carelon Rx

DrugInsights

Q3 2023

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)
Abrysvo™ (respiratory syncytial virus vaccine)	Viral vaccine (recombinant)	Arexvy	For active immunization for the prevention of lower respiratory tract disease (LRTD) caused by respiratory syncytial virus (RSV) in people age 60 and older	0.5 mL single dose intramuscular injection	Pfizer	$295
Beyfortus™ (nirsevimab-alip)	F protein-directed fusion inhibitor monoclonal antibody	Synagis®	Prevention of RSV LRTD in neonates and infants born during or entering their first RSV season and children up to age 24 months who remain vulnerable to severe RSV disease through their second RSV season	**Neonates and infants born during or entering first RSV season:** 50 mg if less than 5 kg in body weight; 100 mg if greater than or equal to 5 kg in body weight **Children who remain vulnerable through second RSV season:** 200 mg (2 x 100 mg injections)	AstraZeneca/ Sanofi	$495 for each single injection

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Columvi™ (glofitamab-gxbm)	Monoclonal antibody; CD20xCD3 bispecific	EpkinlyTM, Xpovio®, Zynlonta®	Treatment of adults with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy	Administer intravenously according to the step-up dosing schedule in product labeling for a maximum of 12 cycles	Genentech	$350K for each course
Elevidys (delandistrogene moxeparvovecr-okl)	Gene therapy	First gene therapy approved for this indication	Treatment of ambulatory children age 4 through 5 with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene	Single intravenous infusion	Sarepta Therapeutics	$3.2M for one-time treatment
ElrexfioTM (elranatamab-bcmm)	Bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager	Abecma®, Carvykti®, 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 immunomodula-tory agent, and an anti-CD38 monoclonal antibody	Step-up dosing is required to initiate therapy; it may then be administered weekly or every two weeks subcutaneously by a healthcare provider	Pfizer	$410K for each year

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Inpefa™ (sotagliflozin)	Sodium-glucose cotransporter 1 & 2 inhibitor (SGLT1i, SGLT2i)	Farxiga®, Jardiance®	To reduce the risk of cardiovascular (CV) death, hospitalization for heart failure (HHF), and urgent heart failure visit in adults with heart failure (HF) or type 2 diabetes mellitus, chronic kidney disease (CKD), and other CV risk factors	Initial: 200 mg by mouth once a day; Maintenance: 400 mg once a day	Lexicon	$600 each month
Izervay™ (avacincaptad pegol)	Complement inhibitor	Syfovre®	Treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD)	2 mg (0.1 mL of 20 mg/mL solution) administered intravitreally to each affected eye once a month (approximately 28 ± 7 days) for up to 12 months)	Iveric Bio	$21K to $36K (for the treatment of one eye)
Litfulo™ (ritlecitinib)	Janus kinase (JAK) inhibitor, tyrosine kinase inhibitor	Olumiant®	Treatment of severe alopecia areata (AA) in adults and adolescents age 12 and older	50 mg by mouth once a day	Pfizer	$49K each year
Paxlovid™ (ritonavir-boosted nirmatrelvir)	Protease inhibitor	Veklury®	Treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults (age 18 and older) who are at high risk for progression to severe COVID-19, including hospitalization or death	Initiate as soon as possible after diagnosis and within 5 days of symptom onset. Take two 150-mg nirmatrelvir tablets by mouth with one 100-mg ritonavir tablet by mouth twice a day for 5 days	Pfizer	Not available

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Roctavian™ (valoctocogene roxaparvovec-rvox)	Gene therapy	First gene therapy approved for this indication	Treatment of adult males with severe hemophilia A (congenital factor VIII deficiency with factor VIII activity < 1 IU/dL) without pre-existing antibodies to adeno-associated virus serotype 5 (AAV5) detected by an FDA-approved test	Administered as a one-time, single-dose intravenous infusion	BioMarin	$2.9M for one-time treatment (weight-based)
Rystiggo® (rozanolixizumab-noli)	Neonatal Fc receptor blocker	Soliris®, Ultomiris®, Vyvgart®, Vyvgart® Hytrulo	Treatment of generalized myasthenia gravis (gMG) in adults who are anti-acetylcholine receptor (AChR) or anti-muscle-specific tyrosine kinase (MuSK) antibody positive	Administered by subcutaneous infusion once a week for 6 weeks. Dosage is based on body weight.	UCB	$73K for each treatment cycle
Sohonos™ (palovarotene)	Retinoid/ Selective retinoic acid receptor gamma (RAR□) agonist	First agent approved for this indication	For reduction in the volume of new heterotopic ossification in adults and children age 8 and older for females and age 10 and older for males with fibrodysplasia ossificans progressive (FOP)	Chronic dosing and dosing during flare-up episodes detailed in labeling. All doses should be taken by mouth with food at the same time every day.	Ipsen	$624K each year for 5 mg per day dose

