### **EPHMRA**

# ANATOMICAL CLASSIFICATION GUIDELINES 2023

## **Section A**

# Changed Classes/Guidelines: Changes Highlighted Final Version

Date of issue: 22nd December 2022

A5	CHOLAGOGUES AND HEPATIC PROTECTORS BILIARY TRACT AND LIVER DISORDER PRODUCTS	<u>r2023</u>
A5A	BILE THERAPY AND CHOLAGOGUESBILIARY TRACT DISORDER PRODUCTS	<u>r2023</u>
A5A1	Choleretics and cholekinetics Cholagogues	<u>r2023</u>
	Includes products, plain and in combination, indicated as choleretics and cholekinetics.	
A5A2	Bile stone therapy	r2018
	Includes products indicated for biliary conditions such as stone dissolvers eg chenodesoxycholic acid, ursodesoxycholic acid. Products containing ursodesoxycholic acid for primary biliary cholangitis are classified here.	
A5A9	Other bile therapy and cholagogues Biliary tract disorder products, other	<u>r</u> 120 <u>23</u> 18
	Includes products containing obeticholic acid for primary biliary cholangitis.	
A5B	HEPATIC PROTECTORS, LIPOTROPICSLIVER DISORDER PRODUCTS, HEPATIC PROTECTORS AND LIPOTROPICS	<u>r2023</u>
	Includes <u>products for liver disorders such as NASH (non-alcoholic steatohepatitis)</u> , hepatic protectors and combinations, but excludes liver extracts indicated for the treatment of anaemia, which are classified in B3B.	
A5C	CHOLAGOGUE/LIPOTROPIC COMBINATIONS	

A7	INTESTINAL DISORDER PRODUCTS	r2019
	Products for functional gastro-intestinal disorders are in A3 and products for constipation and bowel cleansing are in A6.	
A7A	INTESTINAL ANTI-INFECTIVES	r2019
	Includes all products containing one or more intestinal anti-infectives with or without other substances that are used for diarrhoea and/or hepatic encephalopathy. Sulphonamides and special antibacterials such as polymyxin, neomycin, vancomycin or colistin in oral form, when mainly indicated as antidiarrhoeals are included in this group. Combinations with motility inhibitors, intestinal adsorbants and micro-organisms are also included.	
	Products containing rifaximin for either diarrhoea or hepatic encephalopathy are classified here. Products containing fidaxomicin for <i>Clostridium difficile</i> intestinal infections are classified here.	
A7B	INTESTINAL ADSORBENT ANTIDIARRHOEALS	r2011
	Includes products such as kaolin and pectin. Combinations with micro-organisms are also included.	
A7C	Out of use; can be reused.	
A7D	Out of use; can be reused.	
<b>A7E</b>	INFLAMMATORY BOWEL DISORDER PRODUCTS	<u>r</u> R20 <u>2</u>
	Includes products for inflammatory bowel disorders. Immunosuppressant products used for inflammatory bowel disorders as well as other conditions are classified in L4, for example in L4B (anti-TNF products). Products containing ozanimod and indicated for both multiple sclerosis and ulcerative colitis are classified in N7A.	<u>3</u> 17
A7E1	Intestinal aminosalicylate products	I2017
	Includes products containing balsalazide, mesalazine, olsalazine, sulfasalazine and similar aminosalicylates for inflammatory bowel disorders. Products containing aminosalicylates and indicated for rheumatoid arthritis are classified in M1C.	
A7E2	Intestinal corticosteroid products	<u>r</u> I20 <u>23</u> 17
	Includes products containing corticosteroids for inflammatory bowel disorders and for eosinophilic oesophagitis.	

A10X	OTHER DRUGS USED IN DIABETES	R2010
A10X1	Antidiabetic multitherapy combination products	I2010
	Includes combinations of antidiabetics with cardiovascular drugs where the aim is to treat both the diabetes and the cardiovascular condition. For example, rosiglitazone in combination with simvastatin. Also includes combinations of antidiabetics with anti-obesity drugs where the aim is to treat both the diabetes and the obesity. For example, metformin in combination with sibutramine.	
A10X9	Other drugs used in diabetes	<u>r</u> 420 <u>23</u> 40
	Includes products used for the treatment of diabetes, as well as adjuvant therapy in the treatment and prevention of conditions associated with or developing from diabetes.	
	Includes aldose reductase inhibitors (eg epalrestat, tolrestat), guar gum and glucose products specifically intended for the treatment of hypoglycaemic shock.	
	Includes products containing glucokinase activator antidiabetics, eg dorzagliatin.	
	Teas and other herbal extracts used as adjuvant therapy are classified here.	

A11	VITAMINS	
	Products containing vitamins which are specifically for eye conditions are classified in S1M. Multivitamins for parenteral infusion are classified in K4D (less than 100ml).	R2005
A11A	MULTIVITAMINS WITH MINERALS	r2017
	Includes products containing more than two vitamins in combination (and not specified elsewhere) with one or more minerals, eg calcium, potassium, magnesium, iron, copper, manganese and zinc etc. Potassium and magnesium aspartate are not considered as minerals (see A12 and C6X). Excluded are all oral preparations containing procaine where procaine is one of the major components (see A13A1).	
A11A1	Prenatal	R1993
	Includes those products specifically indicated for vitamin supplementation during pre-conception, pregnancy or lactation (eg containing fluoride as mineral).	<u>r2023</u>
A11A2	Paediatric	
	Includes products with halibut liver oil or vitamin D which are indicated only for paediatric conditions. Products with malt extracts are classified in A13A.	
A11A3	Geriatric	
	Includes vitamin preparations with hormones for geriatric patients. The term "ger" often forms part of the name of products in this group (see also A14A2).	
A11A4	Other multivitamins with minerals	
	Includes all other multivitamin products not specified in A11A1, A11A2 or A11A3. Calcium-containing products promoted for osteoporosis or calcium deficiency are classified in A12A. Vitamin C combinations, eg promoted for hypovitaminose C, are classified in A11G2. When in doubt the calcium component takes precedence over the other ingredients. Products based on lecithin or glutamic acid used as tonics are classified in A13A.	

