

Product Name (click for EPAR)	Orphan or Rare	Prevalence in EU (per 10,000)	Product INN	Therapeutic Indication - Summary	Type	Prescribing limitations (Posology and method of administration: Annex I, 4.2)
ADYNOVI	Rare, no orphan designation	1.3	rurioctocog alfa pegol	treatment of haemophilia A	Biological	Treatment should be under the supervision of a physician experienced in the treatment of
Aimovig	Not rare		erenumab	prophylaxis of migraine	Biological	Treatment should be initiated by physicians experienced in the diagnosis and treatment of
AJOVY	Not rare		fremanezumab	prevention of episodic and chronic migraine	Biological	The treatment should be initiated by a physician experienced in the diagnosis and treatment of
Alofisel	Orphan	2.3	darvadstrocel	treatment of complex perianal fistula(s)	ATMP, Biological	Alofisel should only be administered by specialist physicians experienced in the diagnosis and treatment of conditions for which Alofisel is indicated
Alpivab	Not rare		peramivir	treatment of influenza	Chemical	n/a
Alunbrig	Not rare		brigatinib / brigatinib	treatment of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC)	Chemical	Treatment with Alunbrig should be initiated and supervised by a physician experienced in the use of anticancer medicinal products. ALK-positive NSCLC status should be known prior to initiation of Alunbrig therapy. A validated ALK assay is necessary for the selection of ALK-positive NSCLC patients (see section 5.1). Assessment for ALK-positive NSCLC should be performed by laboratories with demonstrated proficiency in the specific technology being utilised.
Besremi	Orphan not confirmed	3	ropeginterferon alfa-2b	treatment of polycythemia vera	Biological	Treatment should be initiated under supervision of a physician experienced in the management of the
Biktarvy	Not rare		bictegravir / emtricitabine / tenofovir alafenamide	treatment of adults infected with human immunodeficiency virus-1 (HIV-1)	Chemical	Therapy should be initiated by a physician experienced in the management of HIV infection.
Braftovi	Not rare		encorafenib	treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation	Chemical	Encorafenib treatment in combination with binimetinib should be initiated and supervised under the responsibility of a physician experienced in the use of anticancer medicinal products
Cablivi	Orphan	2.2-2.9	caplacizumab	indicated for the treatment of acquired thrombotic thrombocytopenic purpura (aTTP).	Biological	Treatment with Cablivi should be initiated and supervised by physicians experienced in the management of patients with thrombotic microangiopathies.
CRYSVITA	Orphan	0.002-0.04	burosumab	treatment of X-linked hypophosphataemia (XLH)	Biological	Treatment should be initiated by a physician experienced in the management of patients with metabolic bone diseases.
Delstrigo	Not rare		doravirine / lamivudine / tenofovir disoproxil	treatment of adults infected with HIV-1 without past or present evidence of viral resistance to doravirine, lamivudine, or	Chemical	Therapy should be initiated by a physician experienced in the management of HIV infection
Dengvaxia	Not rare		dengue tetravalent vaccine (live, attenuated)	prevention of dengue disease caused by dengue virus serotypes 1, 2, 3 and 4	Biological	n/a

