carelon Rx

DrugInsights

Q2 2026

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)
Avlayah™ (tividenofusp alfa-eknm)	Enzyme replacement therapy (ERT)	Elaprase®	Treatment of neurologic manifestations of Hunter syndrome (Mucopolysaccharidosis type II, MPS II) when initiated in presymptomatic or symptomatic pediatrics weighing at least 5 kg prior to advanced neurologic impairment	Starting dosage is 3 mg/kg once weekly by intravenous (IV) infusion, titrated to a recommended maintenance dosage of 15 mg/kg once weekly	Denali Therapeutics	$270K-$811K for annual maintenance depending on weight
Awiqli® (insulin icodec-abae)	Long-acting human insulin analog	Lantus®, Tresiba®	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2D)	Administer by subcutaneous (SC) injection once weekly (on the same day each week) into the thigh, upper arm, or abdomen. Individualize and titrate the dose.	Novo Nordisk	Not available

New molecular entities, *continued*

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Baxfendy™ (baxdrostat)	Aldosterone synthase inhibitor	Tryvio™	Treatment of hypertension in combination with other antihypertensive drugs in adults who are not adequately controlled on other agents	2 mg orally once daily	AstraZeneca	Not available
Beqalzi™ (sonrotoclax)	B-cell lymphoma 2 (BCL-2) inhibitor	Breyanzi®, Jaypirca®, Tecartus®	Treatment of adults with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor	320 mg orally once daily following completion of a 4-week dose ramp-up schedule	BeOne Medicines	Not available
Bysanti™ (milsa-peridone)	Atypical antipsychotic	Fanapt®	Treatment of schizophrenia in adults and acute treatment of manic or mixed episodes associated with bipolar I disorder in adults	After titration, the recommended maintenance dosage for schizophrenia is 6 to 12 mg orally twice daily and 12 mg orally twice daily for bipolar disorder	Vanda	Not available
Foundayo™ (orforglipron)	GLP-1 receptor agonist	liraglutide, Wegovy®, Zepbound®	In combination with a reduced calorie diet and increased physical activity to help reduce excess body weight and maintain long-term weight reduction in adults with obesity or adults with overweight in the presence of ≥1 weight-related comorbid condition	Starting dosage is 0.8 mg orally once daily. Dose may be titrated up based on treatment response and tolerability. Maximum dosage is 17.2 mg once daily.	Eli Lilly	$7,800 per year

New molecular entities, *continued*

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Icotyde™ (icotrokinra)	IL-23 inhibitor (oral peptide)	Otezla®, Otezla XRTM, Sotyktu®	Treatment of moderate-to-severe plaque psoriasis (PsO) in adults and adolescents at least 12 years old who weigh at least 40 kg and are candidates for systemic therapy or phototherapy	200 mg orally once daily	Johnson & Johnson/ Janssen Biotech	$99,420 per year
Idvynso™ (doravirine/ islatravir)	Non-nucleoside reverse transcriptase inhibitor (NNRTI) and next-generation nucleoside analog reverse transcriptase inhibitor (NRTI)	Cabenuva, Juluca	Treatment of human immunodeficiency virus-1 (HIV-1) infection in adults to replace the current antiretroviral regimen for those who are virologically suppressed on a stable antiretroviral regimen with no history of virologic treatment failure and no known substitutions associated with resistance to doravirine	One tablet orally once daily (100 mg doravirine/0.25 mg islatravir)	Merck	$4,455 per month
Kresladi (marnetegra-gene autotemcel)	Gene therapy	First agent approved for this indication	Treatment of pediatric individuals with severe leukocyte adhesion deficiency I (LAD-I) due to biallelic variants in ITGB2 without an available human leukocyte antigen (HLA)-matched sibling donor for allogeneic hematopoietic stem cell transplant (HSCT)	One-time IV infusion	Rocket	Not available