A11B	MULTIVITAMINS WITHOUT MINERALS	R2003
	Includes all multivitamin combinations as defined under A11A but without minerals, except all oral preparations containing procaine (see A13A1). Products for general well-being are classified in A13A.	
A11B1	Prenatal	R1993 r2023
	Includes those products specifically indicated for vitamin supplementation during <a href="mailto:pre-conception">pre-conception</a> , pregnancy or lactation.	
A11B2	Paediatric	
	Analogous to A11A2 but without minerals.	
A11B3	GERIATRIC	
	Analogous to A11A3 but without minerals (see also A14A2).	
A11B4	Other multivitamins without minerals	

<b>B2</b>	BLOOD COAGULATION SYSTEM, OTHER PRODUCTS	r20 <u>23</u> 0
		8
B2A	ANTIFIBRINOLYTICS	
B2A1	Synthetic antifibrinolytics	
	Includes inhibitors of fibrinolytic activity such as epsilon - aminocaproic acid (EACA), para-aminomethylbenzoic acid (PAMBA) and tranexamic acid (AMCHA).	
B2A2	Proteinase	
B2A9	Other antifibrinolytics	
B2B	ANTAGONISTS (ANTIDOTES TO ANTICOAGULANTS)	
B2B1	Vitamin K	
	Essential for the formulation of prothrombin complex factors in the liver.	
B2B2	Protamin sulphate	
	Neutralises the effect of heparin.	
B2B9	Antidotes to anticoagulants, other	I2016
	Includes idarucizumab, andexanet alfa.	
B2C	PROTEINASE INHIBITORS	
B2C1	Coagulation inhibitors	
	Includes coagulation inhibitors eg antithrombin III.	
B2C2	Inhibitors of the Kallikrein-kinin-system	R2015
	Includes products containing eg camostat, gabexate, nafamostat. Products for hereditary angioedema are classified in B6D.	
B2C3	Inhibitors of fibrinolysis	
	Includes aprotinin.	
B2C9	Other proteinase inhibitors	r2013
	Products containing alpha-1-proteinase inhibitor are classified in R3X2.	
	I	

B2D	BLOOD COAGULATION PRODUCTS	r2022
B2D1	Factor VIII, including substitutes	r2019
	Includes antihaemophilic globulin A, emcizumab, etc. Products containing von Willebrand factor only are classified in B2D9.	
B2D2	Factors II, VII, IX and X	
	Includes antihaemophilic globulin B and prothrombin complex.	
B2D3	Anti-inhibitor-coagulation complex	R2003
	Includes aPCC (activated prothrombin complex concentrate), activated FVII (FVIIa), and eptacog alfa.	
B2D4	Factor XIII	
B2D5	Fibrinogen	
B2D6	Fresh frozen plasma and antihaemophilic plasma	
B2D7	Cohn-Fraction I	
B2D8	Platelet concentrates	
B2D9	Other blood fractions	R2005
	Includes products containing von Willebrand factor (single ingredient).	
B2E	THROMBOPOIETIN AGONISTSPLATELET-ENHANCING PRODUCTS	r2021 R2023
	Includes products containing thrombopoietin agonists, such as eltrombopag and romiplostim.	
	Products containing oprelvekin for the prevention of severe thrombocytopenia are classified in B6X.	
B2E1	Thrombopoietin agonists	<u>I2023</u>
	Includes products containing thrombopoietin agonists for thrombocytopenia, eg avatrombopag, eltrombopag, hetrombopag olamine, lusutrombopag, romiplostim, thrombopoietin, etc.	
<u>B2E9</u>	Platelet-enhancing products, other	<u>I2023</u>
	Includes products for thrombocytopenia containing fostamatinib, oprelvekin, etc.	
B2F	TISSUE SEALING PREPARATIONS	r2016
	Includes products imitating the physiological process of fibrin formation which are	

used for tissue sealing, haemostasis and support of wound healing. Products containing thrombin/collagen for the prevention of bleeding prior to implantation of ICDs/pacemakers are classified here.

В3	ANTI-ANAEMIC PREPARATIONS	
B3A	HAEMATINICS, IRON AND ALL COMBINATIONS	
	Any products which contain iron, irrespective of other ingredients (for example, folic acid, vitamin B12, etc.) are classified in B3A.	
B3A1	Plain iron	
	This class also includes preparations containing ingredients for better absorption and/or reducing agents, such as ascorbic acid, as well as combinations with cobalt.	
B3A2	Iron combination products	R1993
	Includes all other iron combinations including those containing liver extract and/or folic acid.	
взв	LIVER EXTRACTS AND COMBINATIONS WITH B12	
	Includes liver extracts, excluding all preparations not used for anaemia. Oral B12 with intrinsic factor allocated is classified in B3B.	
взс	ERYTHROPOIETIN PRODUCTS	R1995
B3D	HIF-PH INHIBITORS	12020
	Includes products containing HIF-PH (hypoxia-inducible factor prolyl hydroxylase) inhibitors (for example, daprodustat, enarodustat, molidustat, roxadustat, vadadustat, etc) for the treatment of anaemia in chronic kidney disease.	
взх	OTHER ANTI-ANAEMIC PRODUCTS, INCLUDING FOLIC ACID, FOLINIC ACID	<u>r</u> R200 <u>23</u> 5
	Folinic acid products with more than one indication are classified in V3D.	
	Includes products containing betibeglogene autotemcel for beta thalassaemia, luspatercept for anaemia associated with beta thalassaemia, sutimlimab for inhibition of haemolysis in cold agglutinin disease, voxelotor for haemolytic anaemia associated with sickle cell disease.	