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Doptelet	Not rare		avatrombopag	treatment of thrombocytopenia	Chemical	Obtain a platelet count prior to the administration of Doptelet therapy and on the day of a procedure to ensure an adequate increase in platelet count, and no unexpectedly high increase in platelet count in the patient populations specified in sections 4.4 and 4.5.
Emgality	Not rare		galcanezumab	prophylaxis of migraine	Biological	Treatment should be initiated by physicians experienced in the diagnosis and treatment of
Erleada	Not rare		apalutamide	treatment of non metastatic castration resistant prostate cancer (NM CRPC)	Chemical	Treatment with apalutamide should be initiated and supervised by specialist physicians experienced in the medical treatment of prostate cancer.
Ervebo	Not rare		recombinant vesicular stomatitis virus - Zaire ebolavirus vaccine (live)	Ebola Vaccine	Biological	Ervebo should be administered by a trained healthcare worker.
Esperoct	Rare, no orphan designation	1.3	turoctocog alfa pegol	treatment and prophylaxis of bleeding in patients with haemophilia A	Biological	Treatment should be initiated under the supervision of a physician experienced in the treatment of haemophilia.
Evenity	Not rare		romosozumab	Treatment of osteoporosis	Biological	Treatment should be initiated and supervised by specialist physicians experienced in the management of osteoporosis.
Fasenra	Not rare		benralizumab	treatment of severe asthma with an eosinophilic phenotype	Biological	Fasenra treatment should be initiated by a physician experienced in the diagnosis and treatment of severe asthma. After proper training in the subcutaneous injection technique and education about signs and symptoms of hypersensitivity reactions (see section 4.4), patients with no known history of anaphylaxis or their caregivers may administer Fasenra if their physician determines that it is appropriate, with medical follow-up as necessary. Self-administration should only be considered in patients already experienced with Fasenra treatment.
Giapreza	Not rare		angiotensin II	treatment of hypotension in adults with distributive or vasodilatory shock who remain hypotensive despite fluid and vasopressor therapy	Chemical	GIAPREZA should be prescribed by a physician experienced in the treatment of shock and is intended for use in an acute and hospital setting.
Hemlibra	Rare, no orphan designation	1.3	emicizumab	routine prophylaxis to prevent bleeding or reduce the frequency of bleeding episodes in patients with haemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors	Chemical	Treatment should be initiated under the supervision of a physician experienced in the treatment of haemophilia and/or bleeding disorders.
Ilumetri	Not rare		tildrakizumab	treatment of moderate-to-severe plaque psoriasis	Biological	Ilumetri is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of plaque psoriasis

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Imfinzi	Not rare		durvalumab	treatment of locally advanced, unresectable non-small cell lung cancer (NSCLC)	Biological	Treatment must be initiated and supervised by a physician experienced in the treatment of cancer.
Jivi	Orphan not confirmed	0.73	damoctocog alfa pegol	Treatment and prophylaxis of haemophilia A	Biological	Treatment should be under the supervision of a physician experienced in the treatment of
Kymriah	Orphan	1.2	tisagenlecleucel	treatment of B cell acute lymphoblastic leukaemia (ALL) and diffuse large B cell lymphoma (DLBCL)	ATMP, Biological	Kymriah must be administered in a qualified treatment centre. Therapy should be initiated under the direction of and supervised by a healthcare professional experienced in the treatment of haematological malignancies and trained for administration and management of patients treated with Kymriah. Tocilizumab for use in the event of cytokine release syndrome and emergency equipment must be available per patient prior to infusion. The treatment centre must have access to additional doses of tocilizumab within 8 hours.
Lamzede	Orphan	0.1	velmanase alfa	indicated for long-term enzyme replacement therapy in patients with alpha-mannosidosis	Biological	The treatment should be supervised by a physician experienced in the management of patients with alpha-mannosidosis or in the administration of other enzyme replacement therapies (ERT) for lysosomal storage disorder. Administration of Lamzede should be carried out by a healthcare professional with the ability to manage ERT and medical emergencies.
LIBTAYO	Not rare		cemiplimab	as monotherapy, indicated for the treatment of patients with metastatic cutaneous squamous cell carcinoma	Biological	Treatment must be initiated and supervised by physicians experienced in the treatment of cancer
Lokelma	Not rare		sodium zirconium cyclosilicate	for the treatment of hyperkalaemia	Chemical	n/a
Lorviqua	Not rare		lorlatinib	treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive advanced non-small cell lung cancer (NSCLC)	Chemical	Treatment with lorlatinib should be initiated and supervised by a physician experienced in the use of anticancer medicinal products.
Luxturna	Orphan	3	voretigene neparvovec	treatment of patients with vision loss due to Leber congenital amaurosis or retinitis pigmentosa inherited retinal dystrophy	ATMP, Biological	Treatment should be initiated and administered by a retinal surgeon experienced in performing macular surgery.
Macimorelin Aeterna Zentaris	Rare, no orphan designation	4.7	macimorelin	diagnosis of Adult growth hormone deficiency (AGHD)	Chemical	The use of Macimorelin Aeterna Zentaris must be supervised by a physician or healthcare professional experienced in diagnosing growth hormone deficiency.
Mektovi	Not rare		binimetinib	treatment of adult patients with unresectable or metastatic melanoma with a BRAF V600 mutation in combination with encorafenib	Chemical	Binimetinib treatment in combination with encorafenib should be initiated and supervised under the responsibility of a physician experienced in the use of anticancer medicinal products.

