carelon Rx

DrugInsights

Q1 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)
Amtagvi (lifileucel)™	Tumor-derived T cell therapy	First Food and Drug Administration (FDA)-approved treatment for this population	Adults with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor)	Single-dose intravenous infusion	Iovance	$515K for one-time treatment
Casgevy™ (exagamglogene autotemcel)	Gene therapy	Lyfgenia™	Treatment of sickle cell disease (SCD) in people 12 years and older with recurrent vaso-occlusive crises (VOCs)	One-time intravenous infusion	Vertex	$2.2M per one-time treatment
Fabhalta® (iptacopan)	Complement factor B inhibitor	Empaveli®, Soliris®, Ultomiris®	Treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH)	200 mg twice daily by mouth without regard to food	Novartis	$550K per year

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Filsuvez® (birch triterpenes)	Herbal product	Vyjuvek®	Treatment of wounds associated with dystrophic and junctional epidermolysis bullosa in adult and pediatric people 6 months of age and older	Apply a 1 mm layer to affected wound surface and cover with wound dressing or apply directly to dressing until wound is healed	Chiesi Global Rare Diseases	Not available
iDose® TR (travoprost)	Prostaglandin analog	Durysta®	Reduction of intraocular pressure (IOP) in open-angle glaucoma (OAG) or ocular hypertension (OHT)	One intracameral implant per eye	Glaukos Corporation	$14K per implant
Iwilfin™ (eflornithine)	Ornithine decarboxylase inhibitor	First FDA-approved agent with this indication	To reduce the risk of relapse in adult and pediatric individuals with high-risk neuroblastoma (HRNB) who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy	Dosage based on body surface area and administered by mouth twice daily with or without food until disease progression, unacceptable toxicity, or for a maximum of two years	US WorldMeds	$6,500 to $25,900 per month
Lyfgenia™ (lovotibeglogene autotemcel)	Gene therapy	Casgevy™	Treatment of people 12 years of age or older with SCD and a history of vaso-occlusive events	One-time intravenous infusion	bluebird bio	$3.1M per one-time treatment

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Ogsiveo™ (nirogacestat)	Gamma secretase inhibitor	First FDA-approved agent with this indication	Adults with progressing desmoid tumors who require systemic treatment	150 mg (three 50 mg tablets) administered by mouth twice daily until disease progression or unacceptable toxicity	SpringWorks Therapeutics	$29K per month
Wainua™ (eplontersen)	Transthyretin-directed antisense oligonucleotide	Amvuttra®, Onpattro®, Tegsedi®	Treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults	45 mg administered by subcutaneous injection once monthly	Ionis Pharma	Not available
Zelsuvmi™ (berdazimer)	Nitric oxide (NO) releasing agent	Ycanth™	Treatment of molluscum contagiosum (MC) in adults and pediatric individuals 1 year of age and older	Dispense equal amounts from Tube A and B per the dosing guide. Mix together and immediately apply a thin layer topically once daily to each lesion for up to 12 weeks.	Ligand	Not available

New formulations

Brand (generic)	Description
Alyglo™ (immune globulin, human-stwk)*	Immune globulin approved for the treatment of adults aged 17 years and older with primary humoral immunodeficiency.
Alvaiz™ (eltrombopag choline)	Eltrombopag choline tablets approved for the treatment of thrombocytopenia in adult and pediatric people 6 years and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy; thrombocytopenia in adults with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy; and adults with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.
Aurlumyn™ (iloprost)	Iloprost injection approved to treat severe frostbite in adults to reduce the risk of finger or toe amputation.
Eohilia™ (budesonide)	Budesonide oral suspension approved for the treatment of adults and pediatric people 11 years of age and older with eosinophilic esophagitis (EoE).
Exblifep® (cefepime/enmetazobactam)*	Cefepime/enmetazobactam injection for intravenous use approved for the treatment of people aged 18 years and older with complicated urinary tract infections (cUTI) including pyelonephritis caused by caused by designated susceptible microorganisms.
Legubeti™ (acetylcysteine)	Acetylcysteine oral solution approved as an antidote to prevent or lessen hepatic injury, which may occur following the ingestion of a potentially hepatotoxic quantity of acetaminophen in adult and pediatric people.
Phyrago (dasatinib)	Dasatinib tablets approved for the treatment of adults with: • newly diagnosed Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase • chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib • Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy
Zorvye® (roflumilast)	Roflumilast foam formulation approved for the treatment of seborrheic dermatitis in people aged 9 years and older.