New molecular entities, *continued*

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Lifyorli™ (relacorilant)	Gluco-corticoid receptor antagonist	Select targeted agents and chemotherapy regimens	In combination with nab-paclitaxel for the treatment of adults with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received 1 to 3 prior systemic treatment regimens, at least one of which included bevacizumab	150 mg orally with food once daily on the day before, the day of, and the day after each nab-paclitaxel infusion	Corcept Therapeutics	$37,900 per 28 days
Lynavoy (linerixibat)	Ileal bile acid transporter (IBAT) inhibitor	First agent approved for this indication	Treatment of cholestatic pruritus in individuals with primary biliary cholangitis	40 mg orally twice daily	GSK	Not available
Loargys® (peg-zilarginase-nbln)	Arginase-1 enzyme	First treatment approved for this indication	Treatment of hyperargininemia in adults and children age 2 and older with Arginase 1 Deficiency (ARG1-D), in conjunction with dietary protein restriction	Recommended starting dosage is 0.1 mg/kg of body weight administered via IV infusion over 30 minutes once weekly. The maximum recommended dosage is 0.2 mg/kg once weekly. After 8 weeks of IV therapy, individuals may be switched to once weekly SC therapy at the same dose.	Immedica Pharma AB	$11,469 per 2 mg/0.4mL vial

New molecular entities, *continued*

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Otarmeni™ (lunsotogene parvec-cwha)	Gene therapy	First treatment approved for this indication	Treatment of children and adults with severe-to-profound and profound sensorineural hearing loss (any frequency >90 dB HL) associated with molecularly confirmed biallelic variants in the otoferlin (OTOF) gene, preserved outer hair cell function, and no prior cochlear implant in the same ear	Single-dose intracochlear infusion	Regeneron	Not available
Veppanu™ (vep-degestrant)	Hetero-bifunctional protein degrader	Inluriyo™, Orserdu™	Treatment of adults with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, estrogen receptor-1 (ESR1)-mutated advanced or metastatic breast cancer, as detected by an FDA-authorized test, with disease progression following at least one line of endocrine therapy	200 mg orally once daily	Avinas Operations	Not available
Yuviwel® (nave-pegritide)	C-type natriuretic peptide (CNP) analog	Voxzogo®	To increase linear growth in children age 2 and older with achondroplasia with open epiphyses	Administer SC once weekly with dosage based on body weight	Ascendis Pharma	$498K per year

New formulations

Brand (generic)	Description
Atoncy™ (atomoxetine)	Atomoxetine oral solution approved for the treatment of attention-deficit/hyperactivity disorder (ADHD) in adults and children age 6 and older.
Avopef™ (etoposide)*	Etoposide injection for IV use approved in combination with other chemotherapy and/or immunotherapy for the treatment of adults with refractory testicular cancer or small cell lung cancer.
Desmoda™ (desmopressin acetate)	Desmopressin oral solution approved for the management of central diabetes insipidus as antidiuretic replacement therapy for adults and children.
Evdi (trabectedin)*	Trabectedin injection approved for the treatment of adults with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen.
Favlyxa™ (fluorouracil)*	Fluorouracil injection for IV use approved for the treatment of colon and rectum adenocarcinoma, breast adenocarcinoma, gastric adenocarcinoma, or pancreatic adenocarcinoma.
Jakafi XR™ (ruxolitinib extended release)	Ruxolitinib extended-release tablets approved for the treatment of intermediate- or high-risk myelofibrosis (MF), including primary MF, post-polycythemia vera MF, and post-essential thrombocythemia MF in adults, polycythemia vera (PV) in adults who have had an inadequate response to or are intolerant of hydroxyurea, steroid-refractory acute graft-versus-host disease (GVHD) in adults and children age 12 and older, and chronic GVHD after failure of one or two lines of systemic therapy in adults and children age 12 and older.
Saphnelo® (anifrolumab-fnia)*	SC autoinjector pen or prefilled pen for use in the treatment of moderate to severe systemic lupus erythematosus (SLE) alongside standard therapy.
Spinraza® (nusinersen)*	Nusinersen 50 mg and 28 mg dosage forms for intrathecal use approved for the treatment of spinal muscular atrophy (SMA).
Trimbow® (beclomethasone dipropionate/ formoterol fumarate/ glycopyrrolate)	Beclomethasone dipropionate, formoterol fumarate, and glycopyrrolate fixed-dose combination oral inhaler approved for the maintenance treatment of asthma in adults age 18 and older.
Wainua® (eplontersen sodium)*	Eplontersen sodium single-dose prefilled syringe approved for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.
Wegovy® HD (semaglutide)*	Semaglutide 7.2 mg SC injection approved in combination with a reduced calorie diet and increased physical activity to reduce excess body weight and maintain long-term weight reduction in adults with obesity, or overweight with one or more weight-related condition.