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Mepsevii	Orphan	0.001	vestronidase alfa	Mepsevii is indicated for the treatment of Mucopolysaccharidosis VII (MPS VII; Sly syndrome) for patients of all ages	Biological	Treatment should be supervised by a healthcare professional experienced in the management of patients with MPS VII or other inherited metabolic disorders. Administration of vestronidase alfa should be carried out by an appropriately trained healthcare professional with the ability to manage medical
Mulpleo	Not rare		lusutrombopag	treatment of thrombocytopenia	Chemical	n/a
Myalepta	Orphan	0.002	metreleptin	treatment of leptin deficiency (lipodystrophy)	Biological	Treatment should be initiated and monitored by a healthcare professional experienced in the diagnosis and management of metabolic disorders.
Mylotarg	Orphan	1	gemtuzumab ozogamicin	combination therapy with daunorubicin (DNR) and cytarabine (AraC) for the treatment of patients with previously untreated, de novo acute myeloid leukaemia (AML)	Biological	MYLOTARG should be administered under the supervision of a physician experienced in the use of anticancer medicinal products and in an environment where full resuscitation facilities are immediately available.
Nerlynx	Not rare		neratinib	extended adjuvant treatment of adult patients with early-stage HER2-overexpressed/amplified breast cancer who have received prior adjuvant trastuzumab based therapy	Chemical	Nerlynx treatment should be initiated and supervised by a physician experienced in the administration of anti-cancer medicinal products.
Ocrevus	Not rare		ocrelizumab	treatment of multiple sclerosis treatment of multiple sclerosis	Biological	Ocrevus treatment should be initiated and supervised by specialised physicians experienced in the diagnosis and treatment of neurological conditions and who have access to appropriate medical support to manage severe reactions such as serious infusion-related reactions (IRRs).
Ondexxya	Not rare		andexanet alfa	treatment of direct or indirect factor Xa(FXa) inhibitor when reversal of anticoagulation is needed	Biological	Restricted to hospital use only.
Onpattro	Orphan	0.14	patisiran	treatment of hereditary transthyretin-mediated amyloidosis	Chemical	Therapy should be initiated under the supervision of a physician knowledgeable in the management of amyloidosis.
Ozempic	Not rare		semaglutide	treatment to improve glycaemic control in adults with type 2 diabetes and to prevent cardiovascular events	Biological	n/a
Palynziq	Orphan	2	pegvaliase	treatment of adults with phenylketonuria (PKU) who have inadequate blood phenylalanine control	Biological	Treatment with Palynziq should be directed by physicians experienced in the management of PKU.

