carelon Rx

DrugInsights

Q2 2024

CarelonRx *DrugInsights* provides a quarterly summary of Food and Drug Administration (FDA)-approved new molecular entities, formulations, and indications. We continue to closely monitor the FDA landscape to help provide our audiences with an understanding of the current drug and biologic market.

New molecular entities

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Anktiva® (nogapendekin alfa inbakicept-pmln)	Interleukin-15 (IL-15) receptor agonist	Adstiladrin®, Keytruda®, valrubicin	Treatment of adults with Bacillus Calmette-Guérin (BCG) unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors.	Induction: 400 mcg administered intravesically with BCG once weekly for 6 weeks. A second induction course may be administered at month 3. Maintenance: 400 mcg administered intravesically with BCG once weekly for 3 weeks at months 4, 7, 10, 13, and 19. Additional maintenance instillations with BCG may be given.	ImmunityBio	$38,500 per dose

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Beqvez™ (fidanacogene elaparvovec-dzkt)	Gene therapy	Hemgenix®	Treatment of adults with moderate to severe hemophilia B (congenital factor IX deficiency) who: • Currently use factor IX prophylaxis therapy, OR • Have current or historical life-threatening hemorrhage, OR • Have repeated, serious spontaneous bleeding episodes, AND • Do not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by a FDA-approved test	One-time intravenous infusion.	Pfizer	$3.5M per one-time single dose
Duvyzat™ (givinostat)	Histone deacetylase inhibitor	New mechanism of action for Duchenne muscular dystrophy (DMD)	Treatment of DMD in individuals 6 years of age and older.	Oral suspension given twice daily; dosing based on body weight.	Italfarmaco S.A.	Not available
Imdelltra™ (tarlatamab-dlle)	Bispecific delta-like ligand 3 (DLL3)-directed CD3 T-cell engager	Hycamtin®, topotecan, Zepzelca®	Treatment of adults with extensive stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy.	After step-up intravenous infusion dosing schedule, administer every 2 weeks until disease progression or unacceptable toxicity.	Amgen	$31,500 for first cycle and $30,000 for subsequent cycles

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Lenmeldy™ (atidarsagene autotemcel)	Gene therapy	First FDA-approved treatment for this indication	Treatment of children with presymptomatic late infantile (PSLI), presymptomatic early juvenile (PSEJ), or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD).	One-time intravenous infusion (part of a hematopoietic stem cell transplant).	Orchard Therapeutics	$4.25M per one-time treatment
Ojemda™ (tovorafenib)	Kinase inhibitor	First FDA-approved agent for this population	Treatment of people 6 months of age and older with relapsed or refractory pediatric low-grade glioma (LGG) harboring a BRAF fusion or rearrangement, or BRAF V600 mutation.	Administer orally once weekly; dosage based on body surface area.	Day One	Not available
Pivya™ (pivmecillinam)	Penicillin anti-infective	cephalexin	Treatment of females 18 years of age and older with uncomplicated urinary tract infections (uUTI) caused by susceptible isolates of Escherichia coli, Proteus mirabilis, and Staphylococcus saprophyticus.	185 mg orally 3 times a day for 3 to 7 days.	Utility Therapeutics	Not available
Rezdiffra™ (resmetirom)	Thyroid hormone receptor-beta (THR-beta) agonist	First FDA-approved treatment for this indication	Treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis). Indicated in conjunction with diet and exercise.	For people weighing: • <100 kg, the recommended dosage is 80 mg orally once daily. • ≥100 kg, the recommended dosage is 100 mg orally once daily.	Madrigal	$47,400 per year

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Tevimbra® (tislelizumab-jsgr)	Programmed cell death protein (PD)-1 blocking antibody	Keytruda, Opdivo®	Treatment of adults with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) after prior systemic chemotherapy that did not include a PD-1 or PD-ligand 1 (PD-L1) inhibitor.	200 mg administered every 3 weeks until disease progression or unacceptable toxicity.	BeiGene	Not available
Tryvio™ (aprocitentan)	Endothelin receptor antagonist	First FDA-approved treatment for this indication	Treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adults who are not adequately controlled on other drugs.	12.5 mg orally once daily.	Idorsia	Not available
Vafseo® (vadadustat)	Hypoxia-inducible factor (HIF) prolyl hydroxylase inhibitor	Jesduvroq®	Treatment of anemia due to chronic kidney disease (CKD) in adults who have been receiving dialysis for at least 3 months.	Starting dose is 300 mg orally once daily; adjust dose in increments of 150 mg, to a maximum 600 mg, to achieve or maintain hemoglobin (Hb) levels within 10 g/dL to 11 g/dL.	Akebia Therapeutics	Not available
Voydeya™ (danicopan)	Complement factor D inhibitor	Empaveli®, Fabhalta®, Soliris®, Ultomiris®	Add-on therapy to Soliris or Ultomiris for the treatment of extravascular hemolysis (EVH) in adults with paroxysmal nocturnal hemoglobinuria (PNH).	Initial dose of 150 mg orally three times daily.	Alexion	Not available

