Optum Rx®

RxHighlights

November 2022

New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Elahere™ (mirvetuximab soravtansine-gynx)†* ImmunoGen	Folate receptor-1 antagonist	Treatment of adult patients with folate receptor-alpha positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have received one to three prior systemic treatment regimens	November 17, 2022
Hemgenix® (etranacogene dezaparvovec-drlb)† CSL Behring	Gene therapy	Treatment of adults with Hemophilia B (congenital Factor IX deficiency) who currently use Factor IX prophylaxis therapy, or have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes	December 8, 2022
Jylamvo® (methotrexate) Therakind	Folate analog metabolic inhibitor	Treatment of adults with acute lymphoblastic leukemia as part of a combination chemotherapy maintenance regimen; or adults with mycosis fungoides (cutaneous T-cell lymphoma) as a single agent or as part of a combination chemotherapy regimen; or adults with relapsed or refractory non-Hodgkin lymphomas as part of a metronomic combination chemotherapy regimen; or adults with rheumatoid arthritis; or adults with severe psoriasis	TBD
Rebyota™ (fecal microbiota, live - jslm)† Ferring Pharmaceuticals	Microbiota suspension	Prevention of recurrence of *Clostridioides difficile* infection (CDI) in individuals 18 years of age and older following antibiotic treatment for recurrent CDI	TBD
Sezaby™ (phenobarbital) Sun Pharma	Barbiturate	Treatment of neonatal seizures in term and preterm infants	4th Quarter 2023

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Tzield™ (teplizumab-mzwv)* Provention Bio	CD3-directed antibody	Delay the onset of stage 3 type 1 diabetes in adults and pediatric patients 8 years of age and older with stage 2 type 1 diabetes	November 21, 2022

*New molecular entity; †Orphan drug

New biosimilars

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Rezvoglar™ (insulin glargine-aglr)† Eli Lilly	Long-acting insulin	To improve glycemic control in adult and pediatric patients with diabetes mellitus	TBD

†Interchangeable to Sanofi's Lantus

New generics

Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Denavir® (penciclovir) Mylan	Teva†	1% cream	Treatment of recurrent herpes labialis (cold sores) in adults and children 12 years of age or older	November 14, 2022
Zioptan® (tafluprost) Akorn	Micro Labs†, Sandoz†	0.0015% ophthalmic solution	Reducing elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	November 19, 2022

†A-rated generic manufacturer

New authorized brand alternatives

Drug name manufacturer(s)	Authorized brand alternative manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Denavir® (penciclovir) Mylan	Viatris	1% cream	Treatment of recurrent herpes labialis (cold sores) in adults and children 12 years of age or older	November 16, 2022
Folotyn® (pralatrexate) Acrotech Biopharma	Fresenius	20 mg/ mL and 40 mg/2 mL injection	Treatment of relapsed or refractory peripheral T-cell lymphoma	November 17, 2022
Zioptan® (tafluprost) Akorn	Prasco	0.0015% ophthalmic solution	Reducing elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension	November 18, 2022

Indications/Label updates

Drug name manufacturer(s)	Type	Description
Adcetris® (brentuximab vedotin) Seagen	New indication	Treatment of pediatric patients 2 years and older with previously untreated high risk classical Hodgkin lymphoma, in combination with doxorubicin, vincristine, etoposide, prednisone, and cyclophosphamide
Brexafemme® (ibrexafungerp) Scynexis	New indication	In adult and post-menarchal pediatric females, for reduction in the incidence of recurrent vulvovaginal candidiasis
Imfinzi® (durvalumab), **Imjudo**® (tremelimumab-actl) AstraZeneca	New indication	In combination with Imjudo and platinum-based chemotherapy, for the treatment of adult patients with metastatic non-small cell lung cancer with no sensitizing epidermal growth factor receptor mutations or anaplastic lymphoma kinase genomic tumor aberrations