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Pifeltro	Not rare		doravirine	treatment of adults infected with HIV-1 without past or present evidence of viral resistance to treatment of adults infected with HIV-1 without past or present evidence of viral resistance to doravirine	Chemical	Therapy should be initiated by a physician experienced in the management of HIV infection.
POTELIGEO	Orphan	2.6	mogamulizumab	treatment mycosis fungoides (MF) or Sézary syndrome (SS)	Biological	Treatment must be initiated and supervised by physicians experienced in the treatment of cancer, and should only be administered by healthcare professionals in an environment where resuscitation equipment is available.
PREVYMIS	Orphan	3.8	letermovir	prophylaxis of cytomegalovirus (CMV) reactivation and disease	Chemical	PREVYMIS should be initiated by a physician experienced in the management of patients who have had an allogeneic haematopoietic stem cell transplant.
Quofenix	Not rare		delafloxacin	treatment of Acute Bacterial Skin and Skin Structure Infections (ABSSSI) in adults	Chemical	n/a
Rhokiinsa	Not rare		netarsudil	indicated for the reduction of elevated intraocular pressure (IOP) in adults with open-angle glaucoma or ocular hypertension.	Chemical	Treatment with Rhokiinsa should only be initiated by an ophthalmologist or a healthcare professional qualified in ophthalmology.
Rinvoq	Not rare		upadacitinib	treatment of moderate to severe active rheumatoid arthritis	Chemical	Treatment with upadacitinib should be initiated and supervised by physicians experienced in the diagnosis and treatment of rheumatoid arthritis.
Rizmoic	Not rare		naldemedine	treatment of opioid-induced constipation (OIC) in adult patients.	Chemical	n/a
Rubraca	Orphan not confirmed	4.6-5.4	rucaparib	treatment of ovarian cancer	Chemical	Treatment with rucaparib should be initiated and supervised by a physician experienced in the use of anticancer medicinal products.
RXULTI	Not rare		brexpiprazole	treatment of schizophrenia	Chemical	n/a
Segluromet	Not rare		ertugliflozin / metformin hydrochloride	treatment of type 2 diabetes mellitus	Chemical	n/a
Shingrix	Not rare		herpes zoster vaccine (recombinant, adjuvanted)	prevention of herpes zoster (HZ) and HZ-related complications	Biological	n/a
Skyrizi	Not rare		risankizumab	treatment of psoriasis	Biological	Skyrizi is intended for use under the guidance and supervision of a physician experienced in the diagnosis and treatment of psoriasis.
Steglatro	Not rare		ertugliflozin	treatment of type 2 diabetes mellitus	Chemical	n/a
Steglujan	Not rare		ertugliflozin / sitagliptin	type 2 diabetes mellitus	Chemical	n/a

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Symkevi	Orphan	0.93	tezacaftor / ivacaftor	treatment of cystic fibrosis	Chemical	Symkevi should only be prescribed by physicians with experience in the treatment of CF. If the patient's genotype is unknown, an accurate and validated genotyping method should be performed to confirm the presence of an indicated mutation using a genotyping assay
TAKHZYRO	Orphan	0.5	lanadelumab	treatment of angioedema attacks	Biological	This medicinal product should be initiated under the supervision of a physician experienced in the management of patients with hereditary angioedema (HAE).
Talzenna	Not rare		talazoparib	treatment of germline breast cancer susceptibility gene (BRCA) mutated human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer	Chemical	Treatment with Talzenna should be initiated and supervised by a physician experienced in the use of anticancer medicinal products. 3 Patients should be selected for the treatment of breast cancer with Talzenna based on the presence of deleterious or suspected deleterious germline BRCA mutations determined by an experienced laboratory using a validated test method. Genetic counselling for patients with BRCA mutations should be performed according to local regulations, as applicable.
Tegsedi	Orphan	3	inotersen	treatment of transthyretin amyloidosis (hATTR)	Chemical	Treatment should be initiated by and remain under the supervision of a physician experienced in the treatment of patients with hereditary transthyretin
Trogarzo	Not rare		ibalizumab	treatment of adults infected with HIV-1 resistant to at least 1 agent in 3 different classes	Chemical	Therapy should be initiated by a physician experienced in the management of HIV infection.
Ultomiris	Orphan not confirmed	0.2	ravulizumab	treatment of paroxysmal nocturnal hemoglobinuria (PNH)	Biological	Ravulizumab must be administered by a healthcare professional and under the supervision of a physician experienced in the management of patients with haematological disorders.
Vaborem	Not rare		meropenem / vaborbactam	treatment of urinary tract infection (cUTI), including pyelonephritis, intra-abdominal infection (cIAI), hospital-acquired pneumonia (HAP), including ventilator associated pneumonia (VAP) including ventilator associated pneumonia (VAP)	Chemical	Vaborem should be used to treat infections due to aerobic Gram-negative organisms in adult patients with limited treatment options only after consultation with a physician with appropriate experience in the management of infectious diseases
Verzenios	Not rare		abemaciclib	treatment of hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative locally advanced or metastatic breast cancer	Chemical	Verzenios therapy should be initiated and supervised by physicians experienced in the use of anti-cancer therapies.