*Injectable

New biosimilars

Brand (generic)	Description
Avzivi® (bevacizumab-tnjn)*	Avzivi approved as a biosimilar to the reference product Avastin® for various oncology indications.
Simlandi® (adalimumab-ryvk)*	Interchangeable, high-concentration, citrate-free Humira® biosimilar approved for adults with rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, ulcerative colitis, Crohn's disease, plaque psoriasis, hidradenitis suppurativa, and noninfectious intermediate and posterior uveitis and panuveitis. In pediatrics, it is indicated for polyarticular juvenile idiopathic arthritis in children 2 years of age and older and Crohn's disease in children 6 years of age and older.
Udenyca Onbody™ (pegfilgrastim-cbqv)*	Udencya Onbody approved as a biosimilar to the on-body injector presentation of Neulasta® 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.

*Injectable

New indications

Brand (generic)	Description
Adbry® (tralokinumab-ldrm)*	Adbry approved for the treatment of moderate-to-severe atopic dermatitis in pediatric people aged 12-17 years.
Avycaz® (avibactam sodium/ ceftazidime)*	Avycaz approved from birth (at least 31 weeks gestational age) to less than 3 months of age for the treatment of complicated intra-abdominal infections (cIAI); complicated urinary tract infections (cUTI) including pyelonephritis; and hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP).
Bivigam® (immune globulin, human, 10% liquid)*	Bivigam approved to include pediatric people 2 years of age and older with primary humoral immunodeficiency (e.g., common variable immunodeficiency, X-linked agammaglobulinemia, congenital agammaglobulinemia, Wiskott-Aldrich syndrome, severe combined immunodeficiencies).
Casgevy™ (exagamglogene autotemcel)*	Casgevy approved for the treatment of people aged 12 years and older with transfusion-dependent □-thalassemia (TDT).
Cresemba® (isavuconazonium sulfate)*	Cresemba oral capsules and injection approved to include treatment of invasive aspergillosis (IA) and invasive mucormycosis (IM) in pediatric people 1 year of age and older.
Dupixent® (dupilumab)*	Dupixent approved for the treatment of pediatric people aged 1 to 11 years, weighing at least 15 kg, with eosinophilic esophagitis (EoE).

