carelon Rx

DrugInsights

Q2 2023

CarelonRx's *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)
Altuviiio™ (efanesoctocog alfa)	Antihemophilic Agent	Eloctate®, Hemlibra®	Adults and children with hemophilia A (congenital factor VIII deficiency) for: -Routine prophylaxis to reduce the frequency of bleeding episodes -On-demand treatment and control of bleeding episodes -Perioperative management of bleeding	Recommended dosing by intravenous infusion is specific by indication	Sanofi	$930K each year for prophylaxis

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Arexvy (respiratory syncytial virus vaccine, adjuvanted)	First agent approved for this indication	Viral vaccine	For active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals age 60 years and older	0.5 mL single dose	GlaxoSmithKline	Not available
Daybue™ (trofinetide)	Synthetic analog of amino-terminal tripeptide of Insulin-like Growth Factor 1 (IGF-1)	First agent approved for this indication	Treatment of Rett syndrome in adults and children age 2 years and older	Weight-based dosage given by mouth twice daily	Acadia	$9,495 for each 450 mL bottle
Elfabrio® (pegunigalsidase alfa-iwxj)	Enzyme	Fabrazyme	Treatment of adults with confirmed Fabry disease	1 mg/kg administered by intravenous infusion every two weeks	Chiesi	Not available
Epkinly™ (epcoritamab-bysp)	Bispecific CD20-directed CD3 T-cell engager	Xpovio®, Zynlonta™	Treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL from indolent lymphoma and high-grade B-cell lymphoma after two or more lines of systemic therapy	Recommended subcutaneous doses are given in prescribing information and should be administered by a healthcare provider	Genmab	$37,500 each month

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Joenja® (leniolisib)	Kinase inhibitor	First agent approved for this indication	Treatment of activated phosphoinositide 3-kinase delta (PI3Kδ) syndrome (APDS) in adults and children age 12 years and older	70 mg given by mouth twice daily approximately 12 hours apart, with or without food	Pharming Technologies	$548K each year
Miebo™ (perfluorohexyloctane)	Semifluorinated alkane	Cequa®, cyclosporine, Lacrisert®, Xiidra®, Tyrvaya®	Treatment of the signs and symptoms of dry eye disease	Put one drop four times daily into each eye	Bausch & Lomb	Not available
Qalsody™ (tofersen)	Antisense oligonucleotide	First approval for this specific population	Treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in superoxide dismutase 1 (SOD1) gene	Recommended dose: 100 mg (15 mL) intrathecally • Initiate treatment with three loading doses at 14-day intervals • A maintenance dose should be administered once every 28 days thereafter	Biogen	Not available
Rezzayo™ (rezafungin)	Echinocandin antifungal	Caspofungin	For people age 18 years or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis	Administer once weekly by intravenous (IV) infusion, with an initial 400 mg loading dose, followed by a 200 mg dose once weekly thereafter	Cidara Therapeutics	Not available

New molecular entities (continued)

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Skyclarys™ (omaveloxolone)	Activator of nuclear factor erythroid 2-related factor 2 (Nrf2)	First agent approved for this indication	Treatment of Friedreich's ataxia in adults and adolescents age 16 years and older	150 mg (three capsules) once a day on an empty stomach at least one hour before eating	Reata	$370K each year
Veozah™ (fezolinetant)	Neurokinin 3 (NK3) receptor antagonist	Divigel®, Evamist®, Femring®, paroxetine, Vivelle-Dot®	Treatment of moderate to severe vasomotor symptoms due to menopause	One 45 mg tablet by mouth once a day	Astellas	$550 each month
Vowst™ (fecal microbiota spores, live-brpk)	Microbiota	Rebyota™	To prevent the recurrence of *Clostridioides difficile* (*C. difficile*) infection (CDI) in people age 18 years and older following antibacterial treatment for recurrent CDI (rCDI)	Four capsules by mouth once a day for three days administered on an empty stomach before the first meal of the day	Seres Therapeutics	$17,500 for each treatment course
Vyjuvek™ (beremagene geperpavec-svdt)	Herpes-simplex virus type 1 (HSV-1) vector-based gene therapy	First agent approved for this indication	Treatment of wounds in people age 6 months and older with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene	Apply topical gel on selected wound(s) once a week; dosing varies by wound size	Krystal Biotech	$24,250 for each vial

