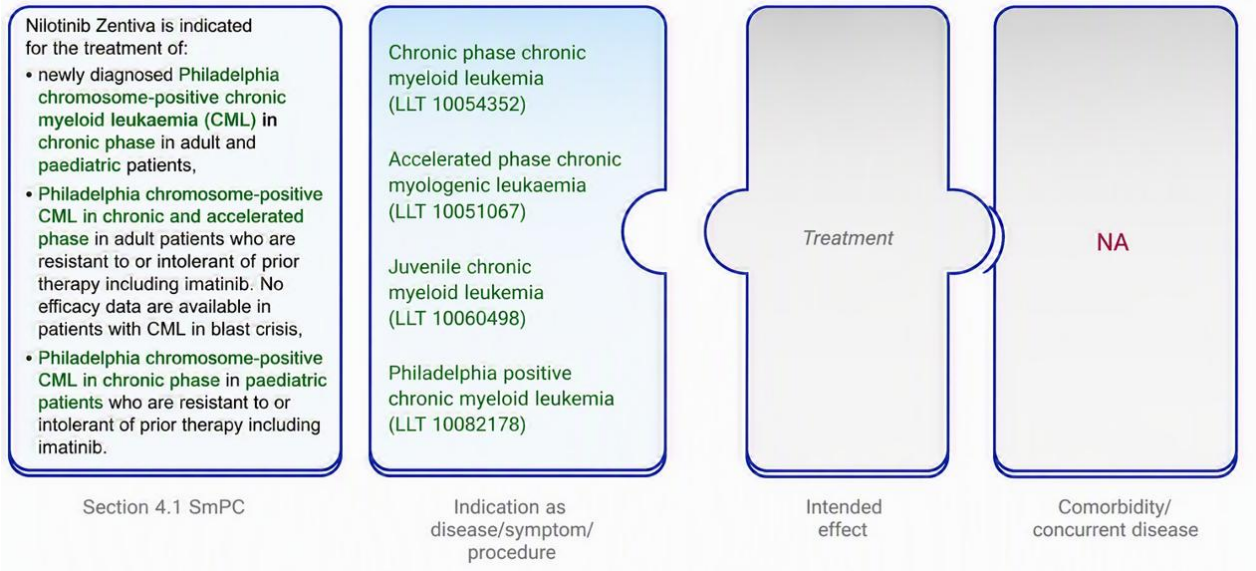
SmPC Text:

"Nilotinib Zentiva is indicated for the treatment of:

newly diagnosed Philadelphia chromosome-positive chronic myeloid leukaemia (CML) in chronic phase in adult and paediatric patients,

Philadelphia chromosome-positive CML in chronic and accelerated phase in adult patients who are resistant to or intolerant of prior therapy including imatinib. No efficacy data are available in patients with CML in blast crisis,

Philadelphia chromosome-positive CML in chronic phase in paediatric patients who are resistant to or intolerant of prior therapy including imatinib."



Low Level Term (LLT)	LLT Code	Preferred Term (PT)	PT Code
Chronic phase chronic myeloid leukaemia	10054352	Chronic myeloid leukaemia	10009013
Accelerated phase chronic myologenic leukaemia	10051067		
Juvenile chronic myeloid leukaemia	10060498	Juvenile chronic myelomonocytic leukaemia	10023249
Philadelphia positive chronic myeloid leukaemia	10082178	Philadelphia positive chronic myeloid leukaemia	10082180

Note: The indication describes Philadelphia chromosome-positive chronic myeloid leukaemia (CML) in different clinical phases and populations. Therefore, separate LLTs should be captured to reflect:

- Chronic phase chronic myeloid leukaemia and Accelerated phase chronic myeloid leukaemia, representing distinct disease phases.
- Philadelphia positive chronic myeloid leukaemia, representing the specific genetic subtype explicitly mentioned in the SmPC.
- Juvenile chronic myeloid leukaemia, reflecting the authorised paediatric population.

