



MEDS ENTRY WATCH

NEW MEDICINES APPROVED IN 2019

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 2019.

Indications for new medicines approved by the FDA, the EMA, and/or Health Canada in 2019

Medicine (trade name)*	Approved indications	Manufacturer
Air polymer-type A (ExEm Foam)	Indication for sonohysterosalpingography to assess fallopian tube patency in women with known or suspected infertility	Giskit B.V.
Alpelisib (Piqray) ^c	Indicated to treat postmenopausal women, and men, with hormone receptor-positive, HER2-negative, PIK3CA-mutated advanced or metastatic breast cancer after disease progression following an endocrine-based regimen	Novartis Pharmaceuticals
Betibeglogene autotemcel (Zynteglo) ^{b,g,o}	Indicated to treat patients with transfusion-dependent β thalassaemia (TDT) who do not have a $\beta 0/\beta 0$ genotype, for whom haematopoietic stem cell (HSC) transplantation is appropriate but a human leukocyte antigen (HLA)-matched related HSC donor is not available	bluebird bio
Bremelanotide (Vyleesi)	Indicated to treat premenopausal women with acquired, generalized hypoactive sexual desire disorder (HSDD) as characterized by low sexual desire that causes marked distress or interpersonal difficulty and is NOT due to: a co-existing medical or psychiatric condition; problems with the relationship; or the effects of a medication or drug substance	Palatin Technologies
Brexanolone (Zulresso)	Indicated for postpartum depression (PPD) in adults	Sage Therapeutics
Brilliant blue G ophthalmic (TissueBlue) ^o	Indicated to selectively stain the internal limiting membrane (ILM)	Dutch Ophthalmic
Brolucizumab (Beovu) ^b	Indicated for neovascular (wet) age-related macular degeneration (AMD)	Novartis Pharmaceuticals
Cefiderocol (Fetroja)	Indicated for complicated urinary tract infections (cUTI)	Shionogi Inc.
Cenobamate (Xcopri)	Indicated for partial-onset seizures in adult patients	SK Life
Crizanlizumab (Adakveo) ^{b,o}	Indicated to reduce the frequency of vasoocclusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease.	Novartis Pharmaceuticals
Darolutamide (Nubeqa) ^c	Indicated for non-metastatic castration-resistant prostate cancer (nmCRPC)	Bayer Inc.
Ebola Zaire vaccine (Ervebo) ^{b,o}	Indicated to treat ebola virus disease caused by the Zaire Ebola virus	Merck Sharp & Dohme Corp.
Elexacaftor (Trikafta) ^o	Indicated to treat cystic fibrosis (CF) in patients aged 12 years and older who have at least one F508del mutation in the CFTR gene	Vertex Pharma Inc.
Enfortumab vedotin (Padcev) ^{b,c}	Indicated for locally advanced or metastatic urothelial cancer who have previously received a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor, and a platinum-containing chemotherapy in the neoadjuvant/adjuvant, locally advanced or metastatic setting	Astellas
Entrectinib (Rozlytrek) ^{b,c,o}	Indicated to treat adult patients with unresectable locally advanced or metastatic extracranial solid tumours	Hoffmann-La Roche Ltd
Erdafitinib (Balversa) ^c	Indicated to treat adult patients with locally advanced or metastatic urothelial carcinoma (UC): · whose tumors have susceptible fibroblast growth factor receptor (FGFR)2 or FGFR3 genetic alterations and · who have disease progression during or following at least one line of prior chemotherapy, including within 12 months of neoadjuvant or adjuvant chemotherapy	Janssen Inc.

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Indications for new medicines approved by the FDA, the EMA, and/or Health Canada in 2019 (continued)

