carelon Rx

DrugInsights

Q3 2025

CarelonRx DrugInsights provides a quarterly summary of Food and Drug Administration (FDA)-approved new molecular entities, formulations, biosimilars, 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)
Andembry® (garadacimab-gxii)	Activated factor XII (FXIIa) inhibitor	Cinryze®, Haegarda®, Orladeyo®, Takhzyro®	Prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric individuals aged 12 years and older	Initial loading dose of 400 mg (two 200 mg injections) administered subcutaneously followed by maintenance dosage of 200 mg once monthly. May be self-administered.	CSL Behring	$685K per year
Anzupgo® (delgocitinib)	Janus kinase (JAK) inhibitor	Topical steroids	Treatment of moderate to severe chronic hand eczema (CHE) in adults who have had an inadequate response to, or for whom topical corticosteroids are not advisable	Apply topically twice daily to skin of the affected areas only on the hands and wrists. Do not use more than 30 grams per 2 weeks or 60 grams per month.	LEO Pharma	$1,986 per tube

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Brinsupri™ (brensocatib)	Dipeptidyl peptidase 1 (DPP1) inhibitor	First agent approved for this indication	Treatment of non-cystic fibrosis bronchiectasis (NCFB) in adults and pediatrics aged 12 years and older	10 mg or 25 mg orally once daily with or without food	Insmed	$88K per year
Dawnzera™ (donidalorsen)	Prekallikrein-directed antisense oligonucleotide	Andembry®, Cinryze®, Haegarda®, Orladeyo®, Takhzyro®	For prophylaxis to prevent hereditary angioedema attacks (HAE) in adult and pediatric individuals 12 years of age and older	Recommended dosage is 80 mg administered subcutaneously every 4 weeks. A dosage of 80 mg every 8 weeks may also be considered.	Ionis	$57K per dose
Ekterly® (sebetralstat)	Plasma kallikrein inhibitor	Berinert®, icatibant, Kalbitor®, Ruconest®	Treatment of acute attacks of hereditary angioedema (HAE) in individuals ≥12 years of age	600 mg (2 tablets) taken orally at earliest recognition of an HAE attack. A second dose of 600 mg may be taken 3 hours later if response is inadequate, symptoms worsen or recur.	KalVista	$16,720 per dose
Enflonsia™ (clesrovimab-cfor)	Monoclonal antibody	Beyfortus®, Synagis®	Prevention of respiratory syncytial virus (RSV) lower respiratory tract disease (LRTD) in neonates and infants who are born during or entering their first RSV season	105 mg single dose intramuscular injection to be administered by a healthcare provider.	Merck	$560 per single dose
Hernexeos® (zongertinib)	Tyrosine kinase inhibitor	Enhertu®	Treatment of adults with unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have human epidermal growth factor receptor-2 (HER2) tyrosine kinase domain activating mutations, as detected by a Food and Drug Administration (FDA)-approved test, and who have received prior systemic therapy	Recommended dosage is once daily orally based on body weight < 90 kg: 120 mg ≥ 90 kg: 180 mg	Boehringer Ingelheim	$400K per year for maximum dosage

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Ibtrozi™ (taletrectinib)	Tyrosine kinase inhibitor	Augtyro™, Rozlytrek™, Xalkori®	Treatment of adults with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC)	600 mg (three 200 mg capsules) orally once daily	Novation Bio	$29,488 per month
Lynozyfic™ (linvoseltamab-gcpt)	Bispecific B-cell maturation antigen (BCMA) directed CD3 T-cell engager	Elrexfio®, Talvey®, Tecvayli®	Treatment of adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti CD38 monoclonal antibody	Step-up doses of 5 mg and 25 mg administered intravenously followed by 200 mg weekly through week 24. Responders will receive 200 mg every 4 weeks thereafter.	Regeneron	$470 per 5 mg vial or $18,800 for 200 mg vial
Modeyso™ (dordaviprone)	Protease activator	First agent approved for diffuse midline gliomas	Treatment of adults and pediatrics aged 1 year and older with diffuse midline glioma harboring an H3 K27M mutation with progressive disease following prior therapy	In adults: 625 mg orally once weekly. Recommended dosage not established for pediatrics who weigh less than 10 kg. For pediatrics who weigh 10 kg or more, dose for those aged 1 to <17 years is based on body weight.	Jazz	$830K per year
Papzimeos™ (zopapogene imadenovec-drba)	Non-replicating adenoviral vector-based immunotherapy	First agent approved for this indication	Treatment of adults with recurrent respiratory papillomatosis (RRP)	Dose of 5x1011 particle units (PU) per subcutaneous injection administered 4 times over a 12-week interval.	Precigen	$460K per course of therapy
Sephience™ (sepiapterin)	Phenylalanine hydroxylase (PAH) activator	Kuvan®, Palynziq®, sapropterin	Treatment of hyperphenylalaninemia (HPA) in adult and pediatric individuals 1 month of age and older with sepiapterin-responsive phenylketonuria (PKU)	Oral once daily weight based dosing.	PTC Therapeutics	$45K per month/ $540K per year based on average weight of 45 kg

