Optum Rx®

RxHighlights

August 2024

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New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Crexont® (carbidopa/levodopa) Amneal Pharmaceuticals	Dopamine precursor/ dopa-decarboxylase inhibitor	Treatment of Parkinson's disease, post-encephalitic parkinsonism, and parkinsonism that may follow carbon monoxide intoxication or manganese intoxication in adults	August 8, 2024
Lazcluze™ (lazertinib)***** J&J	Kinase inhibitor	Treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with epidermal growth factor receptor (EGFR) exon 19 deletions or exon 21 L858R substitution mutations, as detected by an FDA-approved test	August 23, 2024
Livdelzi® (seladelpar)†* Gilead	Peroxisome proliferator-activated receptor delta agonist	Treatment of primary biliary cholangitis in combination with ursodeoxycholic acid in adults who have had an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA	August 16, 2024
Lymphir™ (denileukin diftitox-cxdl)† Citius Pharmaceuticals	CD25-directed cytotoxin	Treatment of adult patients with relapsed or refractory stage I - III cutaneous T-cell lymphoma after at least one prior systemic therapy	TBD
Neffy® (epinephrine) ARS Pharmaceuticals	Non-selective alpha/ beta-adrenergic receptor agonist	Emergency treatment of type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 30 kg or greater	August 15, 2024
Nemluvio® (nemolizumab-ilto)* Galderma	Interleukin-31 receptor antagonist	Treatment of adults with prurigo nodularis	August 14, 2024
Niktimvo™ (axatilimab-csfr)†* Incyte and Syndax Pharmaceuticals	Colony stimulating factor-1 receptor-blocking antibody	Treatment of chronic graft-versus-host disease after failure of at least two prior lines of systemic therapy in adult and pediatric patients weighing at least 40 kg	1Q 2025

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Tecelra® (afamitresgene autoleucel)† Adaptimmune Therapeutics	SPEAR T-cell therapy	Treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA-A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the melanoma-associated antigen A4 antigen as determined by FDA-approved or cleared companion diagnostic devices.	August 5, 2024
Voranigo® (vorasidenib)†* Servier Pharmaceuticals	Isocitrate dehydrogenase-1 and -2 inhibitor	Treatment of adult and pediatric patients 12 years and older with grade 2 astrocytoma or oligodendroglioma with a susceptible isocitrate dehydrogenase-1 or isocitrate dehydrogenase-2 mutation following surgery including biopsy, sub-total resection, or gross total resection.	August 12, 2024
Yorvipath® (palopegteriparatide)†* Ascendia Pharma	Parathyroid hormone	Treatment of hypoparathyroidism in adults	1Q 2025
Zurnai™ (nalmefene) **Purdue Pharma**	Opioid receptor antagonist	Emergency treatment of known or suspected opioid overdose induced by natural or synthetic opioids in adults and pediatric patients aged 12 years and older, as manifested by respiratory and/or central nervous system depression	TBD

***** New molecular entity; †Orphan drug; TBD: To be determined

New biosimilars

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Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Enzeevu™ (aflibercept-abzv) Sandoz	Vascular endothelial growth factor-A (VEGF-A) inhibitor/ placental growth factor (PlGF) inhibitor	Biosimilar to Eylea (aflibercept), Enzeevu, Ahzantive, Opuviz,and Yesafili and share indications for the treatment of 1.) Neovascular (wet) age-related macular degeneration	TBD
Pavblu™ (aflibercept-ayyh) Regeneron	Vascular endothelial growth factor-A (VEGF-A) inhibitor/ placental growth factor (PlGF) inhibitor	Biosimilar to Eylea (aflibercept), Pavblu, Enzeevu, Ahzantive, Opuviz and Yesafili and share indications for the treatment of 1.) Macular edema following retinal vein occlusion 2.) Diabetic macular edema 3.) Diabetic retinopathy	TBD

TBD: To be determined

New generics

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Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Lucemyra® (lofexidine)* Indoco Remedies	US WorldMeds	0.18 mg tablets	Opioid Withdrawal Symptoms	August 21, 2024

