Optum Rx®

RxHighlights

October 2024

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New drugs

Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Bimzelx® (bimekizumab-bkzx) UCB	Interleukin-17 receptor inhibitor	Treatment of plaque psoriasis, psoriatic arthritis, non-radiographic axial spondyloarthritis, and ankylosing spondylitis.	October 14, 2024
Hympavzi™ (marstacimab-hncq) Pfizer	Anti-tissue factor pathway inhibitor	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) without factor VIII inhibitors, or Hemophilia B (congenital factor IX deficiency) without factor IX inhibitors.	October 11, 2024
Itovebi™ (inavolisib) Genentech	Kinase inhibitor	Treatment of adults with endocrine-resistant, PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, as detected by an FDA-approved test, following recurrence on or after completing adjuvant endocrine therapy.	October 10, 2024
Orlynvah™ (sulopenem etzadroxil/probenecid) Iterum Therapeutics	Carbapenem	Treatment of uncomplicated urinary tract infections caused by the designated microorganisms Escherichia coli, Klebsiella pneumoniae, or Proteus mirabilis in adult women who have limited or no alternative oral antibacterial treatment options.	October 25, 2024
Vyalev™ (foscarbidopa/foslevodopa) AbbVie	Aromatic amino acid decarboxylation inhibitor/ aromatic amino acid	Treatment of motor fluctuations in adults with advanced Parkinson's disease.	October 17, 2024
Vyloy® (zolbetuximab-clzb) Astellas	GC182 monoclonal antibody	Treatment of adults with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-negative gastric or gastroesophageal junction adenocarcinoma whose tumors are claudin (CLDN) 18.2 positive as determined by an FDA-approved test.	October 18, 2024

* New molecular entity; †Orphan drug

New biosimilars

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Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Imuldosa™ (ustekinumab-srlf) Accord	Dermatologicals	Biosimilar to Janssen's Stelara® (Ustekinumab) and shares indications for: 1) Adults and pediatric patients 6 years and older with moderate to severe plaque psoriasis, who are candidates for phototherapy or systemic therapy 2) Adults and pediatric patients 6 years and older with active psoriatic arthritis. 3) Adult patients with moderately to severely active Crohn's disease. 4) Adult patients with moderately to severely active ulcerative colitis.	TBD
Pavblu™ (aflibercept-ayyh) Amgen	Ophthalmic Agents	Biosimilar to Regeneron's Eylea® (aflibercept).and approved for the treatment of: 1) Neovascular (wet) age-related macular degeneration 2) Macular edema following retinal vein occlusion 3) Diabetic macular edema 4) Diabetic retinopathy.	October 30, 2024

TBD: To be determined

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New generics

Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Sandostatin® LAR Depot (octreotide) Novartis	Teva	10 mg, 20 mg and 30 mg Intragluteal Injection	• Sandostatin LAR Depot is approved for the following indications: • Long-term maintenance therapy in acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy, is not an option • Long-term treatment of the severe diarrhea and flushing episodes associated with metastatic carcinoid tumors • Long-term treatment of the profuse watery diarrhea associated with Vasoactive Intestinal Peptide (VIP)-secreting tumors.	October 1, 2024
Stendra® (avanafil) Petros	Camber	50 mg, 100 mg, 200 mg tablets	Treatment of erectile dysfunction in adult males.	October 29, 2024

* AB-rated generic versions

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Indications/Label updates

Drug name manufacturer(s)	Type	Description
Abrysvo® (respiratory syncytial virus vaccine) Pfizer	New indication	Prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals 18 through 59 years of age who are at increased risk for LRTD caused by RSV.

Drug name manufacturer(s)	Type	Description
Lumryz™ (sodium oxybate) Avadel Pharmaceuticals	Expanded indication	Treatment of cataplexy or excessive daytime sleepiness in patients 7 years of age and older with narcolepsy.
Opdivo® (nivolumab) Bristol-Myers Squibb	New indication	Neoadjuvant treatment of adult patients with resectable (tumors ≥ 4 cm or node positive) non-small cell lung cancer and no known epidermal growth factor receptor mutations or anaplastic lymphoma kinase rearrangements, in combination with platinum-doublet chemotherapy followed by single-agent Opdivo as adjuvant treatment after surgery.
Scemblix® (asciminib) Novartis	New indication	Treatment of adult patients with newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia in chronic phase.
Selarsdi™ (ustekinumab-aekn) Alvotech and Teva	New Indication and formulation approval	Treatment of adult patients with moderately to severely active Crohn's disease and moderately to severely active ulcerative colitis. Approved for a single-dose vial of 130 mg/26 mL solution for intravenous infusion.
Trodelvy™ (sacituzumab govitecan-hziy) Gilead	Indication withdrawal	Treatment of adult patients with locally advanced or metastatic urothelial cancer who have previously received a platinum-containing chemotherapy and either programmed death receptor-1 or programmed death-ligand 1 inhibitor.

Drug safety news / Drug updates

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Drug name manufacturer(s)	Description
COVID-19 vaccines	The Centers for Disease Control and Prevention's Director endorsed the CDC's Advisory Committee on Immunization Practice's recommendation for people 65 years and older and those who are moderately or severely immunocompromised to receive a second dose of 2024 - 2025 COVID-19 vaccine six months after their first dose.

Drug recalls/Withdrawals/Shortages/Discontinuations

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Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
MiniMed™ insulin pumps Medtronic	600 series or 700 series	Recall	Medtronic announced a consumer level recall of its MiniMed 600 series or 700 series insulin pumps due to reports of shortened battery life. A comprehensive analysis found that pumps that have been dropped, bumped, or experienced physical impact even once may result in shortened battery life due to damage to internal electrical components.
PreHevBrio® (hepatitis B vaccine [recombinant]) VBI Vaccines	10 mcg/mL vial	Discontinuation and Withdrawal	VBI Vaccines announced the decision to discontinue and withdraw PreHevBrio (hepatitis B vaccine [recombinant]) due to business reasons. The discontinuation and withdrawal are not due to any safety or efficacy issues.

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

- Bladder Cancer Version 5.2024
- Breast Cancer Version 5.2024
- Dermatofibrosarcoma Protuberans Version 1.2025
- Head and Neck Cancers Version 5.2024
- Hodgkin Lymphoma Version 4.2024
- Kaposi Sarcoma Version 1.2025
- Mesothelioma: Peritoneal Version 3.2024
- Mesothelioma: Pleural Version 2.2024
- Non-Small Cell Lung Cancer Version 11.2024
- Penile Cancer Version 1.2025
- Small Cell Lung Cancer Version 3.2025
- Testicular Cancer Version 2.2024
- Thymomas and Thymic Carcinomas Version 1.2025
- Wilms Tumor (Nephroblastoma) Version 2.2024
- Genetic/Familial High-Risk Assessment: Colorectal, Endometrial, and Gastric Version 3.2024
- Lung Cancer Screening Version 1.2025
- Hematopoietic Growth Factors Version 1.2025
- Management of Immunotherapy-Related Toxicities Version 2.2024
- Cancer in People with HIV Version 1.2025

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

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