* Injectable

New biosimilars

Brand (generic)	Description
Immgolis™; Immgolis Intri™ (golimumab-sldi)*	Simponi® and Simponi Aria® interchangeable biosimilars approved for the treatment of rheumatoid arthritis and ulcerative colitis.
Langlara™ (insulin glargine-aldy)*	Lantus® interchangeable biosimilar approved for the treatment of adults and children with type 1 diabetes mellitus and adults with type 2 diabetes mellitus.
Ponlimsi™ (denosumab-adet)*	Prolia® biosimilar approved to treat postmenopausal women with osteoporosis at high risk for fracture, increase bone mass in men with osteoporosis at high risk for fracture, treat glucocorticoid-induced osteoporosis in men and women at high risk for fracture, increase bone mass in men at high risk for fracture receiving androgen deprivation therapy for nonmetastatic prostate cancer, and increase bone mass in women at high risk for fracture receiving adjuvant aromatase inhibitor therapy for breast cancer.

* Injectable

New indications

Brand (generic)	Description
Arexvy (respiratory syncytial virus vaccine adjuvanted)*	Arexvy approved to include prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in adults ages 18 to 49 years who are at increased risk.
Asceniv™ (immune globulin IV, human–slra)*	Asceniv approved to include the treatment of primary humoral immunodeficiency (PI) in children age 2 and older.
Auvelity® (dextromethorphan hydrobromide/ bupropion hydrochloride extended-release)	Auvelity approved for the treatment of agitation associated with dementia due to Alzheimer's disease (AD).
Bizengri® (zenocutuzumab-zbco)*	Bizengri approved for adults with advanced, unresectable, or metastatic cholangiocarcinoma harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy.
Breztri Aerosphere® (budesonide/glycopyrrolate/ formoterol fumarate)	Breztri Aerosphere approved for the maintenance treatment of asthma in adults and children age 12 and older.
Calquence® (acalabrutinib)	Calquence approved in combination with Venclexta (venetoclax) for adults with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
Cosentyx® (secukinumab)*	Cosentyx approved for the treatment of children age 12 and older with moderate-to-severe hidradenitis suppurativa (HS).
Cosentyx® (secukinumab)*	Cosentyx approved for the treatment of children age 12 and older with active ankylosing spondylitis.
Dupixent® (dupilumab)*	Dupixent approved for the treatment of adults and children age 6 and older with allergic fungal rhinosinusitis (AFRS) who have a history of sinonasal surgery.
Dupixent® (dupilumab)*	Dupixent approved to include children ages 2 to 11 years with chronic spontaneous urticaria (CSU) who remain symptomatic despite H1 antihistamine treatment.
Jaypirca® (pirtobrutinib)	Jaypirca approved for the treatment of adults with relapsed or refractory (R/R) chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have previously been treated with a covalent Bruton tyrosine kinase (BTK) inhibitor.
Journavx® (suzetrigine)	Journavx approved for the treatment of postoperative pain in adults.
Keytruda® (pembrolizumab)*, Keytruda Qlex™ (pembrolizumab and berahyaluronidase alfa-pmph)*	Keytruda and Keytruda Qlex approved in combination with paclitaxel, with or without bevacizumab, for adults with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express programmed death-ligand 1 (PD-L1) (CPS≥1) as determined by an FDA-authorized test, and who have received one or two prior systemic treatment regimens.