Medicine (trade name)*	Approved indications	Manufacturer
Fam-trastuzumab deruxtecan (Enhertu) ^{B,C}	Indicated for unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting	Daiichi Sankyo
Fedratinib (Inrebic) ^{C,O}	Indicated to treat splenomegaly and/or disease related symptoms in adult patients with intermediate-2 or high-risk primary myelofibrosis, post-polycythemia vera myelofibrosis or post-essential thrombocythemia myelofibrosis, including patients who have been previously exposed to ruxolitinib	Celgene Inc.
Fluorodopa F-18	Indicated for positron emission tomography (PET) to visualize dopaminergic nerve terminals in the striatum for the evaluation of adult patients with suspected Parkinsonian syndromes (PS)	Feinstein
Givosiran (Givlaari) ^O	Indicated to treat acute hepatic porphyria (AHP) in adults	Alnylam Netherlands B.V.
Golodirsen (Vyondys 53) ^O	Indicated to treat Duchenne muscular dystrophy (DMD) in patients who have a confirmed mutation of the DMD gene that is amenable to exon 53 skipping	Sarepta Therapeutics Inc.
Istradefylline (Nourias/Nourianz)	Indicated as an adjunctive treatment to levodopa/carbidopa in adult patients with Parkinson's disease (PD) experiencing "off" episodes	Kyowa Kirin Co. Ltd
Lasmiditan (Reyvow)	Indicated to treat migraine	Eli Lilly and Co.
Lefamulin (Xenleta)	Indicated for community-acquired pneumonia (CAP) caused by: Streptococcus pneumoniae including multi-drug resistant S. pneumoniae (MDRSP); Staphylococcus aureus (methicillin-susceptible isolates); Haemophilus influenzae; Haemophilus parainfluenzae; Moraxella catarrhalis; Legionella pneumophila; Mycoplasma pneumoniae; and Chlamydia pneumoniae	Sunovion Pharmaceuticals Canada Inc.
Lemborexant (Dayvigo)	Indicated to treat insomnia	Eisai Inc.
Lumateperone tosylate (Caplyta)	Indicated to treat schizophrenia	Intra-Cellular Therapies
Luspatercept (Reblozyl) ^{B,O}	Indicated for the treatment of adult patients with red blood cell (RBC) transfusion-dependent anemia associated with beta(β)-thalassemia.	Celgene Inc.
Modified vaccinia Ankara (Jynneos) ^B	Vaccine indicated for prevention of smallpox and monkeypox disease	Bavarian Nordic A/S
Onasemnogene abeparvovec (Zolgensma) ^{B,G,O}	Indicated to treat pediatric patients less than 2 years of age with spinal muscular atrophy (SMA) with bi-allelic mutations in the survival motor neuron 1 (SMN1) gene	Novartis Pharmaceuticals
Pexidartinib (Turalio) ^{C,O}	Indicated to treat adult patients with symptomatic tenosynovial giant cell tumor (TGCT) associated with severe morbidity or functional limitations and not amenable to improvement with surgery	Daiichi Sankyo Inc.
Polatuzumab vedotin (Polivy) ^{B,C,O}	Indicated for relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified, who are not eligible for autologous stem cell transplant and have received at least one prior therapy	Hoffmann-La Roche Ltd
Pretomanid (Pretomanid) ^O	Indicated to treat adults with pulmonary extensively drug resistant (XDR), treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB)	Mylan Ireland Ltd
Relebactam (Recarbrio)	Indicated for complicated urinary and intra-abdominal infections	MSD Merck Co.
Risankizumab (Skyrizi) ^B	Indicated to treat adult patients with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy	Abbvie Corp.
Romosozumab (Evenity) ^B	Indicated for osteoporosis in postmenopausal women at high risk for fracture, defined as a history of osteoporotic fracture, or multiple risk factors for fracture	Amgen Canada Inc.
Selinexor (Xpovio) ^{C,O}	Indicated for patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior therapies and whose disease is refractory to at least two proteasome inhibitors, at least two immunomodulatory agents, and an anti-CD38 monoclonal antibody	Karyopharm Therapeutics Inc.
Siponimod (Mayzent)	Indicated for patients with secondary progressive multiple sclerosis (SPMS) with active disease evidenced by relapses or imaging features characteristic of multiple sclerosis inflammatory activity, to delay the progression of physical disability	Novartis Pharmaceuticals Canada Inc.
Solriamfetol (Sunosi) ^O	Indicated to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea	Jazz Pharmaceuticals
Sotagliflozin (Zynquista)	Indicated to treat type 1 diabetes	Lexicon Pharmaceuticals

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Indications for new medicines approved by the FDA, the EMA, and/or Health Canada in 2019 (*continued*)

Medicine (trade name)*	Approved indications	Manufacturer
Tenapanor (Ibsrela)	Indicated to treat irritable bowel syndrome with constipation (IBS-C)	Ardelyx Inc.
Trifarotene (Aklief)	Indicated to treat acne vulgaris of the face and/or trunk in patients 12 years of age and older	Galderma Canada Inc.
Turoctocog alfa pegol (Esperoct) ^B	Indicated to treat hemophilia A	Novo Nordisk Canada Inc.
Ubrogepant (Ubrely)	Indicated to treat migraine	Allergan
Upadacitinib (Rinvoq)	Indicated to treat patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate	Abbvie Corp.
Volanesorsen (Waylivra) ^O	Indicated to treat familial chylomicronaemia syndrome	Akcea Therapeutics
Voxelotor (Oxbryta) ^O	Indicated to treat sickle cell disease	Global Blood Therapeutics
Zanubrutinib (Brukinsa) ^{C,O}	Indicated to treat patients with mantle cell lymphoma (MCL) who have received at least one prior therapy	BeiGene

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

* B: biologic; C: cancer; O: orphan medicine; G: gene therapy.

Data source: US Food and Drug Administration Novel Drugs 2019; European Medicines Agency Human Medicines Highlights 2019; Health Canada databases.