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Winrevair™	Activin signaling inhibitor	Adempas®, ambrisentan, bosentan, epoprostenol, macitentan, Opsynvi®, sildenafil, tadalafil, treprostinil, Uptravi®	Treatment of adults with pulmonary arterial hypertension (PAH, WHO Group 1) to increase exercise capacity, improve WHO functional class (FC), and reduce the risk of clinical worsening events.	Recommended target dose is 0.7 mg/kg every 3 weeks by subcutaneous injection	Merck	$14K per vial
Xolremdi™ (mavorixafor)	CXC chemokine receptor 4 (CXCR4) antagonist	First FDA-approved treatment for this indication	People 12 years of age and older with WHIM syndrome (warts, hypogammaglob-ulinemia, infections, and myelokathexis) to increase the number of circulating mature neutrophils and lymphocytes.	400 mg once daily orally for people weighing more than 50 kg or 300 mg once daily orally for those weighing 50 kg or less.	X4 Pharma	$500K per year for people weighing more than 50 kg and $370K per year for those who weigh less than or equal to 50 kg
Zevtera®, (ceftobiprole medocaril sodium)	Cephalosporin	Ceftriaxone plus linezolid, daptomycin plus aztreonam, vancomycin plus aztreonam	Treatment of adults with Staphylococcus aureus bloodstream infections (bacteremia) (SAB), including those with right-sided infective endocarditis; adults with acute bacterial skin and skin structure infections (ABSSSI); and adult and pediatric people three months to less than 18 years old with community-acquired bacterial pneumonia (CABP).	Intravenous injection; dosage and duration depends on age and indication.	Basilea	Not available

New formulations

Brand (generic)	Description
Acthar® Gel (repository corticotropin)*	Single-dose, prefilled Acthar Gel Selfject Injector device approved as monotherapy for the treatment of infantile spasms in infants and children under 2 years of age, for the treatment of exacerbations of multiple sclerosis in adults, and for the following disorders and diseases: rheumatic, collagen, dermatologic, allergic states, ophthalmic, respiratory, and edematous state.
Benlysta®, (belimumab)*	Belimumab 200 mg autoinjector approved for children aged 5 years and older with systemic lupus erythematosus (SLE) to allow for at-home administration.
Clobetasol propionate	Clobetasol propionate ophthalmic suspension approved for the treatment of post-operative inflammation and pain following ocular surgery. No trade name has been announced.
Entresto® (sacubitril/valsartan)	Sacubitril/valsartan oral pellets approved for the treatment of symptomatic heart failure with systemic left ventricular systolic dysfunction in children aged one year and older.
Ingrezza® (valbenazine)	Valbenazine oral granule formulation approved for the treatment of tardive dyskinesia and Huntington's chorea.
Libervant™ (diazepam)	Diazepam buccal film approved for the treatment of seizure clusters in children ages 2 to 5 years.
Myhibbin™ (mycophenolate mofetil)	Mycophenolate mofetil oral suspension approved for the prophylaxis of organ rejection in adult and pediatric recipients 3 months of age and older of allogeneic kidney, heart, or liver transplants, in combination with other immunosuppressants.
Opsynvi®, (macitentan/tadalafil)	Macitentan/tadalafil single-tablet combination therapy approved for adults with pulmonary arterial hypertension (PAH).
Rezenopy®, (naloxone hydrochloride)	Naloxone nasal spray approved for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression in adults and children, and is intended for immediate administration as emergency therapy in settings where opioids may be present.
Risvan® (risperidone extended-release)*	Risperidone prolonged-release injection approved for the treatment of schizophrenia in adults.
Vijoice® (alpelisib)	Alpelisib oral granules approved for the treatment of adults and children 2 years of age and older with severe manifestations of PIK3CA-Related Overgrowth Spectrum (PROS) who require systemic therapy.
Xromi® (hydroxyurea)	Hydroxyurea oral solution approved to reduce the frequency of painful crises and reduce the need for blood transfusions in children aged 6 months of age to less than 2 years with sickle cell anemia with recurrent moderate-to-severe painful crises.