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Tryptyr® (acoltremon)	Transient receptor potential melastatin 8 (TRPM8) thermoreceptor agonist	cyclosporine, Eysuvis, Miebo®, Tyrvaya®, Xiidra	Treatment of the signs and symptoms of dry eye disease (DED)	Instill one drop in each eye twice daily (approximately 12 hours apart).	Alcon	Not available
Vizz™ (aceclidine)	Cholinergic agonist	Qlosi™, Vuity®	Treatment of presbyopia in adults	Instill one drop in each eye, wait 2 minutes and instill a second drop in each eye once daily.	LENZ Therapeutics	$75 for 25 doses (approx. one month supply)
Zegfrovy™ (sunvozertinib)	Selective EGFR tyrosine kinase inhibitor	Rybrevant®	Treatment of adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by a Food and Drug Administration (FDA)-approved test, whose disease has progressed on or after platinum-based chemotherapy	200 mg once daily orally with food until disease progression or unacceptable toxicity.	Dizal	Not available
Zusduri (mitomycin)	Alkylating agent	First therapy approved for this indication	Treatment of adults with recurrent low-grade intermediate-risk non-muscle invasive bladder cancer (LG-IR-NMIBC)	75 mg (56 mL) instilled intravesically once weekly for six weeks.	UroGen	$21,500 per dose

New formulations

Brand (generic)	Description
Arynta™ (lisdexamfetamine dimesylate)	Lisdexamfetamine dimesylate oral solution approved for the treatment of attention-deficit/ hyperactivity disorder (ADHD) and binge eating disorder (BED).
Atmeksi® (methocarbamol)	Methocarbamol oral suspension approved as an adjunct to rest, physical therapy, and other measures for the relief of discomfort associated with acute, painful musculoskeletal conditions in individuals 16 and older.
Avgemsi™ (gemcitabine)*	Gemcitabine injection approved in combination with carboplatin for the treatment of advanced ovarian cancer that has relapsed at least 6 months after completion of platinum-based therapy, in combination with paclitaxel for first-line treatment of metastatic breast cancer after failure of prior anthracycline-containing adjuvant chemotherapy unless anthracyclines were clinically contraindicated, in combination with cisplatin for the first-line treatment of inoperable, locally advanced (Stage IIIA or IIIB) or metastatic (Stage IV) non-small cell lung cancer (NSCLC), and as first-line treatment for individuals with locally advanced (nonresectable Stage II or Stage III) or metastatic (Stage IV) adenocarcinoma of the pancreas.
Brukinsa® (zanubrutinib)	Zanubrutinib tablets approved for the treatment of adults with Waldenström's macroglobulinemia (WM), treatment of adults with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL), treatment of adults with mantle cell lymphoma (MCL) who have received at least one prior therapy, treatment of adults with relapsed or refractory marginal zone lymphoma (MZL) who have received at least one anti-CD20-based regimen, and treatment of adults with relapsed or refractory follicular lymphoma (FL), in combination with obinutuzumab, after two or more lines of systemic therapy.
Cyklx (articaine)	Articaine ophthalmic solution approved for ocular surface anesthesia prior to ocular procedures and/or intraocular injections in adults and pediatric individuals.
Gammagard Liquid ERC® (immune globulin infusion, human, 10% solution)*	Ready-to-use immune globulin infusion for intravenous or subcutaneous use for primary humoral immunodeficiency (PI) in adult and pediatric individuals two years of age and older.
Harliku™ (nitisinone)	Nitisinone tablets approved for the reduction of urine homogentisic acid (HGA) in adults with alkaptonuria (AKU).
Khindivi™ (hydrocortisone)	Hydrocortisone oral solution approved as a replacement therapy in pediatric individuals aged 5 years and older with adrenocortical insufficiency.
Kyxata™ (carboplatin)*	Carboplatin injection approved as part of a combination regimen for the initial treatment of advanced ovarian carcinoma or as a single-agent for the treatment of ovarian carcinoma recurrent after prior chemotherapy.
mNexspike® (COVID-19 vaccine)*	COVID-19 vaccine intramuscular injection approved for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