New molecular entities (continued)

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Zavzpret™ (zavegepant)	Calcitonin gene-related peptide (CGRP) receptor antagonist	Nurtec® ODT, Ubrelvy™	Acute treatment of migraine with or without aura in adults	10 mg given as a single spray in one nostril, as needed	Pfizer	Not available
Zynyz™ (retifanlimab-dlwr)	Programmed death receptor-1 (PD-1) inhibitor	Bavencio®, Keytruda®	Treatment of adults with metastatic or recurrent locally advanced Merkel cell carcinoma.	500 mg IV infusion administered over 30 minutes every four weeks	Incyte	$180K each year

New formulations

Brand (generic)	Description
Abilify Asimtufii® (aripiprazole extended-release)*	Aripiprazole extended-release two-month dosing formulation approved for the treatment of schizophrenia in adults and as maintenance monotherapy treatment of bipolar I disorder in adults.
Brixadi™ (buprenorphine-extended-release)*	Buprenorphine extended-release subcutaneous injection approved to treat moderateto severe opioid use disorder (OUD).
Combogesic® (acetaminophen/ibuprofen)	Acetaminophen and ibuprofen combination tablets approved for the short-term management of mild to moderate acute pain.
Hyrimoz® HCF (adalimumab-adaz)*	High-concentration Humira biosimilar approved for the treatment of rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease, ulcerative colitis, and plaque psoriasis.
Liqrev® (sildenafil)	Sildenafil oral suspension approved for the treatment of pulmonary arterial hypertension (WHO Group 1) in adults to improve exercise ability and delay clinical worsening.
Lumryz™ (sodium oxybate extended-release)	Sodium oxybate extended-release oral suspension approved once a night for the treatment of cataplexy or excessive daytime sleepiness in adults with narcolepsy.

*Injectable

New formulations, continued

Brand (generic)	Description
Lupron Depot-Ped® Kit (leuprolide acetate)*	Leuprolide acetate 45 mg single-dose, prefilled syringe for six-month dosing regimen approved for the treatment of central precocious puberty in pediatrics.
Motpoly XR (lacosamide)	Lacosamide extended-release oral capsules approved for the treatment of partial-onset seizures in adults and children weighing at least 50 kg.
Naloxone hydrochloride	Naloxone hydrochloride 4 mg nasal spray approved for the emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression for adults and children.
Opvee® (nalmefene hydrochloride)	Nalmefene hydrochloride nasal spray approved for the emergency treatment of known or suspected opioid overdose in adults and children age 12 years and older.
RizaFilm® (rizatriptan)	Rizatriptan oral film formulation approved for the treatment of acute migraine with or without aura in adults and children age 12 to 17 years weighing 40 kg or more.
Udenyca® (pegfilgrastim-cbqv)*	Udenyca single-dose prefilled autoinjector approved to decrease the incidence of infection, as manifested by febrile neutropenia, in people with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia. It is also indicated to increase survival in people acutely exposed to myelosuppressive doses of radiation.
Uzedy™ (risperidone extended-release)*	Risperidone extended-release injectable suspension approved for the treatment of schizophrenia in adults.
Xacduro® (sulbactam/durlobactam)*	Sulbactam and durlobactam co-packaged for intravenous use approved in people age 18 years and older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by susceptible isolates of *Acinetobacter baumannii-calcoaceticus* complex (*Acinetobacter*).
Zejula (niraparib tablets)	Niraparib tablet formulation approved as maintenance treatment of adults with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy and for maintenance treatment of adults with deleterious or suspected deleterious germline BRCA-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
Zolpidem	Zolpidem 7.5 mg capsule formulation approved for the short-term treatment of transient insomnia characterized by difficulties with sleep initiation in adults younger than age 65.