*Injectable

New biosimilars

Brand (generic)	Description
Cyltezo® (adalimumab-adbm)*	Cyltezo 100 mg/mL high-concentration, citrate-free formulation approved for the treatment of adults with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, moderately-to-severely active Crohn disease, moderately-to-severely active ulcerative colitis, moderate-to-severe plaque psoriasis, moderate-to-severe hidradenitis suppurativa, and noninfectious intermediate, posterior, and panuveitis. This is an interchangeable biosimilar to Humira®.
Hercessi™ (trastuzumab-strf)*	Hercessi, a Herceptin® biosimilar, approved for adjuvant treatment of human epidermal growth factor receptor-2 (HER2)-overexpressing breast cancer, the treatment of HER2-overexpressing metastatic breast cancer, and the treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma.
Jubbonti® (denosumab-bbdz)*	Jubbonti approved as an interchangeable biosimilar to Prolia® to treat postmenopausal women with osteoporosis at high risk for fracture, to increase bone mass in men with osteoporosis at high risk for fracture, to treat glucocorticoid-induced osteoporosis in men and women at high risk for fracture, to increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer, and to increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.
Selarsdi™ (ustekinumab-aekn)*	Stelara® biosimilar approved for subcutaneous use for the treatment of moderate-to-severe plaque psoriasis and for active psoriatic arthritis in adults and children 6 years and older.
Tyenne® (tocilizumab-aazg)*	Tyenne, a biosimilar for Actemra®, approved for both intravenous (IV) and subcutaneous (SC) administration in the following indications: • Adults with moderately-to-severely active rheumatoid arthritis who have had an inadequate response to 1 or more disease-modifying anti-rheumatic drugs (DMARDs) • Adults with giant cell arteritis • Children 2 years of age and older with active polyarticular juvenile idiopathic arthritis or active systemic juvenile idiopathic arthritis
Wyost® (denosumab-bbdz)*	Wyost approved as an interchangeable biosimilar to Xgeva® to prevent skeletal-related events in people with multiple myeloma and in people with bone metastases from solid tumors, to treat adults and skeletally mature adolescents with giant cell tumor of bone that is unresectable or where surgical resection is likely to result in severe morbidity, and to treat hypercalcemia of malignancy refractory to bisphosphonate therapy.
Yesafili™ (aflibercept-jbvf)* and Opuviz™ (aflibercept-yszy)*	Yesafili and Opuviz approved as the first interchangeable biosimilars to Eylea®. They are indicated for neovascular (wet) age-related macular degeneration, macular edema following retinal vein occlusion, diabetic macular edema, and diabetic retinopathy.

*Injectable

New indications

Brand (generic)	Description
Abecma® (idecabtagene vicleucel)*	Abecma approved for the treatment of adults with relapsed or refractory multiple myeloma after two or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.
Alecensa® (alectinib)	Alecensa approved for adjuvant treatment following tumor resection in people with anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC), as detected by an FDA-approved test.
Besponsa® (inotuzumab ozogamicin)*	Besponsa approved for children 1 year and older with relapsed or refractory CD22-positive B-cell precursor acute lymphoblastic leukemia (ALL).
Breyanzi® (lisocabtagene maraleucel)*	Breyanzi approved for the treatment of adults with relapsed or refractory chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL) who have received at least two prior lines of therapy, including a Bruton tyrosine kinase (BTK) inhibitor and a B-cell lymphoma 2 (BCL-2) inhibitor.
Breyanzi (lisocabtagene maraleucel)*	Breyanzi approved for adults with relapsed or refractory follicular lymphoma (FL) who have received two or more prior lines of systemic therapy.
Brukinsa® (zanubrutinib)	Brukinsa approved with obinutuzumab for relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.
Carvykti® (ciltacabtagene autoleucel)*	Carvykti approved for the treatment of adults with relapsed or refractory multiple myeloma who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent, and are refractory to lenalidomide.
Clinolipid® 20% (olive oil/soybean oil)*	Clinolipid 20% indication expanded to include term and preterm neonates for use as a source of calories and essential fatty acids for parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated.
Dovato (dolutegravir/lamivudine)	Dovato approved for the treatment of human immunodeficiency virus-1 (HIV-1) infection in adolescents 12 years of age and older and weighing at least 25 kg with no antiretroviral (ARV) treatment history or to replace the current ARV regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable ARV regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of Dovato.
Edurant® (rilpivirine)	Edurant approved in combination with other antiretroviral agents for the treatment of human immunodeficiency virus-1 (HIV)-1 infection in treatment-naïve children with HIV-1 ribonucleic acid (RNA) less than or equal to 100,000 copies/mL who are 2 years of age and older and weigh at least 14 kg to less than 25 kg. A new 2.5 mg tablet for oral suspension was also approved.