* AB-rated generic versions; †AA-rated generic version

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Indications/Label updates

Drug name manufacturer(s)	Type	Description
ACAM2000™ (smallpox and mpox (vaccinia) vaccine, live)	New Indication	Active immunization for the prevention of smallpox and mpox disease in individuals determined to be at high risk for smallpox or mpox (previously called monkeypox) infection
Fabhalta® (iptacopan) Novartis	New Indication	Reduce proteinuria in adults with primary immunoglobulin A nephropathy at risk of rapid disease progression, generally a urine protein-to-creatinine ratio ≥ 1.5 g/g. Treatment of adults with paroxysmal nocturnal hemoglobinuria.
Furoscix® (furosemide) scPharmaceuticals	Expanded Indication	Treatment of congestion due to fluid overload in adult patients with chronic heart failure
Imfinzi® (durvalumab) AstraZeneca	New Indication	Treatment of adult patients with resectable (tumors ≥ 4 cm and/or node positive) non-small cell lung cancer (NSCLC) and no known epidermal growth factor receptor mutations or anaplastic lymphoma kinase rearrangements
Jemperli (dostarlimab-gxly) GSK	Expanded Indication	Treatment of adult patients with primary advanced or recurrent endometrial cancer
Nexobrid® (anacaulase-bcdb) Vericel Corporation	Expanded Indication	Approved for eschar removal in adults and pediatric patients with deep partial thickness and/or full thickness thermal burns
Protonix® I.V. (pantoprazole) Pfizer	Expanded Indication	Treatment of gastroesophageal reflux disease and a history of erosive esophagitis for up to 10 days in adults and up to 7 days in pediatric patients 3 months and older
Prevymis® (letermovir) Merck	Expanded Indication	Prophylaxis of cytomegalovirus infection and disease in adult and pediatric patients 6 months of age and older and weighing at least 6 kg who are CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant and for prophylaxis of CMV disease in adult and pediatric patients 12 years of age and older and weighing at least 40 kg who are kidney transplant recipients at high risk (donor CMV seropositive/recipient CMV seronegative [D+/R-]).
	New Dosage Formulation	Prevymis was also approved as 20 mg or 120 mg per packet oral pellets.

Drug name manufacturer(s)	Type	Description
Rybrevant® (amivantamab) J&J	New Indication	Treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, as detected by an FDA-approved test. Treatment of adult patients with locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy.

Drug safety news / Drug updates

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Drug name manufacturer(s)	Description
Comirnaty® and Spikevax® (KP.2) 2024 – 2025 vaccines – FDA approval and Emergency Use Authorization	The FDA approved Pfizer/BioNTech's Comirnaty (KP.2) and Moderna's Spikevax (KP.2) COVID-19 vaccine in individuals 12 years of age and older as a single dose at least 2 months since the last dose of any COVID-19 vaccine. The FDA granted emergency use authorization to Pfizer/BioNTech's COVID-19 vaccine (2024-2025 formula) and Moderna's COVID-19 vaccine (2024-2025 formula) in individuals from 6 months to 11 years of age.
Novavax COVID-19 vaccine, adjuvanted (2024-2025 formula) – Emergency Use Authorization	The FDA had previously approved/authorized Pfizer/BioNTech and Moderna's mRNA COVID-19 vaccines (2024-2025 formula) for individuals 6 months of age and older on August 22, 2024. The FDA granted emergency use authorization for Novavax's Novavax COVID-19 vaccine, adjuvanted (2024-2025 formula), for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 in individuals 12 years of age and older.

Drug recalls/Withdrawals/Shortages/Discontinuations

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Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Heparin sodium Baxter	0.9% injection, 2,000 units per 1,000 mL	Recall	Baxter Healthcare Corporation announced a consumer level recall of one lot of heparin sodium injection because there were issues related to the bacterial endotoxin test specific to this lot number. Heparin sodium is indicated as an anticoagulant to maintain catheter patency.

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

- B-Cell Lymphomas - Version 3.2024
- Biliary Tract Cancers - Version 4.2024
- Bone Cancer - Version 1.2025
- Chronic Myeloid Leukemia - Version 1.2025
- Colon Cancer - Version 2.2024
- Gastric Cancer - Version 4.2024
- Gestational Trophoblastic Neoplasia - Version 2.2024
- Myeloproliferative Neoplasms - Version 2.2024
- Non-Small Cell Lung Cancer - Version 8.2024
- Occult Primary - Version 1.2025
- Pediatric Acute Lymphoblastic Leukemia - Version 1.2025
- Pediatric Aggressive Mature B-Cell Lymphomas - Version 2.2024
- Primary Cutaneous Lymphomas - Version 3.2024
- Rectal Cancer - Version 4.2024
- Small Cell Lung - Version 1.2025

- Thyroid Carcinoma - Version 4.2024
- Vaginal Cancer - Version 2.2025
- Breast Cancer Risk Reduction - Version 1.2025
- Genetic/Familial High-Risk Assessment: Colorectal, Endometrial, and Gastric - Version 1.2024
- Hematopoietic Cell Transplantation - Version 2.2024
- Hematopoietic Cell Transplantation - Version 2.2024

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

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