*Injectable

New indications, continued

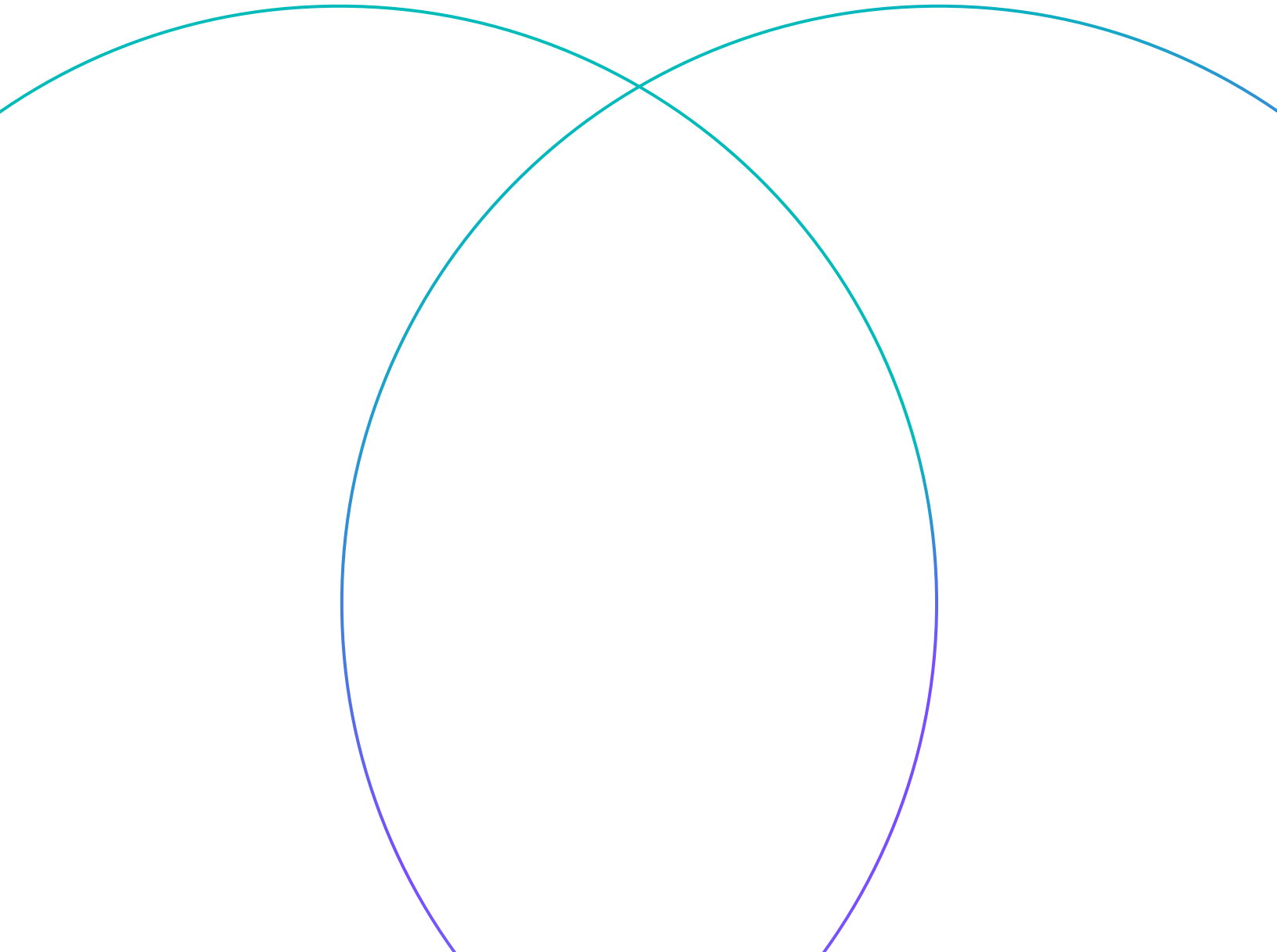
Brand (generic)	Description
Gammagard (immune globulin infusion 10%, human)*	Gammagard approved to improve neuromuscular disability and impairment in adults with chronic inflammatory demyelinating polyneuropathy (CIDP).
Hyqvia (immune globulin infusion 10% [human] with recombinant human hyaluronidase)*	Hyqvia approved for the treatment of chronic inflammatory demyelinating polyneuropathy (CIDP) as maintenance therapy to prevent relapse of neuromuscular disability and impairment in adults.
Jaypirca® (pirtobrutinib)	Jaypirca approved for adults with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/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.
Keytruda® (pembrolizumab)*	Keytruda approved with chemoradiotherapy (CRT) for people with FIGO 2014 Stage III-IVA cervical cancer.
Onivyde® (irinotecan liposome)*	Onivyde approved with oxaliplatin, fluorouracil, and leucovorin, for the first-line treatment of metastatic pancreatic adenocarcinoma.
Piqray® (alpelisib)	Piqray approved for expanded use in pre- and perimenopausal women for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, PIK3CA-mutated, advanced, or metastatic breast cancer.
Tagrisso® (osimertinib) AstraZeneca	Tagrisso approved with platinum-based chemotherapy for people with locally advanced or metastatic non-small cell lung cancer (la/mNSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R mutations, as detected by a Food and Drug Administration (FDA)-approved test.
Welireg™ (belzutifan)	Welireg approved for people with advanced renal cell carcinoma (RCC) following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor (VEGF-TKI).
Wilate (von Willebrand factor/coagulation factor VIII complex [human])*	Wilate approved for routine prophylaxis to reduce the frequency of bleeding episodes in adults and children 6 years of age and older with von Willebrand disease (VWD).
Xolair® (omalizumab)*	Xolair approved for immunoglobulin E-mediated food allergy in certain adults and children 1 year or older for the reduction of allergic reactions (Type I), including reducing the risk of anaphylaxis, that may occur with accidental exposure to one or more foods. To be used in conjunction with food allergen avoidance.