*Injectable

New indications, continued

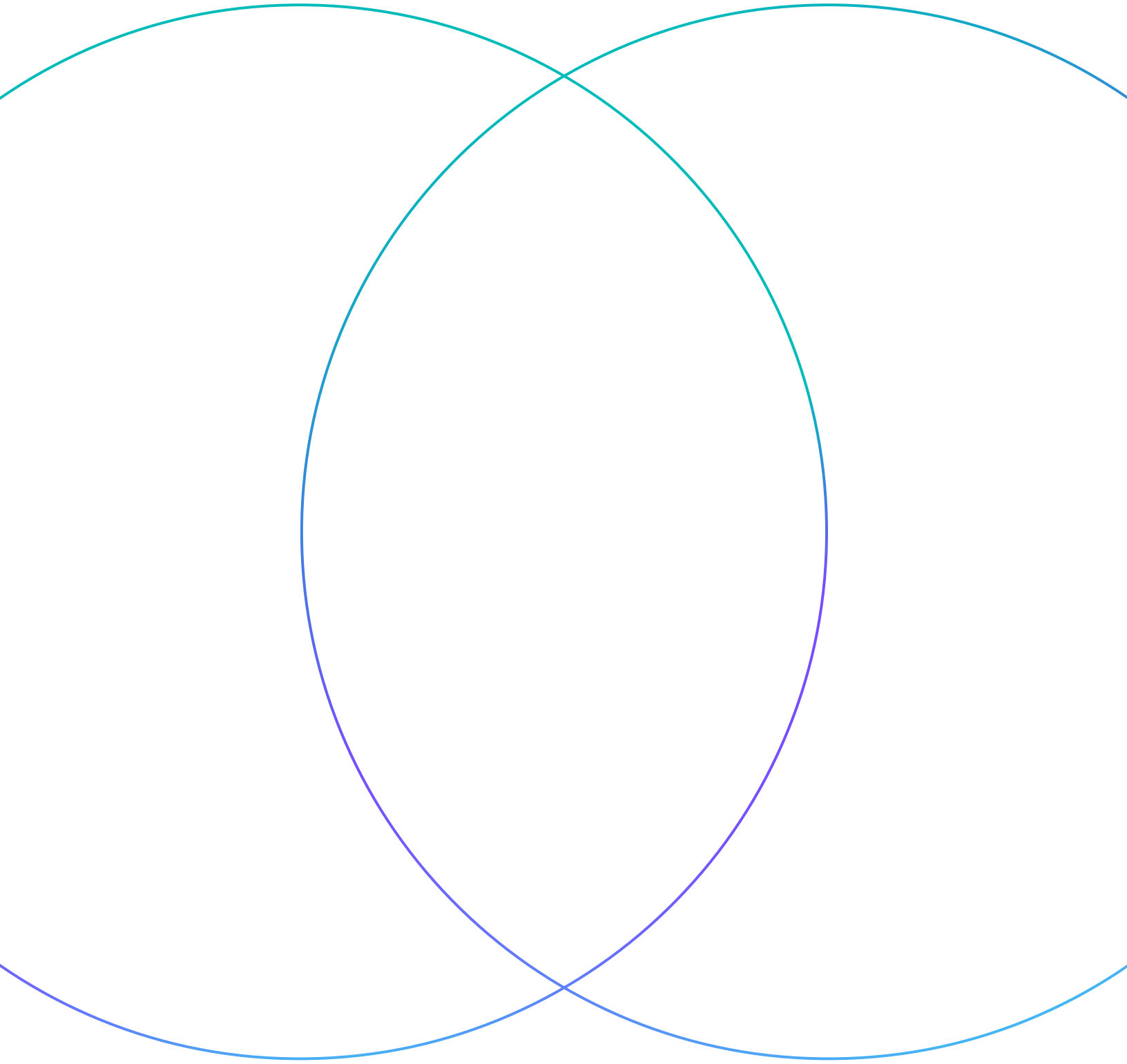
Brand (generic)	Description
Enhertu® (fam-trastuzumab deruxtecan-nxki)*	Enhertu approved for adults with unresectable or metastatic HER2-positive (IHC3+) solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options.
Entyvio® (vedolizumab)*	Entyvio subcutaneous injection approved for maintenance therapy in adults with moderately-to-severely active Crohn's disease after intravenous (IV) induction therapy with Entyvio.
Fasenra® (benralizumab)*	Fasenra approved as add-on maintenance treatment of people aged 6 to 11 years with severe asthma, and with an eosinophilic phenotype.
Iclusig® (ponatinib)	Iclusig approved with chemotherapy for adults with newly diagnosed Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL).
Ixinity® (coagulation factor IX, recombinant)*	Ixinity approved to include people less than 12 years of age for prevention and control of bleeds in hemophilia B.
Livmarli® (maralixibat)	Livmarli approved for the treatment of cholestatic pruritus in people 5 years of age and older with progressive familial intrahepatic cholestasis (PFIC).
Lutathera® (lutetium Lu 177 dotatate)*	Lutathera approved for children 12 years and older with somatostatin receptor (SSTR)-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors.
Mircera® (methoxy polyethylene glycol-epoetin beta)*	Mircera approved for expanded use in the treatment of anemia associated with chronic kidney disease (CKD) in children 3 months to 17 years of age on dialysis and not on dialysis who are converting from another erythropoiesis-stimulating agent (ESA) after their hemoglobin level was stabilized with an ESA. This approval also allows for a subcutaneous route of administration in pediatrics.
Nexletol® (bempedoic acid); Nexlizet® (bempedoic acid/ezetimibe)	Nexletol and Nexlizet label updated to include adults with either established atherosclerotic cardiovascular disease (CVD) or high risk for a CVD event to reduce the risk of myocardial infarction (MI) and coronary revascularization.
Opdivo® (nivolumab)*	Opdivo approved in combination with cisplatin and gemcitabine for first-line treatment of adults with unresectable or metastatic urothelial carcinoma (UC).
Otezla® (apremilast)	Otezla approved for the treatment of children 6 to 17 years of age and weighing at least 20 kg with moderate-to-severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
Praluent® (alirocumab)*	Praluent approved as an adjunct to diet and other low-density lipoprotein cholesterol-lowering therapies to include children aged 8 and older with heterozygous familial hypercholesterolemia.