Example (34): This example applies where the SmPC describes both prevention and treatment of nausea and vomiting associated with multiple procedures (chemotherapy, radiotherapy and surgery). In such cases, prophylaxis indications and treatment indications should be captured separately to ensure complete representation of the authorised indication.

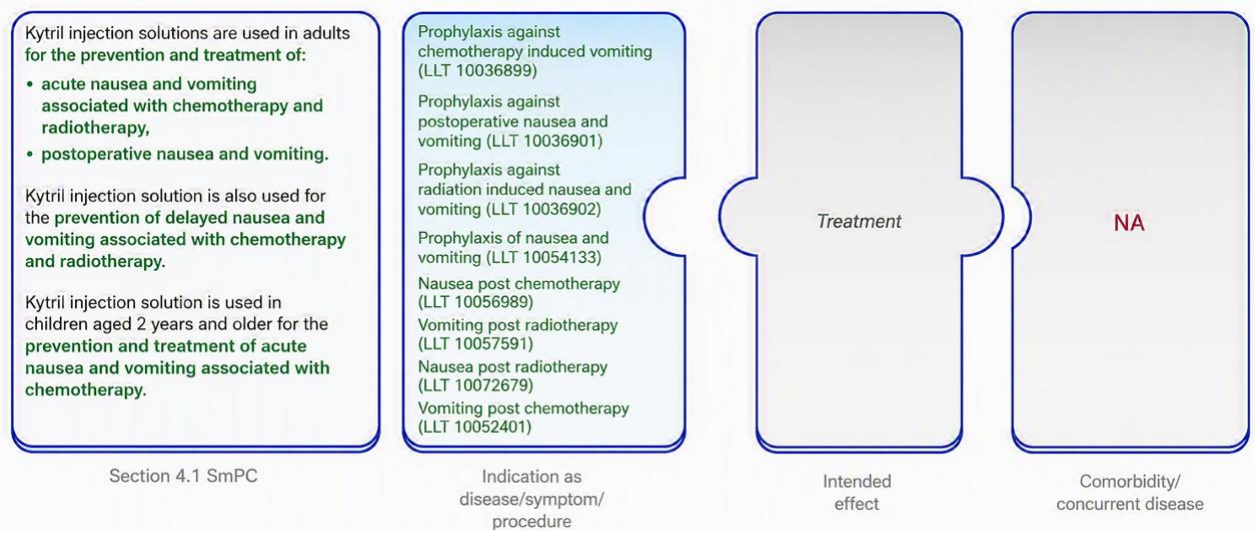
SmPC Text:

"Kytril injection solutions are used in adults for the prevention and treatment of:

- *acute nausea and vomiting associated with chemotherapy and radiotherapy,*
- *postoperative nausea and vomiting.*

Kytril injection solution is also used for the prevention of delayed nausea and vomiting associated with chemotherapy and radiotherapy.

Kytril injection solution is used in children aged 2 years and older for the prevention and treatment of acute nausea and vomiting associated with chemotherapy."



Low Level Term (LLT)	LLT Code	Preferred Term (PT)	PT Code
Prophylaxis against chemotherapy induced vomiting	10036899	Prophylaxis of nausea and vomiting	10054133
Prophylaxis against postoperative nausea and vomiting	10036901		
Prophylaxis against radiation induced nausea and vomiting	10036902		
Prophylaxis of nausea and vomiting	10054133		
Nausea post chemotherapy	10056989	Nausea	10028813
Vomiting post radiotherapy	10057591	Procedural vomiting	10066963
Nausea post radiotherapy	10072679	Procedural nausea	10066962
Vomiting post chemotherapy	10052401	Vomiting	10047700

Note: The SmPC indicates that the medicinal product is authorised for both, prevention and treatment of nausea and vomiting associated with chemotherapy, radiotherapy and surgical procedures. Therefore, both prophylactic and treatment-related concepts should be captured.