* Injectable

New formulations, continued

Brand (generic)	Description
Sdamlo (amlodipine)	Amlodipine oral solution approved for the treatment of hypertension in adults and pediatric individuals 6 years of age and older and for the treatment of coronary artery disease in adults, chronic stable angina, vasospastic angina (Prinzmetal's or variant angina), and angiographically documented coronary artery disease in individuals without heart failure or an ejection fraction < 40% to reduce the risk of a coronary revascularization procedure.
Shingrix (zoster vaccine recombinant, adjuvanted)*	Prefilled-syringe presentation of Shingrix approved for the prevention of shingles (herpes zoster).
Tonmya™ (cyclobenzaprine)	Cyclobenzaprine sublingual tablets approved for the treatment of fibromyalgia in adults.
Tyzavan (vancomycin)*	Ready-to-infuse, room temperature stable formulation of vancomycin injection approved for adult and pediatric individuals 1 month and older for whom appropriate dosing with this formulation can be achieved for the treatment of septicemia, infective endocarditis, early-onset prosthetic valve endocarditis, skin and skin structure infections, bone infections, and lower respiratory tract infections.
Vostally (ramipril)	Ramipril oral solution approved for the treatment of hypertension in adults.
Vyscoxa™ (celecoxib)	Celecoxib oral suspension approved for the management of the signs and symptoms of osteoarthritis (OA), rheumatoid arthritis (RA), juvenile rheumatoid arthritis (JRA) and ankylosing spondylitis (AS).
Widaplik™ (telmisartan/amlodipine/ indapamide)	Telmisartan, amlodipine, and indapamide combination tablet approved for the treatment of hypertension, including as initial treatment, to lower blood pressure.
Yeztugo® (lenacapavir)*	Lenacapavir twice yearly subcutaneous injection approved for pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired human immunodeficiency virus (HIV)-1 in adults and adolescents (≥35 kg) who are at risk for HIV-1 acquisition.

* Injectable

New biosimilars

Brand (generic)	Description
Kirsty™ (insulin aspart-xjhz)*	Rapid-acting interchangeable Novolog® biosimilar product approved as a 3 mL single-use prefilled pen and 10 mL multiple-dose vial to improve glycemic control in adults and pediatric individuals with diabetes mellitus.

