



MEDS ENTRY WATCH NEW MEDICINES APPROVED IN 2018

The following table provides supplementary information on the manufacturer and approved indication(s) for each medicine that received first-time market authorization by the US Food and Drug Administration (FDA), the European Medicines Agency (EMA), and/or Health Canada in 2018.

Indications for new medicines approved by the FDA, the EMA, and/or Health Canada in 2018

Medicine (trade name)*	Approved indications	Manufacturer
Andexanet alfa (Andexxa)	Indicated for patients treated with rivaroxaban and apixaban, when reversal of anticoagulation is needed due to life-threatening or uncontrolled bleeding	Portola Pharma
Apalutamide (Erleada) ^c	Indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer (NM-CRPC)	Janssen Biotech
Avatrombopag (Doptelet) ^o	Indicated to treat low blood platelet count (thrombocytopenia) in adults with chronic liver disease who are scheduled to undergo a medical or dental procedure	AkaRx Inc.
Baloxavir marboxil (Xofluza) ^o	Indicated for the treatment of acute uncomplicated influenza in patients who have been symptomatic for no more than 48 hours	Genentech Inc.
Bictegravir (Biktarvy)	Indicated for the treatment of human immunodeficiency virus 1 (HIV-1) infection in adults	Gilead Sciences Inc.
Binimetinib (Mektovi) ^{c,o}	Indicated to treat unresectable or metastatic melanoma	Array BioPharma Inc.
Burosumab (Crysvita) ^{b,o}	Indicated to treat X-linked hypophosphataemia (XLH) in adult and pediatric patients 1 year of age and older	Ultragenyx Pharma Inc.
Calaspargase pegol (Asparlas) ^{b,c,o}	Indicated to treat acute lymphoblastic leukemia (ALL) in pediatric and young adult patients age 1 month to 21 years	Servier Pharma LLC
Caplacizumab (Cablivi) ^o	Indicated to treat acquired thrombotic thrombocytopenic purpura (aTTP)	Ablynx NV
Cemiplimab (Libtayo) ^{b,c}	Indicated to treat adult patients with metastatic or locally advanced cutaneous squamous cell carcinoma who are not candidates for curative surgery or curative radiation	Regeneron Pharma
Dacomitinib (Vizimpro) ^{c,o}	Indicated for the first-line treatment of adult patients with unresectable locally advanced or metastatic non-small cell lung cancer (NSCLC) with confirmed epidermal growth factor receptor (EGFR) exon 19 deletion or exon 21 L858R substitution mutations	Pfizer Inc.
Damoctocog alfa pegol (Jivi) ^b	Indicated for use in previously treated adults and adolescents (≥12 years of age) with hemophilia A (congenital Factor VIII deficiency) for: <ul style="list-style-type: none"> • Routine prophylactic treatment to prevent or reduce the frequency of bleeding episodes • Control and prevention of episodic bleeding • Peri-operative management of bleeding (surgical prophylaxis) 	Bayer HealthCare LLC
Doravirine (Pifeltro/Delstrigo)	Indicated, in combination with other antiretroviral medicinal products, for the treatment of adults infected with HIV-1 without past or present evidence of viral resistance to doravirine	MSD Merck Co
Duvelisib (Copiktra) ^{c,o}	Indicated to treat relapsed or refractory chronic lymphocytic leukemia, small lymphocytic lymphoma and follicular lymphoma	Verastem Inc.
Elagolix (Orilissa)	Indicated for the treatment of moderate to severe pain associated with endometriosis	AbbVie Inc.
Elapegademase (Revcovi) ^{b,o}	Indicated to treat Adenosine Deaminase-Severe Combined Immunodeficiency (ADA-SCID)	Leadiant Biosci Inc.
Emapalumab (Gamifant) ^{b,o}	Indicated to treat primary hemophagocytic lymphohistiocytosis (HLH)	Novimmune S.A.
Encorafenib (Bravtovi) ^{c,o}	Indicated to treat unresectable or metastatic melanoma	Array Biopharma Inc.

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Indications for new medicines approved by the FDA, the EMA, and/or Health Canada in 2017 (continued)

