MEDS ENTRY WATCH
NEW MEDICINES APPROVED IN 2017

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 2017.

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

Medicine (trade name)*	Approved indications	Manufacturer
Abaloparatide (Tymlos)	Indicated for the treatment of postmenopausal women with osteoporosis at high risk for fracture	Radius Health
Abemaciclib (Verzenio)	A kinase inhibitor indicated: • in combination with fulvestrant for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer with disease progression following endocrine therapy • as monotherapy for the treatment of adult patients with HRpositive, HER2-negative advanced or metastatic breast cancer with disease progression following endocrine therapy and prior chemotherapy in the metastatic setting	Eli Lilly
Acalabrutinib (Calquence)[C,O]	Indicated for the treatment of adult patients with mantle cell lymphoma (MCL) who have received at least one prior therapy	AstraZeneca
Angiotensin II (Giapreza)	A vasoconstrictor to increase blood pressure in adults with septic or other distributive shock	La Jolla Pharmaceutical Company
Avelumab (Bavencio)[B,C,O]	Indicated for the treatment of: • Metastatic Merkel cell carcinoma (MCC) in previously treated adults • Patients with locally advanced or metastatic urothelial carcinoma (UC) who have disease progression during or following platinum-based chemotherapy or within 12 months of neoadjuvant or adjuvant treatment with platinum-based chemotherapy	EMD Serono
Axicabtagene ciloleucel (Yescarta)[B,C,O,G]	Indicated for the treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma, high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma	Kite Pharma
Baricitinib (Olumiant)[O]	Indicated for reducing the signs and symptoms of moderate to severe rheumatoid arthritis (RA) in adult patients who have responded inadequately to one or more disease-modifying anti-rheumatic drugs (DMARDs)	Eli Lilly
Benralizumab (Fasenra)[B]	Indicated as an add-on maintenance treatment of adult patients with severe eosinophilic asthma	AstraZeneca
Benznidazole (Benznidazole)[O]	Indicated in pediatric patients 2 to 12 years of age for the treatment of Chagas disease (American trypanosomiasis), caused by Trypanosoma cruzi	Chemo Research
Betrixaban (Bevyxxa)	Indicated for the prophylaxis of venous thromboembolism (VTE) in adult patients hospitalized for an acute medical illness who are at risk for thromboembolic complications due to moderate or severe restricted mobility and other risk factors for VTE	Portola Pharmaceuticals
Brigatinib (Alunbrig)[C,O]	Indicated as a monotherapy for the treatment of adult patients with anaplastic lymphoma kinase (ALK)-positive metastatic non–small cell lung cancer (NSCLC) who have progressed on or who were intolerant to an ALK inhibitor (crizotinib)	Ariad Pharmaceuticals, Inc.
Brodalumab (Siliq)[B]	Indicated for the treatment of moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy	Valeant Pharmaceuticals
Cenegermin (Oxervate)[B,O]	Treatment of moderate (persistent epithelial defect) or severe (corneal ulcer) neurotrophic keratitis in adults	Dompe Farmaceutici S.p.A.
Cerliponase alfa (Brineura)[B,O]	Indicated to slow the loss of ambulation in symptomatic pediatric patients 3 years of age and older with late infantile neuronal ceroid lipofuscinosis type 2 (CLN2), also known as tripeptidyl peptidase 1 (TPP1) deficiency	BioMarin Pharmaceutical Inc.
Coagulation Factor IX [recombinant], glycoPEGylated (Rebinyn)[B]	Indicated in adults and children with hemophilia B (congenital factor IX deficiency or Christmas disease) for: control and prevention of bleeding episodes; control and prevention of bleeding in the perioperative setting Also indicated in patients 18 years and above with hemophilia B for routine prophylaxis to prevent or reduce the frequency of bleeding episodes	Novo Nordisk