New indications

Brand (generic)	Description
Actemra® (tocilizumab)*	Actemra approved for the treatment of hospitalized individuals aged 2 years and older with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, noninvasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
Ajovy® (fremanezumab-vfrm)*	Ajovy approved for the preventive treatment of episodic migraine in pediatric individuals who are six years and older and who weigh 45 kg (99 lbs) or more.
Alhemo® (concizumab-mtci)*	Alhemo approved to include routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric individuals 12 years of age and older with hemophilia A (congenital factor VIII deficiency) without FVIII inhibitors or hemophilia B (congenital factor IX deficiency) without FIX inhibitors.
Avtozma® (tocilizumab-anoh)*	Avtozma intravenous (IV) formulation approved to include the treatment of chimeric antigen receptor T cell-induced severe or life-threatening cytokine release syndrome (CRS) in adults and pediatric individuals 2 years of age and older.
Benlysta (belimumab)*	Benlysta subcutaneous injection formulation approved to include treatment of pediatric individuals down to 5 years of age with active lupus nephritis who are receiving standard therapy.
Datroway® (datopotamab deruxtecan-dlnk)*	Datroway approved for adults with locally advanced or metastatic epidermal growth factor receptor (EGFR)-mutated non-small cell lung cancer (NSCLC) who have received prior EGFR-directed therapy and platinum-based chemotherapy.
Doptelet® (avatrombopag)	Doptelet approved for the treatment of thrombocytopenia in pediatric individuals 1 year and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to a prior therapy. This approval includes a new Doptelet Sprinkle oral granules formulation.
Dupixent® (dupilumab)*	Dupixent approved for the treatment of adults with bullous pemphigoid (BP).
Empaveli ® (pegcetacoplan)*	Empaveli approved to reduce proteinuria in individuals 12 years and older with C3 glomerulopathy (C3G) and primary immune complex membranoproliferative glomerulonephritis (IC-MPGN).
Gamifant® (emapalumab-lzsg)*	Gamifant approved for the treatment of adult and pediatric (newborn and older) individuals with hemophagocytic lymphohistiocytosis (HLH)/macrophage activation syndrome (MAS) in known or suspected Still's disease, including systemic juvenile idiopathic arthritis (sJIA), with an inadequate response or intolerance to glucocorticoids, or with recurrent MAS.
Kerendia® (finerenone)	Kerendia approved to reduce the risk of cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adults with heart failure with left ventricular ejection fraction (LVEF) ≥ 40%.

* Injectable

New indications, continued

Brand (generic)	Description
Keytruda® (pembrolizumab)*	Keytruda approved for adults with resectable locally advanced head and neck squamous cell carcinoma (HNSCC) whose tumors express PD-L1 [Combined Positive Score (CPS) ≥1] as determined by a Food and Drug Administration (FDA)-approved test, as a single agent as neoadjuvant treatment, continued as adjuvant treatment in combination with radiotherapy (RT) with or without cisplatin after surgery, and then as a single agent.
Leqvio® (inclisiran)*	Leqvio approved for first-line use in the treatment of hypercholesterolemia.
Mavyret® (glecaprevir/pibrentasvir)	Mavyret approved for the treatment of adults and pediatric individuals 3 years and older with acute or chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A).
MenQuadfi® (meningococcal groups A, C, Y, W conjugate vaccine)*	MenQuadfi approved for the prevention of invasive meningococcal disease in children aged 6 weeks to 23 months.
Monjuvi® (tafasitamab-cxix)*	Monjuvi approved with lenalidomide and rituximab for adults with relapsed or refractory follicular lymphoma (FL).
mResvia® (respiratory syncytial virus vaccine)*	mResvia approved for active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV.
Nubeqa® (darolutamide)	Nubeqa approved for the treatment of metastatic castration-sensitive prostate cancer (mCSPC).
Otezla® (apremilast)	Otezla approved for the treatment of psoriatic arthritis in pediatric individuals 6 years of age and older and weighing at least 20 kg.
Phyrago™ (dasatinib)	Phyrago approved for the treatment of pediatric individuals 1 year of age and older with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase and newly diagnosed Ph+ acute lymphoblastic leukemia (ALL) in combination with chemotherapy.
Riabni™ (rituximab-arrx)*	Riabni approved for the treatment of moderate to severe pemphigus vulgaris in adults.
Sirturo® (bedaquiline fumarate)	Sirturo approved for the treatment of pulmonary tuberculosis (TB) due to *Mycobacterium tuberculosis* resistant to at least rifampin and isoniazid as part of a combination therapy to include pediatric individuals 2 years to less than 5 years of age and weighing at least 8 kg.
Skytrofa® (lonapegsomatropin-tcgd)*	Skytrofa approved for the replacement of endogenous growth hormone in adults with growth hormone deficiency (GHD).
Talzenna® (talazoparib tosylate)	Talzenna approved in combination with enzalutamide for the treatment of adults with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).
Wegovy® (semaglutide)*	Wegovy approved to treat metabolic-associated steatohepatitis (MASH) in adults with moderate-to-advanced fibrosis (excessive scar tissue in the liver).

* Injectable

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