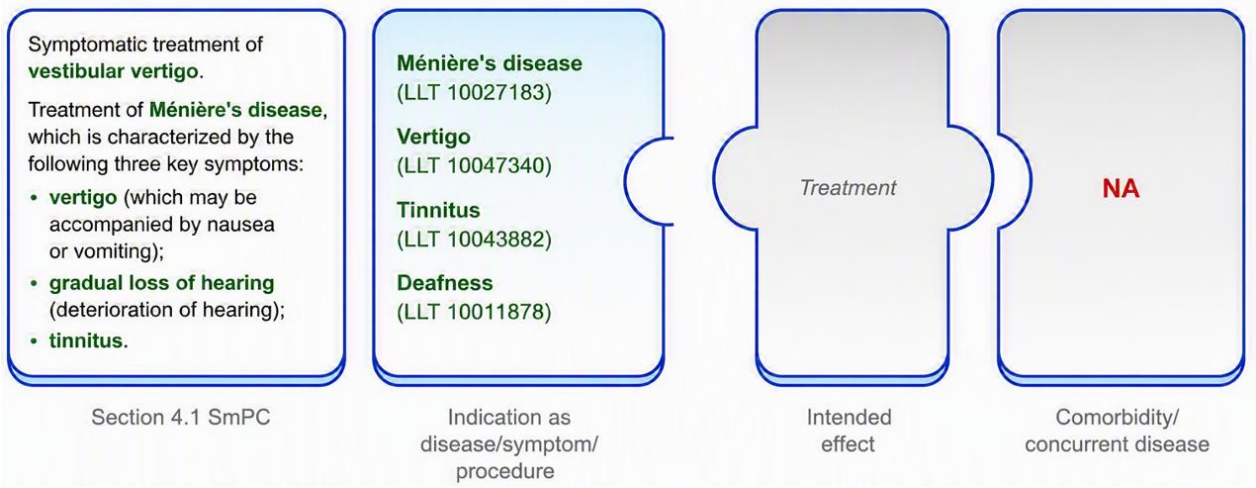
- The LLTs Prophylaxis against chemotherapy induced vomiting, Prophylaxis against postoperative nausea and vomiting, Prophylaxis against radiation induced nausea and vomiting, and Prophylaxis of nausea and vomiting represent the authorised preventive use.
- The LLTs Nausea post chemotherapy, Vomiting post chemotherapy, Nausea post radiotherapy, and Vomiting post radiotherapy represent the treated conditions explicitly described in the indication.
- The paediatric age restriction ("children aged 2 years and older") describes the authorised population and does not constitute a separate indication.
- The term "delayed" describes the timing of the event and does not require separate coding where the underlying prophylaxis concept is already captured.

Example (35): A case of a medicinal product indicated for the symptomatic treatment of vestibular vertigo and Ménière's disease, where separate codes are added to capture the disease and its characteristic symptoms:

SmPC Section 4.1 states:

"Symptomatic treatment of vestibular vertigo.
Treatment of Ménière's disease, which is characterized by the following three key symptoms:

- *vertigo (which may be accompanied by nausea or vomiting);*
- *gradual loss of hearing (deterioration of hearing);*
- *tinnitus."*



Low Level Term (LLT)	LLT Code	Preferred Term (PT)	PT Code
Ménière's disease	10027183	Ménière's disease	10027183
Vertigo	10047340	Vertigo	10047340
Tinnitus	10043882	Tinnitus	10043882
Deafness	10011878	Deafness	10011878

Note: The SmPC indicates that the medicinal product is authorised for the symptomatic treatment of vestibular vertigo and for the treatment of Ménière's disease. In addition to the primary disease indication, the SmPC explicitly identifies the key symptoms that characterise Ménière's disease. Therefore, separate LLTs should be captured for both the disease and the characteristic symptoms described within the authorised indication.