Drug name manufacturer(s)	Type	Description
Kineret® (anakinra) Orphan Biovitrum AB (Sobi)	Emergency use authorization (EUA)	The FDA issued an EUA for Kineret, for the treatment of COVID-19 in hospitalized adults with positive results of direct SARS-CoV-2 viral testing with pneumonia requiring supplemental oxygen (low- or high-flow oxygen) who are at risk of progressing to severe respiratory failure and likely to have an elevated plasma soluble urokinase plasminogen activator receptor.
Libtayo® (cemiplimab-rwlc) Regeneron	Expanded indication	In combination with platinum-based chemotherapy for the first-line treatment of adult patients with non-small cell lung cancer with no EGFR, ALK or ROS1 aberrations and is: locally advanced where patients are not candidates for surgical resection or definitive chemoradiation; or metastatic
Liletta® (levonorgestrel-releasing intrauterine system) Medicines360	Expanded indication	Prevention of pregnancy for up to 8 years
Tecentriq® (atezolizumab) Genentech	Indication withdrawal	Genentech announced that it is voluntarily withdrawing the indication for Tecentriq for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1, or are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status.
Trulicity® (dulaglutide) Eli Lilly	Expanded indication	Adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age and older with type 2 diabetes mellitus
Zejula® (niraparib) GSK	Indication update	Restriction of the second-line maintenance indication for Zejula to only the patient population with deleterious or suspected deleterious germline BRCA mutations

Drug safety news / Drug updates

Drug name manufacturer(s)	Description
Lecanemab Eisai/Biogen	Results from the lecanemab phase 3 pivotal trial, CLARITY-AD, were presented at the Clinical Trials in Alzheimer's Disease Congress. Simultaneously, the trial findings were published in the New England Journal of Medicine. These results were highly anticipated. However, the data indicate a very modest effect on the disease, with a high rate of serious adverse events. Unclear if effect correlates with clinically meaningful change.
Prolia® (denosumab) Amgen	The FDA announced they are investigating the risk of severe hypocalcemia with serious outcomes, including hospitalization and death, in patients with advanced kidney disease on dialysis treated with Prolia.

Drug recalls/Withdrawals/Shortages/Discontinuations

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Blenrep® (belantamab mafodotin-blmf) GSK	100 mg lyophilized powder in a single-dose vial	Discontinuation	GSK announced the market withdrawal of Blenrep following the request of the FDA. This request was based on the previously announced outcome of the DREAMM-3 phase III confirmatory trial, which did not meet the requirements of the FDA Accelerated Approval regulations. Blenrep is indicated for the treatment of adults with relapsed or refractory multiple myeloma who have received at least 4 prior therapies, including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent.
Omnipod DASH Insulin Management System Personal Diabetes Manager Insulet	Recalled models: 18239 ASM Omnipod DASH PDM; PT-000010: Assembly, DASH Final PDM U100, mg/dL;	Recall	The FDA announced a consumer level, class I recall of the Omnipod DASH Insulin Management System after receiving reports of battery issues. The battery of the Personal Diabetes Manager may swell, leak battery fluid, or overheat.

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
	PT-000011: Assembly, DASH Final PDM U100, mmol/L		
Sodium bicarbonate Exela Pharma	8.4% injection	Recall	Exela Pharma Sciences announced an expansion to the voluntary consumer-level recall of sodium bicarbonate 8.4% injection to include an additional 14 lots because the product poses a potential safety concern with vial breakage and flying glass when pressurized while preparing the product for administration. Sodium bicarbonate injection is indicated in the treatment of metabolic acidosis.
Truseltiq® (infigratinib) Helsinn Therapeutics	50 mg, 75 mg, 100 mg, and 125 mg capsules	Discontinuation	Helsinn Therapeutics recently announced the discontinuation of Truseltiq because of difficulties in recruiting and enrolling study participants for the required confirmatory trial. The discontinuation is not due to safety or efficacy reasons. Truseltiq is indicated for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 fusion or other rearrangement as detected by an FDA-approved test.

Key guideline/Literature updates

Topic	Reference
National Institutes of Health – COVID-19 Treatment	*COVID-19 Treatment Guidelines*. December 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma - Version 2.2023	*NCCN Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma*. November 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Occult Primary - Version 2.2023	*NCCN Clinical Practice Guidelines in Oncology: Occult Primary*. November 2022

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma - Version 1.2023	*NCCN Clinical Practice Guidelines in Oncology: Pancreatic Adenocarcinoma*. November 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia - Version 1.2023	*NCCN Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia*. November 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Systemic Light Chain Amyloidosis - Version 2.2023	*NCCN Clinical Practice Guidelines in Oncology: Systemic Light Chain Amyloidosis*. November 2022

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