B6	ALL OTHER HAEMATOLOGICAL AGENTS	R1996
B6A	Out of use; can be reused from 1999.	D1996
B6B	HYALURONIDASE	
B6C	Out of use	D2020
B6D	HEREDITARY ANGIOEDEMA PRODUCTS	I2015
	Includes products containing eg C1 inhibitor/conestat alfa, ecallantide, icatibant, etc when indicated for hereditary angioedema.	
B6X	OTHER HAEMATOLOGICAL AGENTS	r202 <u>3</u> 1
	Includes haemins. Excluded are those preparations used in the treatment of veins and haemorrhoids (C5) and preparations for dermatological use (D3A).	
	Products containing <u>fostamatinib or oprelvekin</u> —for the prevention of severe thrombocytopenia are classified <u>herein B2E9</u> .	

D4	ANTI-PRURITICS, INCLUDING TOPICAL ANTIHISTAMINES, ANAESTHETICS, ETC	
D4A	ANTI-PRURITICS, INCLUDING TOPICAL ANTIHISTAMINES, ANAESTHETICS, ETC	r20 <u>23</u> 4
	Included in this group are topical preparations for the relief of itching, insect bites, etc which may contain antihistamines, anaesthetics, etc but excluding corticosteroid combinations (see D7B). Systemic anti-pruritics are classified in R6A if they contain antihistamines. Oral nalfurafine is classified here. Products containing nemolizumab for pruritus associated with atopic dermatitis are classified in D5X.  Local anaesthetics for use in surgical or medical procedures are in N1B.	

# D5 NONSTEROIDAL PRODUCTS FOR INFLAMMATORY SKIN DISORDERS

r2019

Includes products for psoriasis, hyperkeratosis, ichthyosis, eczema, dermatitis, seborrhoea. Psoralens are classified here when used for inflammatory conditions. Excluded from this class are combinations with antibacterials (D6A), antifungals (D1A) and products specifically indicated in acne (D10A). Sulphur baths which contain other substances besides sulphur and are not used for dermatological purposes, are classified in M2A.

#### D5A TOPICAL ANTIPSORIASIS PRODUCTS

r2019

Includes products containing substances such as tar, coal tar, ichthammol, dithranol, psoralens, salicylic acid for the treatment of psoriasis. These products may also be for other inflammatory skin conditions. Products containing corticosteroids in combination with coal tar or salicylic acid for psoriasis are classified here. These products may also be for other inflammatory skin conditions.

Includes products consisting of coal tar or calcipotriol, alone or in combination, when indicated for psoriasis.

#### D5B SYSTEMIC ANTIPSORIASIS PRODUCTS

r2022

Includes products for the treatment of psoriasis. These products may also be for other inflammatory skin conditions. Products containing brodalumab, ixekizumab, secukinumab or ustekinumab and indicated for psoriasis and also other non-skin conditions, eg arthritis, are classified in L4C. Psoriatic arthritis is defined as a skin condition.

Apremilast is classified here if only for psoriatic skin conditions. Products containing apremilast for multiple conditions are classified in L4X.

## D5X OTHER NONSTEROIDAL PRODUCTS FOR INFLAMMATORY SKIN DISORDERS

r20<u>23</u>4

Includes nonsteroidal products for inflammatory skin disorders which are not indicated for psoriasis. Specific topical immunomodulators for dermatitis are classified here.

Products containing ingenol mebutate or diclofenac gel that are indicated for actinic keratosis are classified here. Products containing aminolaevulinic acid for actinic keratosis, basal cell carcinoma or Bowen syndrome are classified in L1X8. Products containing topical fluorouracil for actinic keratosis are classified in L1B.

Products containing dupilumab for atopic dermatitis only are classified here. Products containing dupilumab for both atopic dermatitis and asthma are classified in L4C.

<u>Products containing nemolizumab for pruritus associated with atopic dermatitis are classified here.</u>

H2	SYSTEMIC CORTICOSTEROIDS	
H2A	SYSTEMIC CORTICOSTEROIDS, PLAIN	
	Includes all systemic products containing one or more corticosteroid(s) and no other active ingredient, with or without lignocaine.	
H2A1	Injectable corticosteroids, plain	R1993
H2A2	Oral corticosteroids, plain	R1993 r2023
	Products containing corticosteroids for eosinophilic oesophagitis are classified in A7E2.	
H2A3	Other systemic corticosteroids, plain	r2017
	Includes suppositories. Corticosteroids to treat inflammatory intestinal disorders are classified in A7E2.	
H2B	SYSTEMIC CORTICOSTEROID COMBINATIONS	r2020
	Systemic products containing one or more corticosteroid(s) and one or more other active ingredient(s) (eg antihistamine). Also includes extracts containing natural corticosteroids, but excluding products classified in the following groups:	
	A7E2 – Intestinal anti-inflammatory agents	
	H4X – Liver extracts with small doses of corticosteroids (mainly in Italy).	
	G3X - Gland extracts (mammary, placenta, etc) and corticoid extracts mainly indicated for sexual disorders.	
	G4C7 – Corticosteroids with alpha-adrenergic antagonists.	
	M1B - Corticosteroids with anti-inflammatory agents, analgesics, muscle relaxants, etc.	
	R1B – Systemic nasal preparations	
	R3D, R3F, R3L3 - Anti-asthmatic inhalants acting topically on the bronchioles.	

