Optum Rx®

RxHighlights

September 2024

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New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Aqneursa™ (levacetylleucine)*† IntraBio	Modified amino acid	Treatment of neurological manifestations of Niemann-Pick disease type C in adults and pediatric patients weighing ≥15 kg.	September 25, 2024
Cobenfy™ (xanomeline and trospium hydrochloride)* Bristol-Meyers Squibb	Muscarinic agonist/ muscarinic antagonist	Treatment of schizophrenia in adults.	September 26, 2024
Ebglyss™ (lebrikizumab-lbkz)* **Eli Lilly**	Interleukin-13 antagonist	Treatment of adults and pediatric patients 12 years of age and older who weigh at least 40 kg with moderate-to-severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable.	September 13, 2024
FluMist (influenza vaccine live) AstraZeneca	Vaccine	Approved intranasal spray, for self- or caregiver-administration. Approved for the prevention of influenza disease caused by influenza virus subtypes A and B in individuals 2 through 49 years of age.	September 20, 2024
Miplyffa™ (arimoclomol)† Zevra Therapeutics	Cytoprotective	Approved for use in combination with miglustat for the treatment of neurological manifestations of Niemann-Pick disease type C in adult and pediatric patients 2 years of age and older.	September 20, 2024
Ocrevus Zunovo™ **(**ocrelizumab/hyaluronidase-ocsq) Roche	CD20-directed cytolytic antibody	Treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults and primary progressive MS, in adults.	September 13, 2024
Tecentriq Hybreza™ (atezolizumab/hyaluronidase-tqjs) Roche	Programmed death-ligand 1 blocking antibody	New subcutaneous formulation.For all intravenous indications of Tecentriq® (atezolizumab) approved for adults, including certain types of lung, liver, skin and soft tissue cancer.	September 12, 2024

* New molecular entity; †Orphan drug

New biosimilars

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Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Otulfi™ (ustekinumab-aauz) Formycon and Fresenius Kabi	Human interleukin-12 and -23 antagonist	Biosimilar to Janssen's Stelara® (ustekinumab) and shares indications for: Adult patients with: 1.) moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy 2.) Active psoriatic arthritis 3.) Moderately to severely active Crohn's disease 4.) Moderately to severely active ulcerative colitis Pediatric patients 6 years and older with 1.) Moderately to severely active plaque psoriasis, who are candidates for phototherapy or systemic therapy 2.) Active psoriatic arthritis	02/22/2025

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New generics

Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Oxtellar XR® (oxcarbazepine)* Apotex	Supernus	150 mg, 300 mg 600 mg tablets	For the treatment of partial-onset seizures in patients 6 years of age and older	September 1, 2024
Sprycel® (dasatinib)* Apotex	Bristol Myers Squibb	20 mg, 50 mg, 70 mg, 80 mg, 100 mg, 140 mg tablets	Adults and pediatrics (1 year and older) with Philadelphia chromosome positive chronic myeloid leukemia or acute lymphoblastic leukemia	September 1, 2024

* AB-rated generic versions

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Indications/Label updates

Drug name manufacturer(s)	Type	Description
Bimzelx® (bimekizumab) **UCB**	New indication	Treatment of adult patients with active psoriatic arthritis, active non-radiographic axial spondyloarthritis with objective signs of inflammation or active ankylosing spondylitis
Cimzia® (certolizumab pegol) UCB	New indication	Treatment of active polyarticular juvenile idiopathic arthritis in patients 2 years of age and older
Dupixent® (dupilumab) Regeneron	Expanded indication	Add-on maintenance treatment in adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps
Dupixent® (dupilumab) Regeneron and Sanofi	New indication approval	Add-on maintenance treatment in adults with uncontrolled COPD and an eosinophilic phenotype

