carelon Rx

DrugInsights

Q2 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)
Avmapki™ Fakzynja™ Co-Pack (avutometinib, defactinib)	Antineoplastic combination; kinase inhibitors	First FDA-approved for this indication	Treatment of adults with KRAS-mutated recurrent low-grade serous ovarian cancer (LGSOC) who have received prior systemic therapy	Dosage of Avmapki is 3.2 mg orally twice weekly (day 1 and day 4) for the first 3 weeks of each 4-week cycle. Dosage of Fakzynja is 200 mg orally twice daily for the first 3 weeks of each 4-week cycle.	Verastem	$48,500 per 28-day treatment course
Blujepa (gepotidacin)	Triaza-acenaphthylene bacterial type II topoisomerase inhibitor	Nitrofurantoin	Treatment of female adult and pediatric individuals 12 years of age and older weighing at least 40 kg with uncomplicated urinary tract infections (uUTIs) caused by susceptible microorganisms	1,500 mg (two 750 mg tablets) taken orally, twice daily (approximately 12 hours apart), for 5 days	GSK	Not available

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Emrelis™ (telisotuzumab vedotin-tllv)	c-Met-directed antibody and microtubule inhibitor conjugate	First FDA-approved for this indication	Treatment of adults with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression, as determined by a Food and Drug Administration (FDA)-approved test, who have received a prior systemic therapy	Dosage is 1.9 mg/kg (up to a maximum of 190 mg for individuals greater than or equal to 100 kg) administered over 30 minutes every 2 weeks until disease progression or unacceptable toxicity	AbbVie	Not available
Imaavy™ (nipocalimab-aahu)	Neonatal Fc receptor (FcRn) blocker	Rystiggo®, Vyvgart®, Vyvgart® Hytrulo	Treatment of generalized myasthenia gravis (gMG) in adults and pediatrics 12 years of age and older who are anti-acetylcholine receptor (AChR+) or anti-muscle-specific tyrosine kinase (MuSK+) antibody positive	Initial dosage is 30 mg/kg via intravenous (IV) infusion over at least 30 minutes Two weeks later, administer maintenance dosage of 15 mg/kg via IV infusion over at least 15 minutes. Continue maintenance dosing every 2 weeks thereafter.	Janssen	$12,480 per 1200 mg vial
Penpulimab-kcqx	Programmed death receptor-1 (PD-1)-blocking antibody	Loqtorzi®	In combination with chemotherapy as a first-line treatment for adults with recurrent or metastatic non-keratinizing nasopharyngeal carcinoma (NPC) and as a monotherapy for adults with metastatic NPC who have progressed following platinum-based chemotherapy and at least one additional line of therapy	In combination with cisplatin or carboplatin and gemcitabine: • 200 mg intravenously over 60 minutes every 3 weeks until disease progression or a maximum of 24 months As a single agent: • 200 mg intravenously over 60 minutes every 2 weeks until disease progression or a maximum of 24 months	Akeso Biopharma	Not available

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Qfitlia™ (fitusiran)	Antithrombin-directed small interfering ribonucleic acid (siRNA)	Alhemo®, Hemlibra®, Hympavzi™	Routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and pediatrics aged 12 years and older with hemophilia A or B with or without factor VIII or IX inhibitors	Initial dose of 50 mg subcutaneously every 2 months. Maintenance doses adjusted to maintain antithrombin (AT) activity goal of 15-35%, given every 1 or 2 months.	Sanofi	$642,000 per year
Vanrafia® (atrasentan)	Endothelin A receptor antagonist	Fabhalta®, Filspari®, Tarpeyo®	Reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression	0.75 mg orally once daily	Novartis	$162K per year
Zevaskyn™ (prademagene zamikeracel)	Gene-based therapeutic	Filsuvez®, Vyjuvek®	Treatment of wounds in adult and pediatric people with recessive dystrophic epidermolysis bullosa (RDEB)	Surgically placed skin graft(s); recommended dose based on surface area of the wound(s)	Abeona Therapeutics	$3.1 M per treatment

