Optum Rx®

RxHighlights

December 2024

Learn more

New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Alhemo® (concizumab-mtci) *† Novo Nordisk	Tissue factor pathway inhibitor antagonist	Approved for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients 12 years of age and older with **Hemophilia A (congenital factor VIII deficiency) with FVIII inhibitors, or Hemophilia B (congenital factor IX deficiency) with FIX inhibitors.**	December 23, 2024
Alyftrek™ (vanzacaftor/tezacaftor/deutivacaftor) *† Vertex	CF transmembrane conductance modulators	Treatment of **cystic fibrosis in patients 6 years of age and older who have at least one F508del mutation or another responsive mutation in the cystic fibrosis transmembrane conductance regulator gene**.	December 20, 2024
Bizengri® (zenocutuzumab-zbco)*† Merus	Bispecific HER2-and HER3-directed antibody	Treatment of adults with: 1) Advanced, unresectable or metastatic non-small cell lung cancer harboring a neuregulin 1 gene fusion with disease progression on or after prior systemic therapy 2) Advanced, unresectable or metastatic pancreatic adenocarcinoma harboring a NRG1 gene fusion with disease progression on or after prior systemic therapy.	December 4, 2024
Crenessity™ (crinecerfont)*† Neurocrine Biosciences	Corticotropin-releasing factor type 1 receptor antagonist	Adjunctive treatment to glucocorticoid replacement to control androgens in adults and pediatric patients 4 years of age and older with classic congenital adrenal hyperplasia.	December 13, 2024
Ensacove™ (ensartinib)* Xcovery	Kinase inhibitor	Treatment of adult patients with **anaplastic lymphoma kinase (ALK)-positive locally advanced or metastatic non-small cell lung cancer** who have not previously received an ALK-inhibitor.	December 18, 2024

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Opdivo Qvantig™ (nivolumab/hyaluronidase-nvhy) Bristol Myers Squibb	Programmed death receptor-1-blocking antibody	Approved indications include renal cell carcinoma, melanoma, non-small cell lung cancer, head and neck squamous cell carcinoma, urothelial carcinoma, colorectal cancer, hepatocellular carcinoma, esophageal carcinoma, gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma.	December 27, 2024
Ryoncil® (remestemcel-L-rknd) † Mesoblast	Cellular therapy	Treatment of steroid refractory **acute graft versus host disease in pediatric patients** 2 months of age and older.	December 18, 2024
Tryngolza™ (olezarsen) *† Ionis Pharmaceuticals	Familial chylomicronemia syndrome	An adjunct to diet **to reduce triglycerides in adults with familial chylomicronemia syndrome.**	December 19, 2024
Unloxcyt™ (cosibelimab-ipdl) Checkpoint Therapeutics	Programmed death ligand-1 blocking antibody	The treatment of **adults with metastatic cutaneous squamous cell carcinoma or locally advanced CSCC** who are not candidates for curative surgery or curative radiation.	December 13, 2024

* New molecular entity; †Orphan drug

New biosimilars

Learn more

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Steqeyma® (ustekinumab-stba) Celltrion	Human interleukin-12 and -23 antagonist	1. Steqeyma is the 7th biosimilar to Janssen's Stelara® (ustekinumab). 2. Steqeyma, Yesintek, Imuldosa, Otulfi, Pyzchiva, Wezlana, Selarsdi and Stelara share the following indications: a) Adults and pediatric patients 6 years and older with moderate to severe plaque psoriasis), who are candidates for phototherapy or systemic therapy b) Adults and pediatric patients 6 years and older with active psoriatic arthritis c) Adult patients with moderately to severely active Crohn's disease	December 18, 2024

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
		d) Adult patients with moderately to severely active ulcerative colitis.	
Yesintek™ (ustekinumab-kfce) Biocon	Human interleukin-12 and -23 antagonist	1. Biosimilar to Janssen's Stelara® (ustekinumab). 2. Yesintek, Imuldosa, Otulfi, Pyzchiva, Wezlana, Selarsdi and Stelara share the following indications: a) Adults and pediatric patients 6 years and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy b) Adults and pediatric patients 6 years and older with active psoriatic arthritis. c) Adult patients with moderately to severely active Crohn's disease, and d) Adult patients with moderately to severely active ulcerative colitis.	TBD

New generics

Learn more

Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Victoza® (liraglutide)† Novo Nordisk	Hikma	18 mg/3 mL (6 mg/mL) injection	Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.	December 24, 2024