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Talvey™ (talquetamab-tgvs)	Bispecific GPRC5D-directed CD3 T-cell engager antibody	Abecma®, Carvykti®, 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 immunom-odulatory agent, and an anti-CD38 monoclonal antibody	Step-up dosing is required to initiate therapy; it may then be administered every week or every two weeks subcutaneously by a healthcare provider	Janssen Biotech	$270K to $360K for 6 to 8 months
Vanflyta® (quizartinib)	Kinase inhibitor targeting FLT3	Rydapt®, Xospata®	Treatment of adults with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive as detected by an FDA-approved test	One tablet by mouth once a day. Dosing regimen may be found in prescribing information.	Daiichi Sankyo	$546 for each tablet
Veopoz™ (pozelimab-bbfg)	Complement inhibitor	First agent approved for this indication	Treatment of CD55-deficient protein-losing enteropathy (PLE), also known as complement hyperactivation, angiopathic thrombosis, and protein-losing enteropathy (CHAPLE) disease in adults and children age 1 and older	Loading dose of 30 mg/kg intravenously on day 1. Then inject 10 mg/kg as a subcutaneous injection once a week starting on day 8 as a maintenance dose. The maximum maintenance dosage is 800 mg once a week. Given by healthcare provider	Regeneron	$35K for single-use vial

New molecular entities, continued

Brand (generic)	Therapeutic class	Competitors	Indication(s)	Dosage	Manufacturer	Estimated wholesale acquisition cost (WAC)
Xdemvy™ (lotilaner)	Ectoparasiticide (anti-parasitic)	First product approved for this indication	Treatment of Demodex blepharitis	Instill one drop in each eye twice a day for 6 weeks	Tarsus	$1,850 per prescription for each 10 mL bottle
Ycanth™ (cantharidin)	Keratolytic agent	First product approved for this indication	Treatment of molluscum contagiosum (MC) in adults and children age 2 and older	Must be administered by healthcare provider. Apply topically as a single application to cover each lesion. Remove with soap and water 24 hours after treatment. May be administered every 3 weeks as needed	Verrica	$685 for each applicator
Zurzuvae™ (zuranolone)	Neuroactive steroid gamma-aminobutyric acid (GABA) A receptor positive modulator	Zulresso®	Treatment of postpartum depression (PPD) in women age 18 and older	50 mg by mouth once a day in the evening for 14 days	Biogen/ Sage Therapeutics	Not available

New formulations

Brand (generic)	Description
Akeega™ (niraparib/abiraterone acetate)	Fixed dose combination of niraparib and abiraterone acetate approved for use with prednisone in adults with deleterious or suspected deleterious BRCA-mutated castration-resistant prostate cancer (mCRPC), as determined by an FDA-approved test.
Balfaxar (prothrombin complex concentrate, human-lans)*	Human prothrombin complex concentrate approved for the urgent reversal of acquired coagulation factor deficiency induced by vitamin K antagonist (VKA, eg, warfarin) therapy in adults with need for an urgent surgery or invasive procedures.
Cyfendus™ (anthrax vaccine adsorbed, adjuvanted)*	Anthrax vaccine approved for post-exposure prophylaxis of disease following suspected or confirmed exposure to Bacillus anthracis in people age 18 to 65 when administered in conjunction with recommended antibacterial drugs.
Eylea® HD (aflibercept)*	Aflibercept 8 mg high dose formulation approved for the treatment of wet age-related macular degeneration (wAMD), diabetic macular edema (DME), and diabetic retinopathy.
Focinvez (fosaprepitant)*	Fosaprepitant injection approved in adults and children age 6 months and older, in combination with other antiemetic agents, for the prevention of acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC), including high-dose cisplatin and delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC).
Hepzato Kit (melphalan)*	Melphalan for injection/hepatic delivery system approved as a liver-directed treatment for adults with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation.
Lodoco® (colchicine)	Colchicine 0.5 mg tablets approved to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death in adults with established atherosclerotic disease or with multiple risk factors for cardiovascular disease.
Ngenla™ (somatrogon-ghla)*	Long-acting once-weekly growth hormone analog approved for treatment of children age 3 and older who have growth failure due to inadequate secretion of endogenous growth hormone.
Pemrydi RTU® (pemetrexed)*	Ready-to-use formulation of pemetrexed for injection approved in combination with pembrolizumab and platinum chemotherapy, for the initial treatment of people with metastatic non-squamous non-small cell lung cancer with no epidermal growth factor receptor (EGFR) or anaplastic lymphoma kinase (ALK) genomic tumor aberration and for initial treatment, in combination with cisplatin, of people with malignant pleural mesothelioma whose disease is unresectable or who are otherwise not candidates for curative surgery.