* Injectable

New formulations

Brand (generic)	Description
Arbli (losartan potassium)	Losartan potassium oral suspension approved for the treatment of hypertension in adults and children greater than 6 years old, reduction of the risk of stroke in individuals with hypertension and left ventricular hypertrophy, and treatment of diabetic nephropathy with an elevated serum creatinine and proteinuria in individuals with type 2 diabetes and a history of hypertension.
Atzumi™ (dihydroergotamine)	Dihydroergotamine nasal powder approved for the acute treatment of migraine with or without aura in adults.
Brekiya® (dihydroergotamine mesylate)*	Dihydroergotamine mesylate autoinjector approved for the acute treatment of migraine with or without aura and the acute treatment of cluster headaches in adults.
Egrifta WR™ (tesamorelin)*	Tesamorelin concentrated formulation approved for the reduction of excess abdominal fat in human immunodeficiency virus (HIV)-infected adults with lipodystrophy.
Hemiclor™ (chlorthalidone)	Chlorthalidone tablets approved for the treatment of hypertension in adults.
Jynneos (smallpox and mpox vaccine, live, non-replicating)*	Freeze-dried formulation of Jynneos vaccine for the prevention of smallpox and mpox disease in adults 18 years of age and older at high risk for smallpox or mpox infection.
Livmarli® (maralixibat)	Maralixibat tablet formulation approved for the treatment of cholestatic pruritus in individuals 3 months of age and older with Alagille syndrome (ALGS), and for the treatment of cholestatic pruritus in individuals 12 months of age and older with progressive familial intrahepatic cholestasis (PFIC).
Mezofy™ (aripiprazole)	Aripiprazole oral soluble film approved for the treatment of schizophrenia in adult and pediatric individuals ages 13 years and older.
Miudella® (copper intrauterine system)	Copper intrauterine system approved for the prevention of pregnancy in females of reproductive potential for up to three years.
Qamzova™ (meloxicam)*	Meloxicam injection approved for use in adults for the management of moderate-to-severe pain alone or in combination with non-NSAID analgesics.
VykatTM XR (diazoxide choline extended-release)	Diazoxide choline extended-release tablets approved for the treatment of hyperphagia (chronic overeating) in adults and pediatric individuals 4 years of age and older with Prader-Willi syndrome (PWS).
Vyvgart® Hytrulo (efgartigimod alfa/hyaluronidase-qvfc)*	Efgartigimod alfa/hyaluronidase pre-filled syringe for self-administration in the treatment of adults with generalized myasthenia gravis (MG) who are anti-acetylcholine receptor antibody positive and for adults with chronic inflammatory demyelinating polyneuropathy (CIDP).
Yutrepia™ (treprostinil)	Treprostinil inhalation powder approved for the treatment of pulmonary arterial hypertension and pulmonary hypertension associated with interstitial lung disease.

* Injectable

New biosimilars

Brand (generic)	Description
Bomyntra (denosumab-bnht)*	Xgeva® biosimilar approved for prevention of skeletal-related events in individuals with multiple myeloma and in individuals with bone metastases from solid tumors, treatment of 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, treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.
Conexxence (denosumab-bnht)*	Prolia® biosimilar approved for the treatment of postmenopausal women with osteoporosis at high risk for fracture, to increase bone mass in men with osteoporosis at high risk for fracture, treatment of 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.
Jobevne™ (bevacizumab-nwgd)*	Avastin biosimilar approved for the treatment of metastatic colorectal cancer, unresectable, locally advanced, recurrent or metastatic nonsquamous non-small cell lung cancer, recurrent glioblastoma, metastatic renal cell carcinoma, persistent, recurrent, or metastatic cervical cancer, and epithelial ovarian, fallopian tube, or primary peritoneal cancer.
Omlyclo® (omalizumab-igec)*	Interchangeable Xolair® biosimilar approved for moderate to severe persistent asthma in individuals greater than 6 years of age whose asthma symptoms are not well controlled with inhaled corticosteroids, chronic rhinosinusitis with nasal polyps in individuals greater than 18 years of age with inadequate response to nasal corticosteroids when used as add-on maintenance treatment, food allergy in people 1 year of age and older to reduce allergic reactions that may occur after accidentally eating one or more foods to which you are allergic, and chronic spontaneous urticaria in people 12 years of age and older who continue to have hives that are not controlled with H1 antihistamine treatment.
Osenvelt® (denosumab-bmwo)*	Xgeva® biosimilar approved for prevention of skeletal-related events in individuals with multiple myeloma and in individuals with bone metastases from solid tumors, treatment of 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 treatment of hypercalcemia of malignancy refractory to bisphosphonate therapy.
Stoboclo® (denosumab-bmwo)*	Prolia® biosimilar approved for treatment of postmenopausal women with osteoporosis at high risk for fracture, to increase bone mass in men with osteoporosis at high risk for fracture or in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer, treatment of glucocorticoid-induced osteoporosis in men and women at high risk for fracture, and to increase bone mass in women at high risk for fracture receiving a adjuvant aromatase inhibitor therapy for breast cancer.