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VITRAKVI	Not rare		larotrectinib	treatment of adult and paediatric patients with locally advanced or metastatic solid tumours	Chemical	Treatment with VITRAKVI should be initiated by physicians experienced in the administration of anticancer therapies. The presence of an NTRK gene fusion in a tumour specimen should be confirmed by a validated test prior to initiation of treatment with VITRAKVI.
Vizimpro	Not rare		dacomitinib	first-line treatment of adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR)-activating	Chemical	Treatment with Vizimpro should be initiated and supervised by a physician experienced in the use of anticancer medicinal products. EGFR mutation status should be established prior to initiation of dacomitinib therapy (see section 4.4).
WAYLIVRA	Orphan	0.1	volanesorsen	treatment of patients with familial chylomicronemia	Chemical	n/a
Xerava	Not rare		eravacycline	treatment of complicated intra-abdominal infections (cIAI) in adults	Chemical	n/a
XOSPATA	Orphan	1.4	gilteritinib	treatment of patients who have relapsed or refractory acute myeloid leukemia (AML) with a FLT3 mutation	Chemical	Treatment with Xospata should be initiated and supervised by a physician experienced in the use of anti-cancer therapies. Before taking gilteritinib, relapsed or refractory AML patients must have confirmation of FMS-like tyrosine kinase 3 (FLT3) mutation (internal tandem duplication [ITD] or tyrosine kinase domain [TKD]) using a validated test. Xospata may be re-initiated in patients following haematopoietic stem cell transplantation (HSCT) (see
YESCARTA	Orphan	0.5	axicabtagene ciloleucel	treatment of diffuse large B-cell lymphoma (DLBCL), primary mediastinal B-cell lymphoma (PMBCL) and transformed follicular lymphoma (TFL)	ATMP, Biological	YESCARTA must be administered in a qualified clinical setting. YESCARTA therapy should be initiated under the direction of and supervised by a healthcare professional experienced in the treatment of haematological malignancies and trained for administration and management of patients treated with YESCARTA. A minimum of four doses of 3 tocilizumab for use in the event of cytokine release syndrome (CRS) and emergency equipment must be available prior to infusion of YESCARTA.
Zynquista	Not rare		sotagliflozin	indicated as an adjunct to insulin therapy to improve glycaemic control in adults with type 1 diabetes mellitus	Chemical	Therapy with Zynquista should be initiated and supervised by a physician experienced in the management of type 1 diabetes mellitus.
Zynteglo	Orphan	0.7	Betibeglogene autotemcel	treatment of transfusion-dependent β -thalassaemia (TDT)	ATMP, Biological	Zynteglo must be administered in a qualified treatment centre by a physician(s) with experience in HSC transplantation and in the treatment of patients with TDT. Patients are expected to enrol in a registry and will be followed in the registry in order to better understand the long-term safety and efficacy of

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ADYNOVI	B02BD02	B	Blood and blood forming organs	Y	STANDARD	2018	Baxalta Innovations GmbH
Aimovig	N02CX07	N	Nervous system	Y	STANDARD	2018	Novartis Europharm Limited
AJOVY	N02	N	Nervous system	Y	STANDARD	2019	TEVA GmbH
Alofisel	L04	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2018	TIGENIX, S.A.U.
Alpivab	J05AH03	J	Antiinfectives for systemic use	Y	STANDARD	2018	Biocryst UK Limited
Alunbrig	L01XE43	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2018	Takeda Pharma A/S
Besremi	L03AB15	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2019	AOP Orphan Pharmaceuticals AG
Biktarvy	J05AR20	J	Antiinfectives for systemic use	Y	STANDARD	2018	Gilead Sciences Ireland UC
Braftovi	L01XE	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2018	Pierre Fabre Medicament
Cabliivi	B01AX07	B	Blood and blood forming organs	Y	STANDARD	2018	Ablynx NV
CRYSVITA	M05BX05	M	Musculo-skeletal system	Y	CONDITIONAL	2018	Kyowa Kirin Limited
Delstrigo	J05AR	J	Antiinfectives for systemic use	Y	STANDARD	2018	Merck Sharp & Dohme B.V.
Dengvaxia	J07BX	J	Antiinfectives for systemic use	Y	STANDARD	2018	Sanofi Pasteur