H4	OTHER HORMONES	
H4A	CALCITONINS	
	This group includes all calcitonin products (pork, salmon, eel and synthetic).	
H4B	GLUCAGON	
H4C	GROWTH HORMONES	r202 <u>3</u> 2
	Includes products for growth conditions and also for AIDS wasting conditions. Products containing anamorelin for cachexia are classified here. Products containing lonapegsomatropin or somatrogon are classified here.	
H4D	ANTIDIURETIC HORMONES	
	This group includes argipressin, desmopressin, lypressin, ornipressin, vasopressin.	
H4E	PARATHYROID HORMONES AND ANALOGUES	I2008
	Includes parathyroid hormone analogues, teriparatide.	
H4F	ANTIPARATHYROID PRODUCTS	r2014
	Includes products containing eg cinacalcet, doxercalciferol, falecalcitriol, maxacalcitol, paricalcitol, when they are indicated for secondary hyperparathyroidism. Products containing vitamin D or its analogues with multiple indications are classified in A11C2.	
H4V	Out of use; can be reused from 2011.	D2008
H4X	OTHER HORMONES AND PREPARATIONS WITH SIMILAR ACTIONS	r2009
	Products containing melatonin only and indicated for sleep rhythm disturbances are classified here. Prolonged-release melatonin indicated for primary insomnia is classified in N5B1. Products for insomnia that contain a sedative/hypnotic plus melatonin are classified in N5B in the appropriate subclass (N5B2, N5B4 or N5B5).	

J5B6	Coronavirus antivirals	<u>r</u> I202 <u>3</u>
		2
	Includes products containing bamlanivimab, casirivimab, etesevimab, favipiravir, imdevimab, molnupiravir, sotrovimab, regdanvimab, remdesivir, etc, for treatment of COVID-19.	
	Products containing favipiravir for influenza only are classified in J5B4 (influenza antivirals). Products containing favipiravir for both influenza and COVID-19 are classified here.	
	Products containing <u>immunosuppressants</u> <u>baricitinib</u> , <u>levilimab</u> , <u>tocilizumab</u> , <u>etc (immunosuppressants</u> that have been used in COVID-19) are classified <u>elsewhere</u> , <u>for example</u> , <u>levilimab is</u> in L4 <u>C</u> . Dexamethasone (has been used in COVID-19) is also classified elsewhere in the appropriate hormone class.	
	Vaccines for coronavirus are classified in J7E6.	
J5B9	Antivirals, others	12008
	Includes products containing lysozyme for viral infections.	

J5C	HIV ANTIVIRALS	r202 <u>3</u> 4
	Includes antiviral products specifically used to treat HIV (human immunodeficiency virus).	
	Combinations of different classes of HIV antivirals are classified in J5C89. Combinations of HIV antivirals from a single class are classified in that relevant specific class, eg a product containing only two nucleoside reverse transcriptase inhibitors is classified in J5C1.	
	Pentamidine isethionate which is used to treat <i>Pneumocystis carinii</i> in AIDS is classified in P1G.	
	Products containing dapivirine (vaginal ring) for the prevention of HIV transmission are classified in G1D.	
J5C1	Nucleoside and nucleotide reverse transcriptase inhibitors	r2018
	Includes abacavir, didanosine, emtricitabine, lamivudine, stavudine, tenofovir disoproxil, zalcitabine, zidovudine. Single-ingredient products containing tenofovir disoproxil and indicated for either HIV and/or hepatitis are classified here.	
	Products containing single-ingredient lamivudine or tenofovir alafenamide and for hepatitis B only are classified in J5D2.	
J5C2	Protease inhibitors	r2011
	Includes amprenavir, atazanavir, darunavir, fosamprenavir, indinavir, lopinavir, nelfinavir, ritonavir, saquinavir, tipranavir.	
J5C3	Non-nucleoside reverse transcriptase inhibitors	r2011
	Includes delavirdine, efavirenz, etravirine, nevirapine.	
J5C4	HIV antivirals, entry inhibitors	I2011
	Includes products containing entry inhibitors such as enfuvirtide, maraviroc.	
J5C5	HIV antivirals, integrase inhibitors	I2015
	Includes products containing integrase inhibitors eg dolutegravir, elvitegravir, raltegravir.	
<u>J5C8</u>	HIV antivirals, multiclass combination products	<u>I2023</u>
	Includes products containing two or more substances from different HIV subclasses. For example, an integrase inhibitor in combination with a nucleoside reverse transcriptase inhibitor.	
	Combinations of HIV antivirals from a single class are classified in that relevant specific class, eg a product containing only nucleoside reverse transcriptase	

J5C9	HIV antivirals, other	<u>R</u>
	Includes—Ceombinations of different classes of HIV antivirals are classified in J5C8. For example, an integrase inhibitor in combination with a nucleoside reverse transcriptase inhibitor. Combinations of HIV antivirals from a single class are classified in that relevant specific class, eg a product containing only nucleoside reverse transcriptase inhibitors is classified in J5C1.	
	Products containing cobicistat as a single ingredient are classified here. Products containing cobicistat in combination with HIV antivirals are classified in the appropriate class for the antivirals.	

J6E	POLYVALENT IMMUNO-GLOBULINS - INTRAMUSCULAR	R2006
JOE		K2000
	The action of these homologous substances is based on a wide spectrum of antibodies mainly belonging to the IgG fraction. Includes subcutaneous as well as intramuscular forms.	
J6F	POLYVALENT IMMUNOGLOBULINS - COMBINATION MODULATION - MAINLY INTRAMUSCULAR	
	These homologous immunoglobulins include: - those whose action is not exclusively based on the IgG fraction those which exist in combination with other substances those which cause a modulation of the immune response.	
J6G	SPECIFIC IMMUNOGLOBULINS - ANTIBACTERIAL	r2022
	These homologous substances (given intramuscularly or intravenously) have a certain antibody titre against a certain specified antigen. Products for post-exposure prophylaxis are classified here. Products for both post-exposure prophylaxis and for treatment are classified here.	
J6G1	Tetanus immunoglobulin	
J6G2	Pertussis immunoglobulin	
J6G9	Other antibacterial immunoglobulins	
	This group includes diphtheria, streptococci, staphylococci and pseudomonas immunoglobulins.	
Ј6Н	SPECIFIC IMMUNOGLOBULINS - ANTIVIRAL	r202 <u>3</u> 2
	These homologous substances (given intramuscularly or intravenously) have a certain antibody titre against a certain specified antigen. Products for <a href="mailto:prevention/post-exposure">prevention/post-exposure</a> prophylaxis are classified here. Products for both <a href="mailto:prevention/post-exposure">prevention/post-exposure</a> prophylaxis and for treatment are classified here. Monoclonal antibodies for treatment <a href="mailto:only">only</a> of COVID-19 are classified in J5B6.	
J6H1	Mumps immunoglobulin	
Ј6Н2	Measles immunoglobulin	
Ј6Н3	Rubella immunoglobulin	
Ј6Н4	Hepatitis immunoglobulin	
J6H5	Rabies immunoglobulin	