*Injectable

New formulations, continued

Brand (generic)	Description
ReVive™ (naloxone hydrochloride)	Naloxone hydrochloride nasal spray approved for opioid overdose reversal for over-the-counter (OTC) nonprescription use.
Suflave® (polyethylene glycol 3350/sodium sulfate/ potassium chloride/ magnesium sulfate/ sodium chloride)	Polyethylene glycol 3350, sodium sulfate, potassium chloride, magnesium sulfate, and sodium chloride for oral solution approved for cleansing of the colon in preparation for colonoscopy in adults.
Vevye (cyclosporine)	Cyclosporine ophthalmic solution approved for the treatment of the signs and symptoms of dry eye disease.
Vyvgart® Hytrulo (efgartigimod alfa and hyaluronidase-qvfc)*	Efgartigimod subcutaneous formulation approved for use in adults with generalized myasthenia gravis who also have an antibody known as acetylcholine receptor (AchR). It must still be administered by a healthcare provider.

New indications

Brand (generic)	Description
Abrilada™ (adalimumab-afzb)*	Abrilada approved for treatment of moderate to severe hidradenitis suppurativa in adults.
Abrilada (adalimumab-afzb)*	Abrilada approved for the treatment of non-infectious intermediate, posterior, and panuveitis in adults.
Abrysvo™ (respiratory syncytial virus vaccine)*	Abrysvo approved for active immunization of pregnant women at 32 through 36 weeks gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months.
Amjevita™ (adalimumab-atto)*	Amjevita approved for the treatment of non-infectious intermediate, posterior, and panuveitis in adults.
Bylvay™ (odevixibat)	Bylvay approved for the treatment of cholestatic pruritus in people from age 12 months with Alagille syndrome (ALGS).
Cyltezo® (adalimumab-adbm)*	Cyltezo approved for the treatment of non-infectious intermediate, posterior, and panuveitis in adults.
Daxxify® (daxibotulinumtoxinA-lanm)*	Daxxify approved for the treatment of cervical dystonia in adults.
Ervebo® (Ebola Zaire vaccine, live)*	Ervebo approved to include people age 12 months and older for the prevention of disease caused by Zaire ebolavirus.