* Injectable

New indications, *continued*

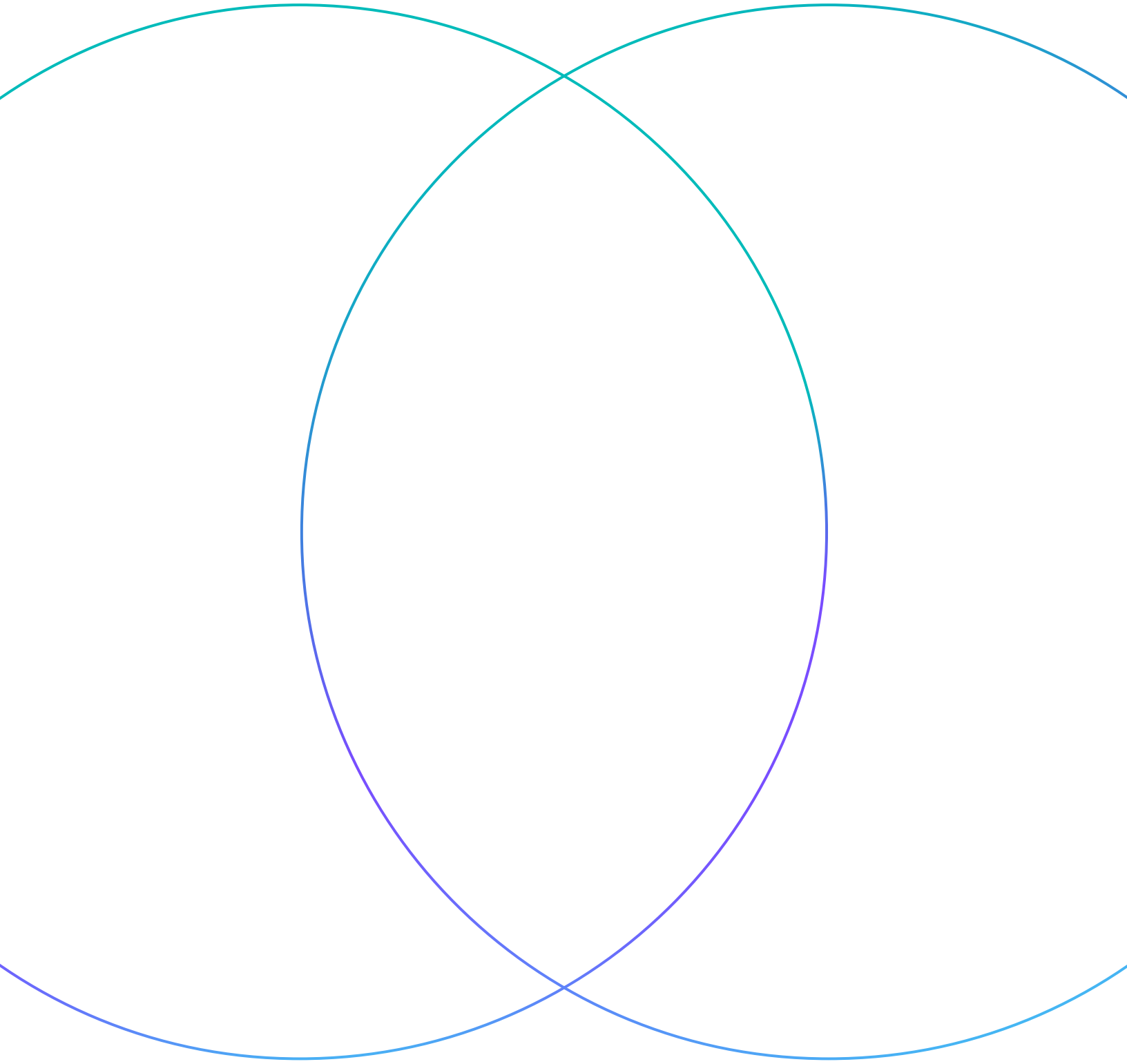
Brand (generic)	Description
Enhertu® (fam-trastuzumab deruxtecan-nxki)*	Enhertu approved for neoadjuvant treatment of adults with human epidermal growth factor receptor 2 (HER2)-positive (IHC 3+ or ISH+) Stage II or III breast cancer, as determined by an FDA-authorized test and for the adjuvant treatment of adults with HER2-positive (IHC 3+ or ISH+) breast cancer who have residual invasive disease following neoadjuvant treatment with trastuzumab (with or without pertuzumab) and taxane-based treatment.
Fasenra® (benralizumab)*	Fasenra approved for the treatment of adults and children age 12 and older with hypereosinophilic syndrome (HES) without an identifiable non-hematologic secondary cause.
Filspari® (sparsentan)	Filspari approved to reduce proteinuria in adults and children age 8 and older with focal segmental glomerulosclerosis (FSGS) without nephrotic syndrome.
Hernexeos® (zongertinib)	Hernexeos approved for adults with unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have human epidermal growth factor receptor 2 (HER2) erythroblastic B cell leukemia viral oncogene homolog 2 (ERBB2) tyrosine kinase domain (TKD) activating mutations, as detected by an FDA-authorized test.
Imcivree® (setmelanotide)*	Imcivree approved to reduce excess body weight and maintain reduction long term in adults and children age 4 and older with acquired hypothalamic obesity (HO).
Inqovi® (decitabine/cedazuridine)	Inqovi approved with venetoclax for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults age 75 and older or who have comorbidities that preclude the use of intensive induction chemotherapy.
Juxtapid® (lomitapide)	Juxtapid approved to include treatment of children age 2 and older with homozygous familial hypercholesterolemia (HoFH), as an adjunct to a low-fat diet and exercise and other low-density lipoprotein cholesterol (LDL-C) therapies. A 2 mg strength capsule was also approved.
Licart® (diclofenac epolamine)	Licart approved to include children ages 6 to less than 17 for the treatment of acute pain due to minor strains, sprains, and contusions.
Ocrevus® (ocrelizumab)*	Ocrevus approved for children age 10 and older with relapsing-remitting multiple sclerosis (RRMS) who weigh at least 55 lbs (25 kg).
Opdivo® (nivolumab)*	Opdivo approved with doxorubicin, vinblastine, and dacarbazine (AVD) for adults and children age 12 and older with previously untreated, Stage III or IV classical Hodgkin lymphoma (cHL).
Palynziq® (pegvaliase-pqpz)*	Palynziq approved to include treatment of adolescents age 12 and older with phenylketonuria (PKU).
Prezcobix® (darunavir/cobicistat)	Prezcobix approved to include treatment of human immunodeficiency virus-1 (HIV-1) infection in children age 3 and older who weigh 15kg or more. A tablet for oral suspension formulation was also approved.