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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
Copanlisib (Aliqopa)[C,O]	Indicated for the treatment of adult patients with relapsed follicular lymphoma (FL) who have received at least two prior systemic therapies	Bayer Healthcare
Delafloxacin (Baxdela)	A fluoroquinolone antibacterial indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria	Melinta Therapeutics
Deutetrabenazine (Austedo)[O]	Indicated for the treatment of: chorea associated with Huntington's disease; tardive dyskinesia in adults	Teva
Dupilumab (Dupixent)[B]	Indicated for the treatment of adult patients with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable	Sanofi-Aventis
Durvalumab (Imfinzi)[B,C]	Indicated for the treatment of patients with: • Locally advanced or metastatic urothelial carcinoma who: have disease progression during or following platinum-containing chemotherapy; have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy • Locally advanced, unresectable non-small cell lung cancer (NSCLC) whose disease has not progressed following platinum-based chemoradiation therapy	AstraZeneca
Edaravone (Radicava)[O]	Indicated for the treatment of amyotrophic lateral sclerosis (ALS)	Mitsubishi Tanabe
Emicizumab (Hemlibra)[B,O]	Indicated for hemophilia A (congenital factor VIII deficiency) patients with factor VIII inhibitors as routine prophylaxis to prevent bleeding or reduce the frequency of bleeding episodes	Genetech, Inc.
Enasidenib (Idhifa)[C,O]	Indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test	Celgene
Ertugliflozin (Steglatro)	Indicated for use as an adjunct to diet and exercise to improve glycemic control in adult patients with type 2 diabetes mellitus for whom metformin is inappropriate due to contraindications or intolerance Also indicated in adult patients with type 2 diabetes mellitus to improve glycemic control in combination with: metformin, metformin and sitagliptin when the therapy listed above, along with diet and exercise, does not provide adequate glycemic control	Merck
Glecaprevir, pibrentasvir (Maviret)	Indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection with or without compensated cirrhosis. This includes patients with HCV genotype 1 infection who were previously treated with either a regimen of NS5A inhibitor or with a NS3/4A protease inhibitor but not both classes of inhibitors	AbbVie
Guselkumab (Tremfya)[B]	Indicated for the treatment of adult patients with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy	Janssen Pharma
Inotuzumab ozogamicin (Besponsa)[B,C,O]	Indicated as a monotherapy for the treatment of adults with relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL)	Pfizer
Latanoprostene bunod (Vyzulta)	Indicated for the reduction of intraocular pressure in patients with open-angle glaucoma or ocular hypertension	Valeant Pharmaceuticals
Lutetium Lu 177 dotatate† (Lutathera)[C,O]	Indicated to treat unresectable or metastatic, well-differentiated, somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs) in adults with progressive disease	Advanced Accelerator Applications
Letermovir (Prevymis)[O]	Indicated for the prophylaxis of cytomegalovirus (CMV) infection in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT)	Merck & Co.
Macimorelin (Macrilen)[O]	Indicated for the diagnosis of adult growth hormone deficiency	Strongbridge Biopharma
Midostaurin (Rydapt)[C,O]	Indicated in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation chemotherapy for the treatment of adult patients with newly diagnosed FLT3-mutated acute myeloid leukemia (AML)	Novartis Pharma
Naldemedine (Symproic)	Indicated for the treatment of opioid-induced constipation (OIC) in adult patients with chronic non-cancer pain	Purdue Pharma
Neratinib (Nerlynx)[C]	Indicated for the extended adjuvant treatment of adult patients with early stage HER2-overexpressed/amplified breast cancer, to follow adjuvant trastuzumab-based therapy	Puma Biotechnology
Netarsudil (Rhopressa)	Indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	Aerie Pharmaceuticals, Inc.
Niraparib (Zejula)[C,O]	Indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy	Tesaro Inc.
Ocrelizumab (Ocrevus)[B]	Indicated for the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) with active disease defined by clinical and imaging features; and for the management of adult patients with early primary progressive multiple sclerosis (PPMS) as defined by disease duration and level of disability, in conjunction with imaging features characteristic of inflammatory activity	Roche
Ozenoxacin (Ozanex)	Indicated for the topical treatment of impetigo in patients aged 2 months and older	Ferrer internacional, S.A.