J6	Н9	Other antiviral immunoglobulins	r2022
		This group includes varicella-zoster, tick-borne meningo-encephalitis, poliomyelitis, cytomegaly and herpes immunoglobulins. Products containing palivizumab for the prevention of RSV infections are classified here.	

L1G	MONOCLONAL ANTIBODY ANTINEOPLASTICS	R2019
	Antineoplastic monoclonal antibodies against protein kinases are classified here and not in L1H.	
L1G1	Monoclonal antibody antineoplastics, CD20	r2022
	Includes products containing obinutuzumab, ofatumumab, rituximab with hyaluronidase, etc. Products containing ofatumumab for multiple sclerosis only are classified in N7A.	
L1G2	Monoclonal antibody antineoplastics, VEGF/VEGFR	I2019
	Includes products containing bevacizumab, ramucirumab, etc.	
L1G3	Monoclonal antibody antineoplastics, HER-2	r2021
	Includes products containing margetuximab, pertuzumab, trastuzumab deruxtecan, trastuzumab emtansine, etc.	
L1G4	Monoclonal antibody antineoplastics, EGFR	I2019
	Includes products containing cetuximab, necitumumab, nimotuzumab, panitumumab, etc.	
L1G5	Monoclonal antibody antineoplastics, PD-1/PD-L1	<u>r</u> 120 <u>23</u> 19
	Includes products containing atezolizumab, avelumab, cemiplimab, durvalumab, nivolumab, pembrolizumab, tislelizumab, etc. <u>Products containing a combination of nivolumab with relatlimab are classified in L1G9.</u>	

## L1G9 Monoclonal antibody antineoplastics, other r12023 19 Includes antibodies with other targets including other CD targets, CTLA-4 (ipilimumab), etc. Includes antibody drug conjugates (ADCs) if not classified with the target class (brentuximab vedotin, gemtuzumab ozogamicin, inotuzumab ozogamicin). Includes radio-labelled antibodies (ibritumomab tiuxetan, tositumomab iodine-131). Includes alemtuzumab, blinatumomab, brentuximab vedotin, catumaxomab, daratumumab, dinutuximab, elotuzumab, gemtuzumab ozogamicin, ibritumomab tiuxetan, inotuzumab ozogamicin, ipilimumab, mogamulizumab, olaratumab, racotumomab, rovalpituzumab tesirine, siltuximab, tositumomab, tositumomab iodine-131, etc. Includes products containing a combination of nivolumab with relatlimab. Products containing nivolumab alone are classified in L1G5. Products containing alemtuzumab and indicated for cancer only are classified here.

Products containing alemtuzumab and indicated for multiple sclerosis are

classified in N7A.

L1H	PROTEIN KINASE INHIBITOR ANTINEOPLASTICS	R2019
	Antineoplastic monoclonal antibodies against protein kinases are classified in L1G.	
L1H1	Protein kinase inhibitor antineoplastics, BCR-ABL	I2019
	Includes products containing bosutinib, dasatinib, imatinib, nilotinib, ponatinib, radotinib, etc.	
L1H2	Protein kinase inhibitor antineoplastics, EGFR	I2019
	Includes products containing afatinib, dacomitinib, erlotinib, gefitinib, icotinib, olmutinib, osimertinib, varlitinib, etc.	
L1H3	Protein kinase inhibitor antineoplastics, ALK	I2019
	Includes products containing alectinib, brigatinib, ceritinib, crizotinib, lorlatinib, etc.	
L1H4	Protein kinase inhibitor antineoplastics, BRAF/MEK	I2019
	Includes products containing binimetinib, cobimetinib, dabrafenib, encorafenib, selumetinib, trametinib, vemurafenib, etc.	

L1H5	Protein kinase inhibitor antineoplastics, CDK 4/6	I2019
	Includes products containing abemaciclib, palbociclib, ribociclib, etc. Products containing both ribociclib and letrozole are classified here.	
L1H6	Protein kinase inhibitor antineoplastics, BTK	I2021
	Includes products containing acalabrutinib, ibrutinib, tirabrutinib, zanubrutinib, etc.	
L1H9	Protein kinase inhibitor antineoplastics, other	r202 <u>3</u> 2
	Includes all other protein kinase inhibitor antineoplastics, for example those inhibiting HER-2, JAK 1-2, Pi3K, etc. Pi3K inhibitors are included even though they are lipid kinase inhibitors and not strictly protein kinase inhibitors.	
	Includes axitinib, cabozantinib, erdafitinib, everolimus, idelalisib, lapatinib, lenvatinib, midostaurin, neratinib, nintedanib, pazopanib, regorafenib, rivoceranib (apatinib), ruxolitinib, sorafenib, sunitinib, temsirolimus, tivozanib, vandetanib, etc.	
	Products containing nintedanib for idiopathic pulmonary fibrosis only are	

classified in R7D. Products containing nintedanib for cancer only are classified here. Products containing nintedanib for both cancer and idiopathic pulmonary fibrosis are classified in R7D.