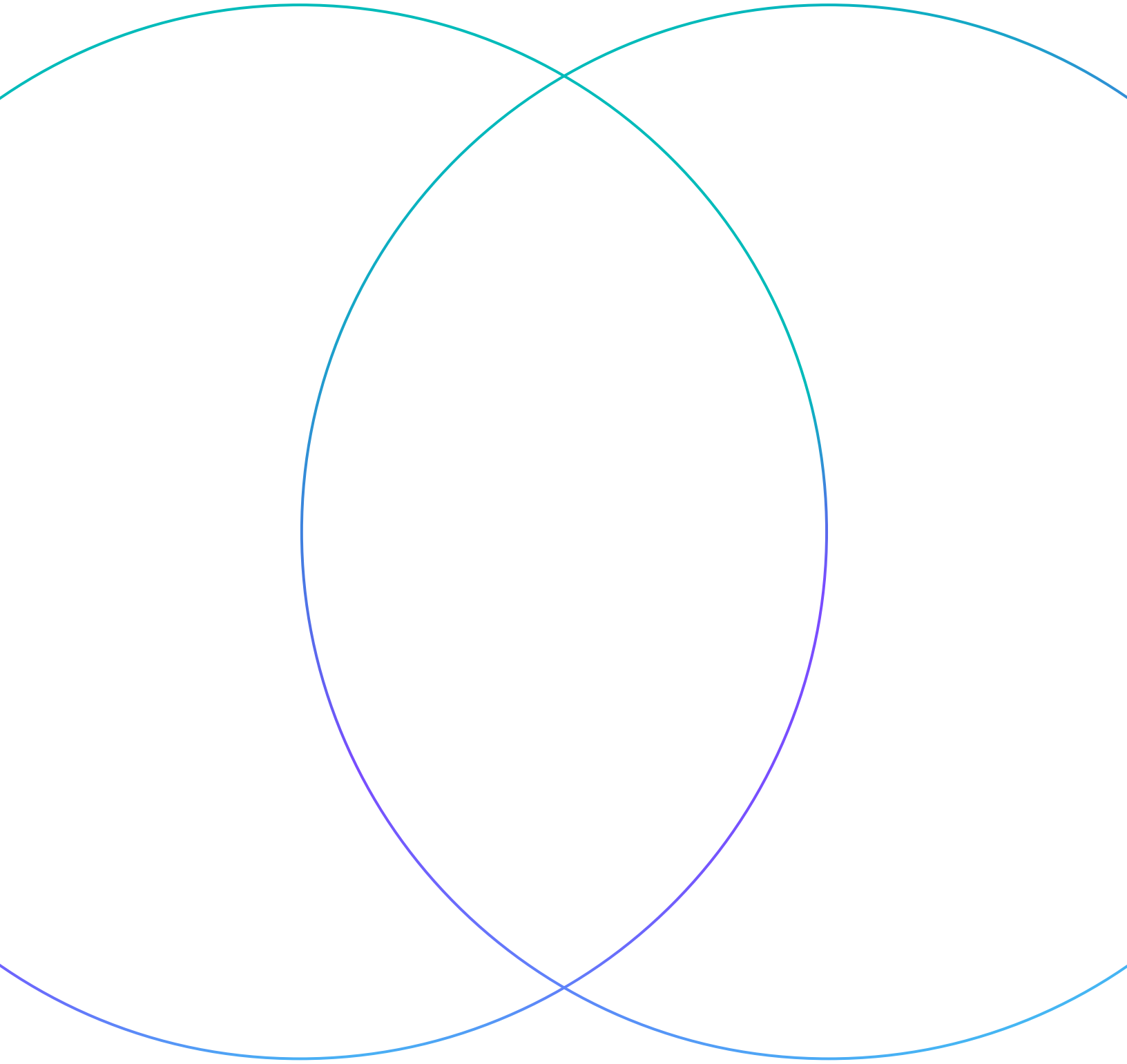
*Injectable

New indications, continued

Brand (generic)	Description
Yuflyma® (adalimumab-aaty)*	Yuflyma approved for the treatment of non-infectious intermediate, posterior, and panuveitis in adults.
Zynrelef® (bupivacaine/meloxicam)*	Zynrelef approval expanded to include postsurgical analgesia for up to 72 hours for soft tissue and orthopedic surgical procedures, including foot and ankle procedures and other orthopedic procedures (e.g., total joint arthroplasty) in which direct exposure to articular cartilage is avoided.

*Injectable





1067338MUEENCRX 03/24

carelon Rx