†AP-rated generic manufacturer

Indications/Label updates

Learn more

Drug name manufacturer(s)	Type	Description
Arixtra® (fondaparinux) Mylan	New Indication	Treatment of venous thromboembolism in **pediatric patients aged 1 year or older weighing at least 10 kg.**
Braftovi® (encorafenib) Pfizer	New Indication	In combination with Erbitux® (cetuximab) and mFOLFOX6 (fluorouracil, leucovorin, and oxaliplatin), for the treatment of patients **with metastatic colorectal cancer with a *BRAF V600E* mutation**, as detected by an FDA-approved test.
Gemtesa® (vibegron) Sumitomo Pharma	New Indication	Treatment of **overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency in adult males on pharmacological therapy for benign prostatic hyperplasia.**
Imcivree® (setmelanotide) Rhythm Pharmaceuticals	Expanded Indication	To reduce excess body weight and maintain weight reduction long term in **adults and pediatric patients aged 2 years and older with syndromic or monogenic obesity due to:** (1) Bardet-Biedl syndrome (BBS) and (2) pro-opiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency as determined by an FDA-approved test demonstrating variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance.
Invokana® (canagliflozin), **Invokamet/Invokamet® XR** (canagliflozin/metformin) Janssen	Expanded Indication	Adjunct to diet and exercise to improve glycemic control in adults and pediatric patients aged 10 years and older with type **2 diabetes mellitus.**
Nemluvio® (nemolizumab-ilto) Galderma	New Indication	Treatment of adults and pediatric patients 12 years of age and older with **moderate-to-severe atopic dermatitis** in combination with topical corticosteroids and/or calcineurin inhibitors when the disease is not adequately controlled with topical prescription therapies.
Vtama® (tapinarof) Dermavant Sciences	New Indication	Topical treatment of **atopic dermatitis in adults and pediatric patients 2 years of age and older**.
Zepbound® (tirzepatide) **Eli Lilly**	New Indication	Treatment of **moderate to severe obstructive sleep apnea in adults with obesity.**

Drug safety news / Drug updates

Learn more

Drug name manufacturer(s)	Description
Ocaliva® (obeticholic acid) Intercept Pharmaceuticals	The FDA announced that they have identified cases of serious liver injury among patients being treated for primary biliary cholangitis (PBC) with Intercept's Ocaliva (obeticholic acid) who did not have cirrhosis of the liver. The FDA had previously identified that PBC patients with advanced cirrhosis were at risk of serious liver injury when taking Ocaliva and updated the prescribing information to restrict its use in these patients. What is new is the identification of serious liver injury in individuals without cirrhosis.
Trikafta® (elexacaftor/tezacaftor/ivacaftor; ivacaftor) Vertex	**The FDA approved the expanded use of Trikafta** (elexacaftor/tezacaftor/ivacaftor; ivacaftor) for the treatment of people with cystic fibrosis ages 2 and older who have at least one *F508del* mutation in the cystic fibrosis transmembrane conductance regulator *(CFTR)* gene or a mutation that is responsive to Trikafta based on clinical and/or *in vitro* data.
Veozah® (fezolinetant)	The FDA approved a label update to Astellas' Veozah (fezolinetant), adding a ***Boxed Warning*** **for the risk of hepatotoxicity.**

Drug recalls/Withdrawals/Shortages/Discontinuations

Learn more

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Astagraf XL® (tacrolimus extended-release capsules) Astellas	0.5 mg XL capsules, 30 count	Recall	Astellas announced a voluntary, consumer level recall of one lot of Astagraf XL (tacrolimus) extended-release capsules and one lot of Prograf (tacrolimus) capsules because some bottles may contain empty capsules.
Prograf® (tacrolimus) Astellas	0.5 mg capsules, 100 count		
Jesduvroq® (daprodustat) GSK	1 mg, 2 mg, 4 mg, 6 mg, and 8 mg tablets	Withdrawal	GSK announced the decision to voluntarily withdraw Jesduvroq (daprodustat) from the US marketplace due to business reasons. The withdrawal is not due to any safety or efficacy issues.

Key guideline/Literature updates from the National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology – December 2024

- **Acute Lymphoblastic Leukemia Version 3.2024**
- **Acute Myeloid Leukemia Version 1.2025**
- **Ampullary Adenocarcinoma Version 1.2025**
- **Anal Carcinoma Version 1.2025**
- **B-Cell Lymphomas Version 1.2025**
- **Castleman Disease Version 1.2025**
- **Cervical Cancer Version 1.2025**
- **Esophageal and Esophagogastric Junction Cancers Version 5.2024**
- **Gastric Cancer Version 5.2024**
- **Gestational Trophoblastic Neoplasia Version 1.2025**
- **Hodgkin Lymphoma Version 1.2025**
- **Melanoma: Cutaneous Version 1.2025**
- **Non-Small Cell Lung Cancer Version 1.2025**
- **Pancreatic Adenocarcinoma Version 1.2025**
- **Pediatric Acute Lymphoblastic Leukemia Version 2.2025**
- **Prostate Cancer Version 1.2025**
- **Small Bowel Adenocarcinoma Version 1.2025**
- **Uterine Neoplasms Version 1.2025**
- **Vaginal Cancer Version 3.2025**
- **Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma Version 2.2025**
- **Management of Immunotherapy-Related Toxicities Version 1.2025**
- **Survivorship Version 2.2024**
- **Older Adult Oncology Version 1.2025**

Reference: https://www.nccn.org/guidelines/recently-published-guidelines