L1X8	Photosensitisers for cancer therapy	r20 <u>23</u>
	Includes products containing photosensitisers for use in cancer therapy, eg aminolaevulinic acid, methyl aminolaevulinate, methoxsalen, porfimer, talaporfin, temoporfin, etc.	
	Products containing aminolaevulinic acid for actinic keratosis, basal cell carcinoma or Bowen syndrome are classified here. Products containing aminolaevulinic acid for use in diagnostic procedures are classified in T1X.	
	Products containing methoxsalen for other skin conditions such as psoriasis or vitiligo are classified in the appropriate D classes.	
	Products containing vertoporfin verteporfin for macular degeneration are classified in S1P.	

#### L1X9 | All other antineoplastics

r202<del>2</del>3

Includes amsacrine, enzymes, estramustine, gallium nitrate, methylhydralazine, mitotane, <u>pentostatin</u>, procarbazine, substituted urea, tasonermin, vosaroxin. Also includes celecoxib for familial adenomatous polyposis (FAP).

Products containing aflibercept for cancer are classified here. Products containing aflibercept for macular degeneration are classified in S1P.

Products containing BCG vaccine for cancer are classified here; those for general immunostimulation are classified in L3A9. Products containing BCG vaccine for active immunisation against tuberculosis are classified in J7D6.

<u>Products containing miltefosine for skin metastases of breast cancer are classified here.</u> Products containing miltefosine for leishmaniasis are classified in P1G.

L4	IMMUNOSUPPRESSANTS	R2010
L4A	Out of use; can be reused from 2013.	D2010
L4B	ANTI-TNF PRODUCTS	r2020
	Products containing anti-TNF substances are classified here, eg adalimumab, afelimomab, certolizumab pegol, etanercept, golimumab, infliximab. These products can be indicated for multiple conditions, eg rheumatoid arthritis, Crohn's disease, psoriasis.	
	Products containing apremilast for psoriatic conditions only are classified in D5B. Products containing apremilast for multiple conditions are classified in L4X.	
L4C	INTERLEUKIN INHIBITORS	r202 <u>3</u> 4
	Includes products containing interleukin inhibitors, eg basiliximab, canakinumab, daclizumab, rilonacept.	
	Includes interleukin inhibitors indicated for the treatment of rejection in organ transplants and for auto-inflammatory diseases such as CAPS (cryopyrin-associated periodic syndromes).	
	Products containing tocilizumab or anakinra and indicated for arthritic conditions are classified in M1C. Products containing tocilizumab or anakinra and indicated for both arthritic and also other conditions and also giant cell arteritis are classified in M1C. Products containing brodalumab, ixekizumab, secukinumab or ustekinumab and indicated for skin conditions such as psoriasis and also other non-skin conditions, eg rheumatoid arthritis, are classified here. Psoriatic arthritis is defined as a skin condition.	
	Products containing daclizumab and indicated for use in kidney transplantation are classified here. Products containing daclizumab and indicated for multiple sclerosis and other conditions are classified in N7A.	
	Products containing mepolizumab—interleukin inhibitors for asthma only are classified in R3M. or for asthma and EGPA (eosinophilic granulomatosis with polyangiitis) are classified in R3M. Products containing interleukin inhibitors for asthma and any of the following conditions, EGPA (eosinophilic granulomatosis with polyangiitis), chronic rhinosinusitis with nasal polyposis, nasal polyps, hypereosinophilic syndrome are classified in R3M.	
	Products containing dupilumab for atopic dermatitis are classified in D5X. Products containing dupilumab for both atopic dermatitis and asthma are classified here.	

Products containing levilimab for use in COVID-19 are classified here.

#### L4X OTHER IMMUNOSUPPRESSANTS

Immunosuppressants used in the treatment of rejection in organ transplants are classified here, or in L4C if they contain interleukin inhibitors.

Includes eg antilymphocyte and antithymocyte immunoglobulins, azathioprine, cyclosporin, muromonab-cd3, mycophenolate mofetil, tacrolimus — unless classified elsewhere because of a specific indication or formulation. For example, ophthalmic cyclosporin for dry eye is classified in S1K9 and dermatological tacrolimus is classified in D5X.

Products for multiple sclerosis are classified in N7A. Products containing natalizumab and indicated for multiple sclerosis and other conditions are classified in N7A.

Products containing apremilast for psoriatic skin conditions only, are classified in D5B. Psoriatic arthritis is defined as a skin condition. Products containing apremilast for multiple conditions are classified here.

Products containing lenalidomide, pomalidomide or thalidomide for multiple myeloma and other cancers are classified in L1K. Products containing thalidomide for both cancer and erythema nodosum leprosum (ENL) are classified in L1K. Products containing thalidomide for erythema nodosum leprosum only are classified here.

Products containing baricitinib, <u>filgotinib</u>, tofacitinib or upadacitinib (JAK inhibitors) for multiple conditions are classified here. Products containing baricitinib, <u>filgotinib</u>, tofacitinib or upadacitinib for rheumatoid arthritis only are classified in M1C.

Products containing leflunomide for multiple conditions are classified here. Products containing leflunomide for rheumatoid arthritis only are classified in M1C.

Corticosteroids are not classified here.

#### M1C | SPECIFIC ANTI-RHEUMATIC AGENTS

r2023<del>2</del>

This class includes abatacept, anakinra, tocilizumab, gold preparations, bucillamine, penicillamine and quinolines (eg oxycinchophen). Includes products containing mesalazine, olsalazine, and sulphasalazine if specifically indicated for rheumatic conditions. Products containing aminosalicylates and used for intestinal inflammatory conditions, are classified in A7E1.

Azathioprine is in L4X. Products containing methotrexate for rheumatic conditions are classified here; otherwise methotrexate is classified in LIB or in D.

Products containing anti-TNF substances are classified in L4B.