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Doptelet	B02BX08	B	Blood and blood forming organs	Y	STANDARD	2019	Dova Pharmaceuticals Ireland Limited
Emgality	N02CX08	N	Nervous system	Y	STANDARD	2018	Eli Lilly Nederland B.V.
Erleada	L02BB05	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2019	Janssen-Cilag International N.V.
Ervebo	J07BX02	J	Antiinfectives for systemic use	Y	CONDITIONAL	2019	Merck Sharp & Dohme B.V.
Esperoct	B02BD02	B	Blood and blood forming organs	Y	STANDARD	2019	Novo Nordisk A/S
Evenity	M05BX06	M	Musculo-skeletal system	Y	STANDARD	2019	UCB Pharma S.A.
Fasenra	R03DX10	R	Respiratory system	Y	STANDARD	2018	AstraZeneca AB
Giapreza	C01CX09	C	Cardiovascular system	Y	STANDARD	2019	La Jolla Pharmaceutical II B.V.
Hemlibra	B02BX06	B	Blood and blood forming organs	Y	STANDARD	2018	Roche Registration GmbH
Ilumetri	L04AC17	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2018	Almirall S.A

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Imfinzi	L01XC28	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2018	AstraZeneca AB
Jivi	B02BD02	B	Blood and blood forming organs	Y	STANDARD	2018	Bayer AG
Kymriah	L01	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2018	Novartis Europharm Limited
Lamzede	A16AB15	A	Alimentary tract and metabolism	Y	EXCEPTIONAL	2018	Chiesi Farmaceutici S.p.A.
LIBTAYO	L01XC	L	Antineoplastic and Immunomodulating agents	Y	CONDITIONAL	2019	Regeneron Ireland Designated Activity Company (DAC)
Lokelma	V03AE10	V	Various	Y	STANDARD	2018	AstraZeneca AB
Lorviqua	L01XE44	L	Antineoplastic and Immunomodulating agents	Y	CONDITIONAL	2019	Pfizer Europe MA EEIG
Luxturna	-	-	-	Y	STANDARD	2018	Novartis Europharm Limited
Macimorelin Aeterna Zentaris	V04CD06	V	Various	Y	STANDARD	2019	Aeterna Zentaris GmbH
Mektovi	L01XE41	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2018	Pierre Fabre Medicament

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Mepsevii	A16AB18	A	Alimentary tract and metabolism	Y	EXCEPTIONAL	2018	Ultragenyx Germany GmbH
Mupleo	B02BX	B	Blood and blood forming organs	Y	STANDARD	2019	Shionogi B.V.
Myalepta	A16AA07	A	Alimentary tract and metabolism	Y	EXCEPTIONAL	2018	Aegerion Pharmaceuticals B.V.
Mylotarg	L01XC05	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2018	Pfizer Europe MA EEIG
Nerlynx	L01XE45	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2018	Puma Biotechnology Limited
Ocrevus	L04AA36	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2018	Roche Registration Limited
Ondexxya	V03AB38	V	Various	Y	CONDITIONAL	2019	Portola Netherlands B.V.
Onpattro	N07	N	Nervous system	Y	STANDARD	2018	Alnylam Netherlands B.V.
Ozempic	A10BJ06	A	Alimentary tract and metabolism	Y	STANDARD	2018	Novo Nordisk A/S
Palynziq	A16AB19	A	Alimentary tract and metabolism	Y	STANDARD	2019	BioMarin International Limited