* Injectable

New indications, *continued*

Brand (generic)	Description
RizaFilm® (rizatriptan benzoate)	RizaFilm oral film approved for the acute treatment of migraine with or without aura to include children ages 6 to 11. A 5 mg strength was also approved.
Sogroya® (somapacitan-beco)*	Sogroya approved to include the treatment of children age 2.5 and older with short stature born small for gestational age (SGA) and with no catch-up growth by 2 years old, growth failure associated with Noonan syndrome (NS), and idiopathic short stature (ISS).
Sotyktu® (deucravacitinib)	Sotyktu approved for the treatment of adults with active psoriatic arthritis (PsA).
Stelara® (ustekinumab)*	Stelara approved for the treatment of children age 2 and older with moderately to severely active Crohn's disease.
Symbicort Aerosphere® (budesonide/formoterol fumarate)	Symbicort Aerosphere approved for the treatment of asthma in adults and children age 12 and older.
Tecentriq® (atezolizumab)*; Tecentriq Hybreza™ (atezolizumab and hyaluronidase-tqjs)*	Tecentriq and Tecentriq Hybreza approved as adjuvant treatments for adults with muscle invasive bladder cancer (MIBC) after cystectomy who have circulating tumor DNA molecular residual disease (ctDNA MRD) as determined by an FDA-authorized test.
Tecvayli® (teclistamab-cqyv)*	Tecvayli approved in combination with daratumumab hyaluronidase-fihj for 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.
Tzield® (teplizumab-mzwv)*	Tzield approved to include children as young as 1 year old with stage 2 type 1 diabetes (T1D) to delay the onset of stage 3 T1D.
Vyvgart® (efgartigimod alfa-fcab)*; Vyvgart Hytrulo® (efgartigimod alfa and hyaluronidase-qvfc)*	Vyvgart and Vyvgart Hytrulo approved for the treatment of all serotypes of adults with generalized myasthenia gravis (gMG) including anti-AChR-Ab positive, anti-MuSK-Ab positive, anti-LRP4-Ab positive, and triple seronegative.
Zerbaxa™ (ceftolozane sulfate/tazobactam sodium)*	Zerbaxa approved for the treatment of hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP) in pediatric patients (at least 32 weeks gestational age). Also, the age range for pediatrics for the approved indications of complicated intra-abdominal infections (cIAI), where Zerbaxa is used in combination with metronidazole, and complicated urinary tract infections (cUTI), including pyelonephritis, was updated to read as "at least 32 weeks gestational age" instead of "birth to less than 18 years old."

* Injectable



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