Products containing baricitinib, <u>filgotinib</u>, tofacitinib or upadacitinib <u>(JAK inhibitors)</u>, and indicated for rheumatoid arthritis only, are classified here. Products containing baricitinib, <u>filgotinib</u>, tofacitinib or upadacitinib for multiple conditions are classified in L4X.

Products containing leflunomide, and indicated for rheumatoid arthritis only, are classified here. Products containing leflunomide for multiple conditions are classified in L4X.

Products containing interleukin inhibitors and only indicated for arthritic conditions are classified here, eg anakinra. Products containing tocilizumab or anakinra and indicated for both arthritics and giant cell arteritis other conditions are classified here. Other interleukin inhibitors indicated for multiple conditions including arthritis are classified in L4C.

Psoriatic arthritis is defined as a skin condition.

N2	ANALGESICS	R2003
	Only includes general purpose analgesics with multiple indications and uses. Thus products specifically used for rheumatic disorders are classified in group M, analgesic cold preparations are classified in R5, products specifically for dysmennorrhoea are classified in G2X.	
N2A	NARCOTICS	R1993
	Includes all analgesics classified as narcotics in accordance with the legal definition of narcotic analgesics in each country.	
N2B	NON-NARCOTICS AND ANTI-PYRETICS	r20 <u>23</u> 4
	Includes systemic products for non-specific analgesia except those classified in N2A (narcotics), N2C (specific anti-migraine preparations), R5A (analgesic/antihistamine cold preparations) and G2X1 (specific dysmenorrhoea preparations).	
	Topical products for analgesia are classified in M2A.  Products containing acetylsalicylic acid only are classified in N2B, not M1A.  Products containing low-dose oral solid acetylsalicylic acid (162mg and below) are classified in B1C1 (platelet aggregation inhibition).	
	Products containing non-steroidal anti-inflammatories and for both musculoskeletal conditions and analgesia are classified in M1A.	
	Alka-Seltzer, when it contains an analgesic, is classified in N2B. Otherwise, it is classified in A2A1.	
	Products containing muscle relaxants in combination with analgesics are classified in M3.	
	Includes products containing mirogabalin for neuropathic pain only.	
	4th level used in Austria, Finland, Hungary, Germany, South Africa, Sweden and Switzerland only.	
N2B1	Prescription-bound non-narcotics and anti-pyretics	
N2B2	Non-prescription-bound non-narcotics and anti-pyretics	
N2C	ANTI-MIGRAINE PREPARATIONS	
N2C1	Antimigraine triptans Anti-migraine selective serotonin agonists	12001 <u>r</u> 2023
	These are selective 5HT1 receptor agonists eg almotriptan, eletriptan, frovatriptan, lasmiditan, naratriptan, rizatriptan, sumatriptan, zolmitriptan. Includes triptans and ditans.	

N2C2	Anti_migraine CGRP antagonists	<u>r</u> ¥202 <u>3</u>
		0
	Includes products containing CGRP (calcitonin gene-related peptide) antagonists, for example, atogepant, eptinezumab, erenumab, fremanezumab, galcanezumab, rimegepant, ubrogepant, etc.	
N2C9	All other anti-migraine preparations	r2015
	Includes products containing indoramin alone if indicated for migraine.	

N3	ANTI-EPILEPTICS	
N3A	ANTI-EPILEPTICS	r20 <u>23</u> 1
	Also includes products for non-epileptic convulsions, eg in pregnancy.	
	Products containing clonazepam are classified here. Products containing gabapentin or pregabalin for either epilepsy or neuropathic pain are classified here. Products containing mirogabalin for neuropathic pain only are classified in N2B.	

N5	PSYCHOLEPTICS	
N5A	ANTIPSYCHOTICS	R2005
	Combinations with psychoanaleptics eg antidepressants are classified in N6C.	
N5A1	Atypical antipsychotics	R2005
	Includes products containing substances such as amisulpride, aripiprazole, clozapine, olanzapine, quetiapine, remoxipride, risperidone, sertindole, ziprasidone, zotepine.	
N5A9	Conventional antipsychotics	R2005
	Includes eg phenothiazines, thioxanthenes, butyrophenones. Also includes sulpiride, in all countries except Japan, Korea and Taiwan where it is classified in A2B9 (all other anti-ulcerants).	
N5B	HYPNOTICS/SEDATIVES	r2008
	Products for sleep rhythm disturbances containing melatonin only are classified in H4X. Products for insomnia that contain a hypnotic/sedative plus melatonin are classified in N5B in the appropriate subclass (N5B2, N5B4 or N5B5).	
N5B1	Non-barbiturates, plain	r20 <u>23</u> 0
	Includes benzodiazepines indicated exclusively for the treatment of insomnia, eg nitrazepam, flurazepam. Includes orexin inhibitors for the treatment of insomnia, eg daridorexant, lemborexant, suvorexant. Prolonged-release melatonin is classified here when indicated for primary insomnia. Products containing melatonin only and indicated for sleep rhythm disturbances are classified in H4X.	
N5B2	Non-barbiturates, combinations	
N5B3	Barbiturates, plain	
N5B4	Barbiturates, combinations	
N5B5	Herbal hypnotics/sedatives	r2009
	Includes products containing one or more herbal substances. Products classified here can also contain other non-sedative substances. Prolonged-release melatonin indicated for primary insomnia is classified in N5B1. Melatonin (any form/strength) in combination with a hypnotic/sedative is classified in the appropriate N5B subclass. Other products in N5B containing both herbal and non-herbal substances are classified according to the non-herbal substance.	