*Injectable

New indications, continued

Brand (generic)	Description
Rinvoq® (upadacitinib)	Rinvoq approved for the treatment of people 2 years of age and older with active polyarticular juvenile idiopathic arthritis who have had an inadequate response or intolerance to one of more tumor necrosis factor (TNF) blockers, and the treatment of people 2 years of age and older with active psoriatic arthritis who have had an inadequate response or intolerance to one or more TNF blockers, respectively. An oral solution formulation was also approved.
Rybrevant® (amivantamab-vmjw)*	Rybrevant approved with carboplatin and pemetrexed for the first-line treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test.
Spevigo® (spesolimab-sbzo)*	Spevigo approved to include the treatment of generalized pustular psoriasis (GPP) in adults and children 12 years of age and older and weighing at least 40 kg.
Ultomiris® (ravulizumab-cwvz)*	Ultomiris approved for the treatment of adults with AQP4 antibody-positive (Ab+) neuromyelitis optica spectrum disorder (NMOSD).
Veklury® (remdesivir)*	Veklury approved for the treatment of coronavirus disease 2019 (COVID-19) in children from birth to less than 28 days of age weighing at least 1.5 kg to less than 3 kg.
Vemlidy® (tenofovir alafenamide fumarate)	Vemlidy approval expanded to include once-daily treatment of chronic hepatitis B virus (HBV) or HBV infection in children aged 6 years and older weighing at least 25 kg, with compensated liver disease.
Wegovy® (semaglutide)*	Wegovy approved for use in combination with a reduced-calorie diet and increased physical activity to reduce the risk of major adverse cardiovascular (CV) events (CV death, non-fatal heart attack, or non-fatal stroke) in adults with established CV disease and either obesity or overweight.
Xhance® (fluticasone propionate)	Xhance approved for the treatment of chronic rhinosinusitis without nasal polyps in people 18 years of age and older.

*Injectable



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