Drug name manufacturer(s)	Type	Description
Fasenra® (benralizumab) AstraZeneca	New indication	Treatment of adult patients with eosinophilic granulomatosis with polyangiitis
Filspari® (sparsentan) Travere Therapeutics	Updated indication, accelerated approval converted to full approval	To slow kidney function decline in adults with primary immunoglobulin A nephropathy who are at risk for disease progression.
Keytruda® (pembrolizumab) Merck	New indication	In combination with pemetrexed and platinum chemotherapy, for the first-line treatment of adult patients with unresectable advanced or metastatic malignant pleural mesothelioma.
Kisqali® (ribociclib) Novartis	New indication	In combination with an aromatase inhibitor for the adjuvant treatment of adults with hormone receptor positive, human epidermal growth factor receptor 2 negative stage II and III early breast cancer at high risk of recurrence.
Rybrevant® (amivantamab-vmjw) J&J	New indication	In combination with carboplatin and pemetrexed, for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer with EGFR exon 19 deletions or exon 21 L858R substitution mutations, whose disease has progressed on or after treatment with an EFGR tyrosine kinase inhibitor.
Sarclisa® (isatuximab-irfc) Sanofi	New indication	In combination with bortezomib, lenalidomide, and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplant.
Tagrisso® (osimertinib) AstraZeneca	New indication	Treatment of adult patients with locally advanced, unresectable (stage III) non-small cell lung cancer whose disease has not progressed during or following concurrent or sequential platinum-based chemoradiation therapy and whose tumors have epidermal growth factor receptor exon 19 deletions or exon 21 L858R mutations, as detected by an FDA-approved test.
Tremfya® (guselkumab) J&J	New indication	Treatment of adult patients with moderately to severely active ulcerative colitis.

Drug recalls/Withdrawals/Shortages/Discontinuations

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Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Atovaquone Bionpharma	750 mg/5 mL oral suspension	Recall	Bionpharma announced a consumer level recall of one lot of atovaquone oral suspension because the lot contained Cohnella bacteria. Atovaquone is indicated for prevention and treatment of *Pneumocystis jiroveci pneumonia* in adults and children 13 years of age and older who cannot tolerate other medicines, such as trimethoprim-sulfamethoxazole.
Oxbryta® (voxelotor) Pfizer	300 mg & 500 mg tablets 300 mg soluble tablets	Withdrawal	Pfizer announced a voluntary withdrawal of all lots of Oxbryta (voxelotor) tablets because the overall benefit of Oxbryta no longer outweighs the risk in the approved sickle cell patient population. Oxbryta is approved for the treatment of sickle cell disease in adults and pediatric patients 4 years of age and older.
Veklury® (remdesivir) Gilead	100 mg injection	Recall	Gilead announced a voluntary, consumer level recall of one lot of Veklury (remdesivir) injection because of the presence of a glass particle in the vial. Veklury is indicated for the treatment of COVID-19 in adults and pediatric patients (birth to less than 18 years of age weighing at least 1.5 kg) who are hospitalized, or not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19, including hospitalization or death.

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

- Central Nervous System Cancers - Version 3.2024
- Cervical Cancer - Version 4.2024
- Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma - Version 1.2025
- Hairy Cell Leukemia - Version 1.2025
- Hepatocellular Carcinoma - Version 3.2024
- Melanoma: Cutaneous - Version 3.2024
- Mesothelioma: Peritoneal - Version 3.2024
- Mesothelioma: Pleural - Version 2.2024
- Multiple Myeloma - Version 1.2025
- Non-Small Cell Lung Cancer - Version 10.2024
- Occult Primary - Version 2.2025
- Small Bowel Adenocarcinoma - Version 5.2024
- Soft Tissue Sarcoma - Version 3.2024
- Systemic Light Chain Amyloidosis - Version 1.2025
- Uterine Neoplasms - Version 3.2024
- Waldenström Macroglobulinemia/Lymphoplasmacytic Lymphoma - Version 1.2025
- Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic - Version 1.2025
- Genetic/Familial High-Risk Assessment: Colorectal, Endometrial, and Gastric - Version 2.2024
- Antiemesis - Version 2.2024
- Prevention and Treatment of Cancer-Related Infections - Version 3.2024
- Adolescent and Young Adult (AYA) Oncology - Version 2.2025

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