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Pifeltro	J05AG06	J	Antiinfectives for systemic use	Y	STANDARD	2018	Merck Sharp & Dohme B.V.
POTELIGEO	L01XC25	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2018	Kyowa Kirin Holdings B.V.
PREVYMIS	J05AX18	J	Antiinfectives for systemic use	Y	STANDARD	2018	Merck Sharp & Dohme Limited
Quofenix	J01MA23	J	Antiinfectives for systemic use	Y	STANDARD	2019	A. Menarini Industrie Farmaceutiche Riunite s.r.l.
Rhokiinsa	S01EX05	S	Sensory organs	Y	STANDARD	2019	Aerie Pharmaceuticals Ireland Ltd
Rinvog	L04AA	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2019	AbbVie Deutschland GmbH & Co. KG
Rizmoic	A06AH	A	Alimentary tract and metabolism	Y	STANDARD	2019	Shionogi B.V.
Rubraca	L01XX55	L	Antineoplastic and Immunomodulating agents	Y	CONDITIONAL	2018	Clovis Oncology Ireland Limited
RXULTI	N05AX16	N	Nervous system	Y	STANDARD	2018	Otsuka Pharmaceutical Netherlands B.V.
Segluromet	A10BD23	A	Alimentary tract and metabolism	Y	STANDARD	2018	Merck Sharp & Dohme B.V.
Shingrix	J07BK03	J	Antiinfectives for systemic use	Y	STANDARD	2018	GlaxoSmithkline Biologicals SA
Skyrizi	L04AC18	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2019	AbbVie Deutschland GmbH & Co. KG
Steglatro	A10BK04	A	Alimentary tract and metabolism	Y	STANDARD	2018	Merck Sharp & Dohme B.V.
Steglujan	A10BD24	A	Alimentary tract and metabolism	Y	STANDARD	2018	Merck Sharp & Dohme B.V.

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Symkevi	R07AX31	R	Respiratory system	Y	STANDARD	2018	Vertex Pharmaceuticals (Ireland) Limited
TAKHZYRO	B06AC05	B	Blood and blood forming organs	Y	STANDARD	2018	Shire Pharmaceuticals Ireland Limited
Talzenna	L01XX60	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2019	Pfizer Europe MA EEIG
Tegsedi	N07	N	Nervous system	Y	STANDARD	2018	Akcea Therapeutics Ireland Limited
Trogarzo	J05AX23	J	Antiinfectives for systemic use	Y	STANDARD	2019	Theratechnologies Europe Limited
Ultomiris	L04AA43	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2019	Alexion Europe SAS
Vaborem	J01DH52	J	Antiinfectives for systemic use	Y	STANDARD	2018	Menarini International Operations Luxembourg S.A.
Verzenio	L01XE50	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2018	Eli Lilly Nederland B.V.

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VITRAKVI	L01XE53	L	Antineoplastic and Immunomodulating agents	Y	CONDITIONAL	2019	Bayer AG
Vizimpro	L01XE47	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2019	Pfizer Europe MA EEIG
WAYLIVRA	C10AX	C	Cardiovascular system	Y	CONDITIONAL	2019	Akcea Therapeutics Ireland Limited
Xerava	J01AA13	J	Antiinfectives for systemic use	Y	STANDARD	2018	Tetraphase Pharmaceuticals Ireland Limited
XOSPATA	L01XE54	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2019	Astellas Pharma Europe B.V.
YESCARTA	L01X	L	Antineoplastic and Immunomodulating agents	Y	STANDARD	2018	Kite Pharma EU B.V.
Zynquista	A10BK06	A	Alimentary tract and metabolism	Y	STANDARD	2019	Navigant Germany GmbH
Zynteglo	B06	B	Blood and blood forming organs	Y	CONDITIONAL	2019	bluebird bio (Netherlands) B.V

Products with positive decision per ATC code (1- Jan 2018 - 31 Dec 2019)