Medicine (trade name)*	Approved indications	Manufacturer
Eravacycline (Xerava)	Indicated to treat complicated intra-abdominal infections in patients 18 years of age and older	Tetraphase Pharma
Erenumab (Aimovig)	Indicated to treat migraine in adults who have at least 4 migraine days per month	Amgen Inc.
Fostamatinib (Tavalisse) ^o	Indicated to treat thrombocytopenia in adult patients with persistent or chronic immune thrombocytopenia (ITP)	Rigel Pharma Inc.
Fremanezumab (Ajovy) ^B	Indicated for the preventive treatment of migraine in adults	Teva Pharma USA
Galcanezumab (Emgality) ^B	Indicated to treat migraine in adults who have at least 4 migraine days per month	Eli Lilly and Co.
Gilteritinib (Xospata) ^{C,o}	Indicated to treat patients who have relapsed or refractory acute myeloid leukemia (AML)	Astellas
Glasdegib (Daurismo) ^{C,o}	Indicated to treat newly-diagnosed acute myeloid leukemia (AML) in adult patients	Pfizer Inc.
Ibalizumab (Trogarzo) ^{B,o}	Indicated to treat HIV patients who have limited treatment options	TaiMed Biologics USA
Inotersen (Tegsedi) ^o	Indicated to treat stage 1 or stage 2 polyneuropathy in adult patients with hereditary transthyretin amyloidosis (hATTR)	Akcea Theraps
Ivosidenib (Tibsovo) ^{C,o}	Indicated to treat patients with relapsed or refractory acute myeloid leukemia	Agios Pharma Inc.
Lanadelumab (Takhzyro) ^o	Indicated for routine prevention of attacks of hereditary angioedema (HAE) in adolescents and adults	Dyax Corp.
Larotrectinib (Vitrakvi) ^{C,o}	Indicated to treat adult and pediatric patients with solid tumours that: <ul style="list-style-type: none"> • have a Neurotrophic Tyrosine Receptor Kinase (NTRK) gene fusion without a known acquired resistance mutation, • are metastatic or where surgical resection is likely to result in severe morbidity, and • have no satisfactory treatment options 	Bayer Healthcare
Lorlatinib (Lorbrena) ^{C,o}	Indicated to treat adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on: crizotinib and at least one other ALK inhibitor, or patients who have progressed on ceritinib or alectinib	Pfizer Inc.
Lusutrombopag (Mulpleta)	Indicated to treat thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure	Shionogi Inc.
Mogamulizumab (Poteligeo) ^{B,C,o}	Indicated to treat two rare types of non-Hodgkin lymphoma	Kyowa Kirin
Moxetumomab pasudotox (Lumoxiti) ^{B,C,o}	Indicated to treat hairy cell leukemia	Astrazeneca AB
Moxidectin (Moxidectin) ^o	Indicated to treat onchocerciasis due to Onchocerca volvulus in patients aged 12 years and older	MDGH
Omadacycline (Nuzyra)	Indicated to treat community-acquired bacterial pneumonia and acute bacterial skin and skin structure infections	Paratek Pharma Inc.
Patisiran (Onpattro) ^o	Indicated to treat polyneuropathy in adult patients with hereditary transthyretin-mediated amyloidosis (hATTR amyloidosis)	Alnylam Pharma Inc.
Pegvaliase (Palyngiq) ^{B,o}	Indicated to treat adults with a rare and serious genetic disease known as phenylketonuria (PKU)	BioMarin Pharm
Plazomicin (Zemdri)	Indicated to treat adults with complicated urinary tract infections	Cipla USA
Ravulizumab (Ultomiris) ^o	Indicated to treat adult patients with paroxysmal nocturnal hemoglobinuria (PNH)	Alexion Pharm
Revefenacin (Yulperi)	Indicated to treat patients with chronic obstructive pulmonary disease (COPD)	Mylan Ireland Ltd
Sarecycline (Seysara)	Indicated to treat inflammatory lesions of non-nodular moderate to severe acne vulgaris in patients 9 years of age and older	Almirall
Segesterone acetate (Annovera)	New vaginal ring used to prevent pregnancy for an entire year	TherapeuticsMD Inc.
Tafenoquine (Krintafel) ^o	Indicated to the radical cure (prevention of relapse) of Plasmodium vivax malaria	GlaxoSmithKline
Tagraxofusp (Elzonris) ^o	Indicated to treat blastic plasmacytoid dendritic cell neoplasm (BPDCN)	Stemline Therapeutics Inc.

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Indications for new medicines approved by the FDA, the EMA, and/or Health Canada in 2017 (continued)

Medicine (trade name)*	Approved indications	Manufacturer
Talazoparib (Talzenna) ^C	Indicated to treat adult patients with a deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated human epidermal growth factor receptor 2 (HER2)-negative locally advanced (not amenable to curative radiation or surgery) or metastatic breast cancer, who have previously been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting, unless patients were inappropriate for these treatments	Pfizer Inc.
Tecovirimat (Tpoxx) ^O	Indicated to treat smallpox	SIGA Technologies
Tezacaftor (Symdeko) ^O	Indicated to treat cystic fibrosis (CF) aged 12 years and older who are homozygous for the F508del mutation or who are heterozygous for the F508del mutation and have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: P67L, D110H, R117C, L206W, R352Q, A455E, D579G, 711+3A→G, S945L, S977F, R1070W, D1152H, 2789+5G→A, 3272-26A→G, and 3849+10kbC→T	Vertex Pharma Inc.
Tildrakizumab (Ilumya/Ilumetri) ^B	Indicated to treat adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy	Sun Pharma Global
Velmanase alfa (Lamzede) ^O	Indicated to treat mild to moderate alpha-mannosidosis	Chiesi Farmaceutici S.p.A.
Zirconium cyclosilicate (Lokelma)	Indicated to treat hyperkalemia in adult patients	Astrazeneca Pharma

Indications from ■ Health Canada; ■ US Food and Drug Administration (FDA); ■ European Medicines Agency (EMA).

* B: biologic; C: cancer; O: orphan medicines.

Data source: US Food and Drug Administration Novel Drugs 2018; European Medicines Agency Human Medicines Highlights 2018; Health Canada databases.