N7	OTHER CNS DRUGS	R1996
N7A	MULTIPLE SCLEROSIS PRODUCTS	r202 <u>3</u> 2
	Products containing alemtuzumab, dimethyl fumarate, fingolimod, glatiramer acetate, laquinimod, teriflunomide, etc, and indicated for multiple sclerosis only, are classified here.	
	Products containing natalizumab and indicated for multiple sclerosis and other conditions are classified here.	
	Products containing alemtuzumab and indicated for cancer only, are classified in L1G9.	
	Products containing daclizumab and indicated for multiple sclerosis and also other conditions are classified here. Products containing daclizumab for use in kidney transplantation only are classified in L4C.	
	Products containing beta interferons and indicated for multiple sclerosis only are classified here. Products containing beta interferons and indicated for both multiple sclerosis and other conditions are classified in L3B2.	
	Products containing mitoxantrone and indicated for both cancer and multiple sclerosis are classified in L1D.	
	Products containing fampridine for improvement in walking in multiple sclerosis are classified in N7X.	
	Products containing of atumumab for cancer are classified in L1G1.	
	Products containing ozanimod and indicated for both multiple sclerosis and ulcerative colitis are classified here.	
	Products containing other substances, eg corticosteroids, immunosuppressants such as azathioprine, that have multiple uses, are classified elsewhere.	
N7B	ANTISMOKING PRODUCTS	
	Includes products used to stop smoking.	
N7C	ANTIVERTIGO PRODUCTS	I1996
	Includes betahistine, cinnarizine and flunarizine when indicated for vertigo and Meniere's disease.	

P	PARASITOLOGY	
P1	ANTIPROTOZOALS AND ANTHELMINTICS	R2003
P1A	AMOEBICIDES	R2006
	Includes products whose major indication is amoebiasis. Trichomonacides, eg metronidazole, will be classified in G1A or J8B, except when they are used primarily as amoebicides. Products indicated for both trichomoniasis and amoebiasis are classified in G1A1.	
P1B	ANTHELMINTICS, EXCLUDING SCHISTOSOMICIDES	
	In an anthelmintic combination product the anthelmintic component takes precedence over other components.	
P1C	SCHISTOSOMICIDES	
	Products used to treat bilharziasis.	
P1D	ANTI-MALARIALS	r2018
	If a product contains an antimalarial ingredient and also a second ingredient which is not a specific antimalarial, then this is considered a single-ingredient antimalarial.	
	Vaccines against malaria are classified in J7F1.	
P1D1	Anti-malarials, single ingredient	12000
P1D2	Anti-malarials, multi-ingredient	12000
P1E	Out of use; can be reused from 2006.	D2003
P1F	Out of use; can be reused	
P1G	OTHER ANTI-PARASITIC AGENTS	R1998
	Includes products for the treatment of leishmaniasis and toxoplasmosis. Pentamidine (used to treat Pneumocystis carinii) is classified here. Products containing miltefosine for leishmaniasis are classified here. Products containing miltefosine for skin metastases of breast cancer are classified in L1X9.	<u>r2023</u>

R3M	INTERLEUKIN INHIBITOR ANTI-ASTHMATICS	r20 <u>23</u> ‡
	Includes products containing interleukin inhibitors for asthma, eg benralizumab, mepolizumab, reslizumab, etc.	
	Products containing mepolizumab-interleukin inhibitors for asthma only and for asthma and any of the conditions, EGPA (eosinophilic granulomatosis with polyangiitis), chronic rhinosinusitis with nasal polyposis, nasal polyps, hypereosinophilic syndrome are classified here.  Products containing dupilumab for both asthma and atopic dermatitis are classified in L4C.	

R3X	ALL OTHER ANTI-ASTHMA AND COPD PRODUCTS	R2000
R3X1	All other anti-asthma and COPD products, inhalant	R2003
	This subgroup includes anti-asthmatic cigarettes.	
R3X2	All other anti-asthma and COPD products, systemic	r20 <u>23</u> 1
	Includes products containing alpha-1-proteinase inhibitor (alpha-1-antitrypsin), omalizumab, tezepelumab, etc.	8

R5	COUGH AND COLD PREPARATIONS	
R5A	COLD PREPARATIONS WITHOUT ANTI-INFECTIVES	R1994
	This group consists of all products indicated for colds, influenza, etc. It therefore includes combination products such as those containing antihistamines with decongestants, analgesics, antipyretics, vitamins, etc and since symptoms of colds and influenza may include a cough, an antitussive, and possibly an expectorant may also be included (see also R5D2 and R5C).	
R5B	COUGH/COLD PREPARATIONS WITH ANTI-INFECTIVES	r2016
	Includes combinations with anti-infectives (including antivirals) indicated specifically for coughs, colds, influenza and other respiratory conditions. Combinations of antiseptics with expectorants are classified in R5C and with antitussives are classified in R5D2.	
R5C	EXPECTORANTS	r2021
	'Expectorants' mean substances with secretolytic or secretomotoric activity, so that mucolytics are classified in this group.	
	The group includes all cough preparations with an expectorant as the main ingredient (eg guaiacol, saponin, ammonium chloride). These may also include antihistamines and bronchodilators but excluded are combinations of expectorants with antitussives (R5D2), with analgesics and antipyretics (R5A), and with anti-infectives (R5B). Lozenges indicated for cough and containing expectorants are classified here. Products containing dornase alfa for cystic fibrosis are classified here.	
R5D	ANTITUSSIVES	
R5D1	Plain antitussives	<u>r2023</u>
	Includes all plain antitussives. <u>Products containing gefapixant are classified here.</u>	
R5D2	Antitussives in combinations	R1994
	Includes combinations with expectorants, antihistamines, ephedrine, herbal tinctures, etc. Excluded are combinations with analgesics and antipyretics (R5A) and combinations with anti-infectives (R5B).	
R5E	Out of use; can be reused.	

R5F	OTHER COUGH AND COLD PREPARATIONS	r2009
	This group includes: - combinations without a clearly expectorating or antitussive effect; - lozenges indicated for cough unless they contain anti-infectives, R5B or antitussives, R5D, or expectorants, R5C); - expectorant teas.	