* Injectable

New indications

Brand (generic)	Description
Amvuttra® (vutrisiran)*	Amvuttra approved for cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis in adults to reduce cardiovascular mortality, cardiovascular hospitalizations and urgent heart failure visits.
Baqsimi® (glucagon)	Baqsimi approved to include the treatment of severe hypoglycemia in individuals aged 1 year and older with diabetes.
Cabometyx® (cabozantinib)	Cabometyx approved for adult and pediatric individuals 12 years of age and older with previously treated, unresectable, locally advanced or metastatic, well-differentiated pancreatic neuroendocrine tumors (pNET) and well-differentiated extra-pancreatic neuroendocrine tumors (epNET).
Dextenza® (dexamethasone)	Dextenza approved for the treatment of ocular inflammation and pain following ophthalmic surgery in pediatric individuals and the treatment of ocular itching associated with allergic conjunctivitis in pediatric individuals aged 2 years and older.
Dupixent® (dupilumab)*	Dupixent approved for the treatment of chronic spontaneous urticaria (CSU) in individuals aged 12 years and older who remain symptomatic despite H1 antihistamine treatment.
Eliquis®; Eliquis® Sprinkle (apixaban)	Eliquis and Eliquis Sprinkle approved for the treatment of venous thromboembolism (VTE) and reduction in the risk of recurrent VTE in pediatric individuals from birth and older after at least 5 days of initial anticoagulant treatment. Addition of 0.5 mg tablets for oral suspension also approved.
Fabhalta® (iptacopan)	Fabhalta approved for the treatment of adults with complement 3 glomerulopathy (C3G) to reduce proteinuria.
Furoscix® (furosemide)*	Furoscix approved for the treatment of edema in individuals with chronic kidney disease (CKD).
Fylnetra® (pegfilgrastim-pbbk)*	Fylnetra approved to increase survival in individuals acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome, H-ARS).
Gvoke Vialdx (glucagon)*	Gvoke Vialdx approved for intravenous use as a diagnostic aid during radiologic examinations to temporarily inhibit movement of the gastrointestinal tract in adults. A new 1 mg/0.2 mL single-dose vial and carton and container labeling for intravenous use were also approved.
Iluvien® (fluocinolone acetonide intravitreal implant)*	Iluvien approved for the treatment of chronic non-infectious uveitis affecting the posterior segment of the eye.
Imfinzi® (durvalumab)*	Imfinzi approved with gemcitabine and cisplatin as neoadjuvant treatment, followed by single agent durvalumab as adjuvant treatment following radical cystectomy, for adults with muscle invasive bladder cancer (MIBC).
Isturisa® (osilodrostat)	Isturisa approved for the treatment of endogenous hypercortisolemia in adults with Cushing syndrome for whom surgery is not an option or has not been curative.
Jivi® (antihemophilic factor, recombinant, PEGylated-aucl)*	Jivi approved to include previously treated pediatric individuals aged 7 years and older with hemophilia A (congenital Factor VIII deficiency).
Neffy® (epinephrine)	Neffy approved for emergency treatment of type I allergic reactions, including anaphylaxis, in individuals who weigh between 15 and 30 kilograms.