*Injectable

New indications, continued

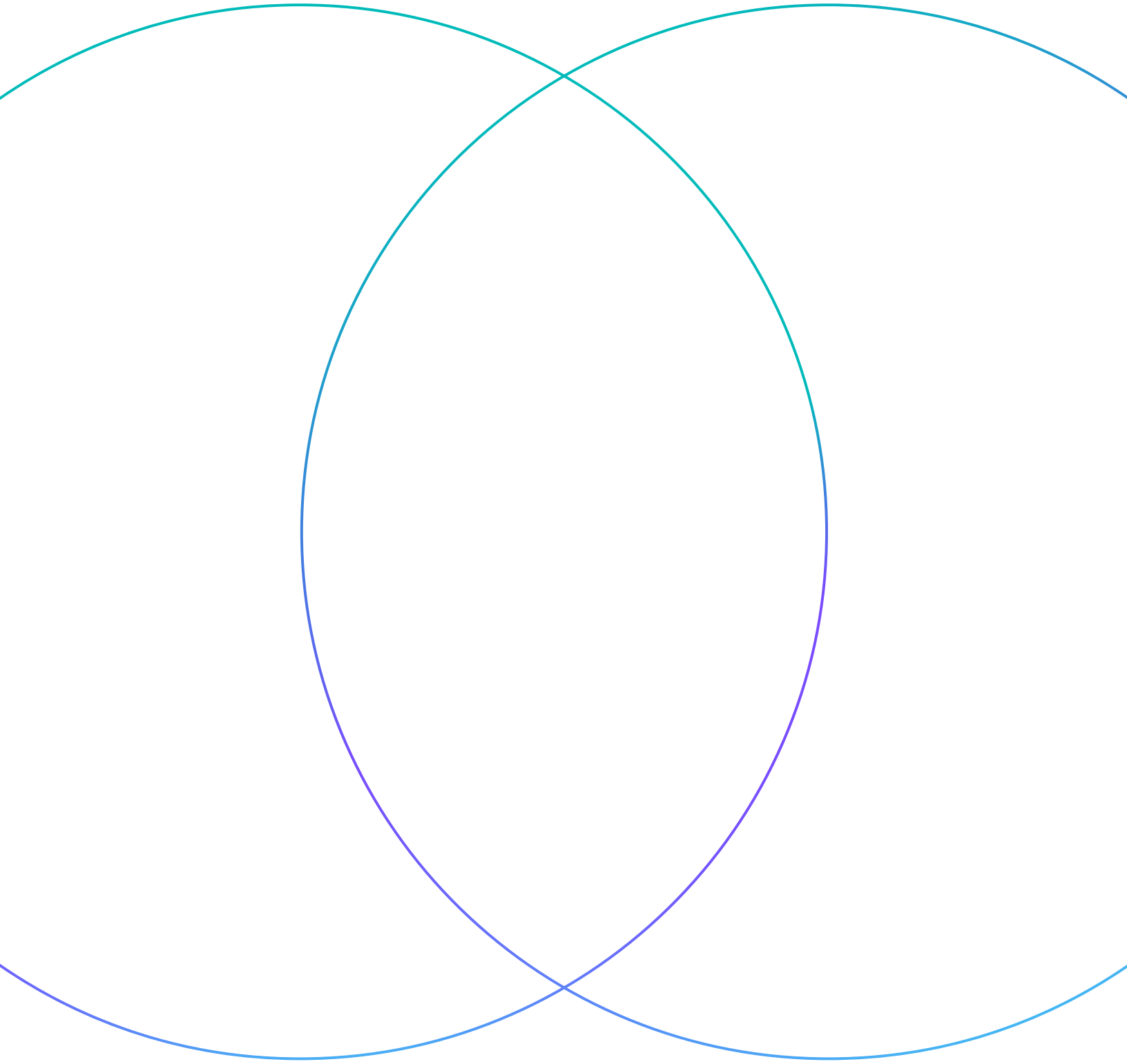
Brand (generic)	Description
Hadlima™ (adalimumab-bwwd)*	Hadlima approved for treatment of moderate to severe hidradenitis suppurativa in adults.
Hadlima™ (adalimumab-bwwd)*	Hadlima approved for the treatment of non-infectious intermediate, posterior, and panuveitis in adults.
Ingrezza® (valbenazine)	Ingrezza approved for the treatment of chorea associated with Huntington's disease (HD).
Injectafer® (ferric carboxymaltose)*	Injectafer approved for the treatment of iron deficiency in adults with heart failure and New York Heart Association Class II/III to improve exercise capacity.
Jardiance® (empagliflozin)	Jardiance approved as addition to diet and exercise to improve blood sugar control in children age 10 and older with type 2 diabetes.
Jemperli (dostarlimab-gxly)*	Jemperli approved in combination with carboplatin and paclitaxel, followed by monotherapy, for primary advanced or recurrent endometrial cancer (EC) that is mismatch repair deficient (dMMR), as determined by an FDA-approved test, or microsatellite instability-high (MSI-H).
Leqvio® (inclisiran)*	Leqvio approved for the treatment of adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH), to reduce low-density lipoprotein cholesterol (LDL-C), as an adjunct to diet and statin therapy.
Liletta® (levonorgestrel)	Liletta approved for the treatment of heavy menstrual bleeding for up to 5 years in women who choose intrauterine contraception as their method of contraception.
Linzess® (linaclotide)	Linzess approved to treat functional constipation in children age 6 to 17.
Lonsurf® (trifluridine/tipiracil)	Lonsurf approved in combination with bevacizumab for metastatic colorectal cancer (mCRC) previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-vascular endothelial growth factor (VEGF) biological therapy, and if RAS wild-type, an anti-epidermal growth factor receptor (EGFR) therapy.
Lynparza® (olaparib)	Lynparza approved in combination with abiraterone and prednisone (or prednisolone) for adults with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC), as determined by an FDA-approved companion diagnostic test.
Nucynta® (tapentadol hydrochloride)	Nucynta approved for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults and children age 6 and older with a body weight of at least 40 kg.
Prevymis® (letermovir)*	Prevymis oral and injectable formulation approved for prophylaxis of cytomegalovirus (CMV) disease in adult kidney transplant recipients at high risk (Donor CMV-seropositive/Recipient CMV-seronegative [D+/R-]).

*Injectable

New indications, continued

Brand (generic)	Description
Synjardy® (empagliflozin hydrochloride/metformin)	Synjardy approved as addition to diet and exercise to improve blood sugar control in children age 10 and older with type 2 diabetes.
Talzenna® (talazoparib)	Talzenna approved in combination with enzalutamide for homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).
Triumeq; Triumeq PD (abacavir sulfate/dolutegravir sodium/ lamivudine)	Triumeq and Triumeq PD approved for the treatment of human immunodeficiency virus (HIV)-infection in children at least 3 months and weighing at least 6 kg.
Veklury® (remdesivir)*	Veklury approved to include treatment of COVID-19 in people with severe renal impairment, including those on dialysis.
Veklury® (remdesivir)*	Veklury approved to include COVID-19 treatment in people with mild to severe hepatic impairment with no dose adjustments.

*Injectable



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