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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
Padeliporfin di-potassium (Tookad)[C]	Indicated as monotherapy for adult patients with previously untreated, unilateral, low-risk, adenocarcinoma of the prostate with a life expectancy ≥ 10 years and: • clinical stage T1c or T2a • Gleason Score ≤ 6, based on high-resolution biopsy strategies • PSA ≤ 10 ng/mL • 3 positive cancer cores with a maximum cancer core length of 5 mm in any one core or 1-2 positive cancer cores with ≥ 50% cancer involvement in any one core or a PSA density ≥ 0.15 ng/mL/cm^3	Steba Biotech S.A.
Plecanatide (Trulance)	Indicated in adults for treatment of chronic idiopathic constipation (CIC)	Synergy Pharm
Ribociclib (Kisqali)[C]	Indicated in combination with letrozole for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer as an initial endocrine-based therapy	Novartis
Sarilumab (Kevzara)[B]	Indicated in the treatment of adult patients with moderately to severely active rheumatoid arthritis (RA) who have had an inadequate response or intolerance to one or more biologic or non-biologic disease-modifying anti-rheumatic drugs (DMARDs)	Sanofi-Aventis
Semaglutide (Ozempic)	Indicated for the once-weekly treatment of adult patients with type 2 diabetes mellitus to improve glycemic control, in combination with: • diet and exercise in patients for whom metformin is inappropriate due to contraindication or intolerance • metformin, when diet and exercise plus maximal tolerated dose of metformin do not achieve adequate glycemic control • metformin and a sulfonylurea, when diet and exercise plus dual therapy with metformin and a sulfonylurea do not achieve adequate glycemic control • basal insulin with metformin, when diet and exercise plus basal insulin with metformin do not achieve adequate glycemic control	Novo Nordisk
Telotristat etiprate (Xermelo)[C,O]	Indicated for the treatment of carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in adults inadequately controlled by SSA therapy	Lexicon Pharma
Tisagenlecleucel (Kymriah)[B,C,O,G]	Indicated for the treatment of: • Patients up to 25 years of age with B-cell precursor acute lymphoblastic leukemia (ALL) that is refractory or in second or later relapse • Adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma	Novartis Pharma
Tivozanib (Fotivda)[C]	Indicated for the first line treatment of adult patients with advanced renal cell carcinoma (RCC) and for adult patients who are VEGFR and mTOR pathway inhibitor-naïve following disease progression after one prior treatment with cytokine therapy for advanced RCC	EUSA Pharma (UK) Ltd
Vaborbactam (Vabomere)	Indicated for the treatment of patients 18 years and older with complicated urinary tract infections (cUTI) including pyelonephritis caused by designated susceptible bacteria	The Medicines Company
Valbenazine (Ingrezza)[O]	Indicated for the treatment of adults with tardive dyskinesia	Neurocrin Biosciences
Herpes zoster vaccine [recombinant, adjuvanted] (Shingrix Vaccine)[B]	Indicated for prevention of herpes zoster (HZ, or shingles) in adults 50 years of age or older	GlaxoSmithKline
Vestronidase alfa (Mepsevii)[B,O]	Indicated in pediatric and adult patients for the treatment of mucopolysaccharidosis VII (MPS VII, Sly syndrome)	Ultragenyx
Voretigene (Luxturna)[B,O,G]	Indicated for the treatment of patients with confirmed biallelic RPE65 mutation-associated retinal dystrophy	Spark Therapeutics, Inc.
Voxilaprevir (Vosevi)	Indicated for the treatment of chronic hepatitis C virus (HCV) infection in adult patients, without cirrhosis or with compensated cirrhosis, who have: • genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor; • genotype 1, 2, 3, or 4 infection and have been previously treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor	Gilead Sciences

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

* B: biologic; C: cancer; O: orphan medicines; G: gene therapies.
† This medicine was added to the 2017 list as of the 2018 edition of *Meds Entry Watch*. Although it was approved separately in France in 2015, it received its first market authorization from the EMA in 2017.
Data source: US Food and Drug Administration Novel Drugs 2017; European Medicines Agency Human Medicines Highlights 2017; Health Canada databases.