New indications, continued

Brand (generic)	Description
Nucala (mepolizumab)*	Nucala approved for the add-on maintenance treatment of adults with inadequately controlled chronic obstructive pulmonary disease (COPD) and an eosinophilic phenotype.
Odactra® (house dust mite *[Dermatophagoides farinae and Dermatophagoides pteronyssinus]* allergen)	Odactra approved to include the treatment of house dust mite (HDM)-induced allergic rhinitis, with or without conjunctivitis, in pediatric individuals aged 5 to 11 years.
Opdivo® (nivolumab)*	Opdivo approved with Yervoy (ipilimumab) for the first-line treatment of adults with unresectable or metastatic hepatocellular carcinoma (HCC).
Pluvicto® (lutetium Lu 177 vipivotide tetraxetan)*	Pluvicto approved to include adults with prostate-specific membrane antigen (PSMA)-positive metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor pathway inhibitor (ARPI) therapy and are considered appropriate to delay taxane-based chemotherapy.
Posfrea™ (palonosetron hydrochloride)*	Posfrea approved to include prevention of acute nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, including highly emetogenic cancer chemotherapy, in pediatric individuals 1 month to less than 17 years of age.
Prezcobix® (cobicistat/darunavir)	Prezcobix approved for the treatment of human immunodeficiency virus type 1 (HIV-1) infection in treatment-naïve and treatment-experienced adults and pediatric individuals weighing at least 25 kg to less than 40 kg. A new fixed dose tablet containing 675 mg of darunavir and 150 mg of cobicistat is also approved.
Releuko® (filgrastim-ayow)*	Releuko approved for the mobilization of autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis (MAHPC) and to increase survival in individuals acutely exposed to myelosuppressive doses of radiation (hematopoietic syndrome of acute radiation syndrome, H-ARS).
Rinvoq® (upadacitinib)	Rinvoq approved for the treatment of giant cell arteritis in adults.
Rivfloza® (nedosiran)*	Rivfloza approved expansion to lower urinary oxalate levels in children 2 to <9 years of age with primary hyperoxaluria type 1 (PH1) and relatively preserved kidney function.
Sivextro® (tedizolid phosphate)*	Sivextro oral tablets and injection approved to include treatment of acute bacterial skin and skin structure infections (ABSSSI) in pediatric individuals <12 years of age.
Soliris® (eculizumab)*	Soliris approved for the treatment of generalized myasthenia gravis (gMG) in pediatric individuals six years of age and older who are anti-acetylcholine receptor (AChR) antibody positive.
Susvimo™ (ranibizumab)*	Susvimo approved for the treatment of individuals with diabetic retinopathy who have previously responded to at least 2 intravitreal injections of a vascular endothelial growth factor (VEGF) inhibitor medication.

New indications, continued

Brand (generic)	Description
Syndardy® (empagliflozin/metformin hydrochloride); Syndardy® XR (empagliflozin/metformin hydrochloride extended-release)	Syndardy and Syndardy XR approved in adults with type 2 diabetes mellitus to reduce the risk of sustained decline in estimated glomerular filtration rate (eGFR), end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression.
Tevimbra® (tislelizumab)*	Tevimbra approved in combination with platinum-containing chemotherapy for the first-line treatment of adults with unresectable or metastatic esophageal squamous cell carcinoma (ESCC) whose tumors express PD-L1 (≥1).
Tremfya® (guselkumab)*	Tremfya approved to treat adults with moderately-to-severely active Crohn's disease (CD), with both subcutaneous (SC) and intravenous (IV) induction options.
Uplizna® (inebilizumab)*	Uplizna approved for the treatment of immunoglobulin G4-related disease (IgG4-RD) in adults.
Valtoco® (diazepam)	Valtoco nasal spray approved to include the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (ie, seizure clusters, acute repetitive seizures) that are distinct from an individual's usual seizure pattern in individuals with epilepsy as young as 2 years old.
Welireg™ (belzutifan)	Welireg approved for adult and pediatric individuals 12 years and older with locally advanced, unresectable, or metastatic pheochromocytoma or paraganglioma (PPGL).
Zoryve® (roflumilast)	Zoryve topical foam approved for the treatment of plaque psoriasis of the scalp and body in adult and pediatric individuals 12 years of age and older.
Zynyz® (retifanlimab-dlwr)*	Zynyz approved with carboplatin and paclitaxel for the first-line treatment of adults with inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC). It was also approved as a single agent for adults with locally recurrent or metastatic SCAC with disease progression on or intolerance to platinum-based chemotherapy.

*Injectable

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