*Injectable

New indications

Brand (generic)	Description
Amjevita™ (adalimumab-atto)*	Amjevita approved for the treatment of moderate to severe hidradenitis suppurativa in adults.
Ayvakit® (avapritinib)	Ayvakit approved for the treatment of adults with indolent systemic mastocytosis (ISM).
Breo Ellipta (fluticasone furoate/ vilanterol)	Breo Ellipta 100/25 mcg approval expanded to include maintenance treatment of asthma for children age 12 to 17 years and new dosage strength of 50/25 mcg approved for maintenance treatment of asthma in children age 5 to 11 years.
Caldolor® (ibuprofen)*	Caldolor approval expanded to include children age 3 months and older for the management of mild to moderate pain, the management of moderate to severe pain as an adjunct to opioid analgesics, and for the reduction of fever.
Coagadex® (human coagulation factor X)*	Coagadex approval expanded to include perioperative management of bleeding in people with severe hereditary Factor X deficiency.
Cyltezo® (adalimumab-adbm)*	Cyltezo approved for the treatment of moderate to severe hidradenitis suppurativa in adults.
Evkeeza™ (evinacumab)*	Evkeeza expanded approval to include children age 5 to 11 years for the treatment of homozygous familial hypercholesterolemia.
Farxiga® (dapagliflozin)	Farxiga approved to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visit in adults with heart failure (previously for adults with heart failure and reduced ejection fraction).
HyQvia (immune globulin 10% [human] with recombinant human hyaluronidase)*	HyQvia approval expanded to include children age 2 to 16 years with primary immunodeficiency (PI).
Kalydeco® (ivacaftor)	Kalydeco approved for use in children with cystic fibrosis (CF) age 1 month to less than 4 months old who have at least one mutation in their cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to Kalydeco based on clinical and/or in vitro assay data.
Keytruda (pembrolizumab)*	Keytruda approved for use in combination with Padcev (enfortumab vedotin-ejfv) for people with locally advanced or metastatic urothelial carcinoma who are ineligible for cisplatin-containing chemotherapy.
Kevzara® (sarilumab)*	Kevzara approved for the treatment of polymyalgia rheumatica (PMR), an inflammatory rheumatic disease, in adults who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper.

*Injectable

New indications, continued

Brand (generic)	Description
Lexapro™ (escitalopram oxalate)	Lexapro approved for generalized anxiety disorder (GAD) in children 7 to 17 years of age.
Livmarli® (maralixibat)	Livmarli expanded approval to include the treatment of cholestatic pruritus in people as young as 3 months old with Alagille syndrome.
Mekinist® (trametinib) and Tafinlar® (dabrafenib)	Mekinist with Tafinlar approved for children age 1 year and older with low-grade glioma (LGG) with a BRAF V600E mutation who require systemic therapy. New oral formulations of both drugs were also approved.
Polivy® (polatuzumab vedotin-piiq)*	Polivy approved in combination with rituximab, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for the treatment of adults who have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index (IPI) score of two or greater.
Prevnar 20® (20-valent pneumococcal conjugate vaccine)*	Prevnar approved for the prevention of invasive pneumococcal disease (IPD) caused by the 20 *Streptococcus pneumoniae* (pneumococcal) serotypes contained in the vaccine in infants and children age 6 weeks through 17 years, and for the prevention of otitis media in infants and children age 6 weeks through 5 years caused by the original seven serotypes contained in Prevnar.
Qulipta™ (atogepant)	Qulipta approved for the preventative treatment of chronic migraines in adults.
Rexulti® (brexpiprazole)	Rexulti approved for use in the treatment of agitation associated with dementia due to Alzheimer's disease.
Rinvoq® (upadacitinib)	Rinvoq approved for adults with moderately to severely active Crohn's disease who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.
Sogroya® (somapacitan-beco)*	Sogroya approved for the treatment of children age 2 ½ and olderwho have growth failure due to inadequate secretion of endogenous growth hormone (GH).
Trikafta® (elexacaftor/tezacaftor/ivacaftor)	Trikafta tablets and oral granules approved to include treatment of children with cystic fibrosis (CF) age 2 through 5 years who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive to Trikafta based on in vitro data.
Verzenio® (abemaciclib)	Verzenio approved for the adjuvant treatment of adults with hormone receptor-positive, human epidermal growth factor receptor 2-negative, node-positive, early breast cancer at high risk for recurrence. This approval also expands the indication by removing the Ki-67 testing requirement to identify high-risk people.
Yusimry (adalimumab-aqvh)*	Yusimry approved for the treatment of moderate to severe hidradenitis suppurativa in adults.

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