Optum Rx®

# RxHighlights

## July 2024

Learn more

### New drugs

| Drug name manufacturer(s) | Therapeutic category | Indication(s) | Launch information |
|---|---|---|---|
| **Erzofri®™** (paliperidone palmitate)<br>Luye Pharma | Atypical antipsychotic | Treatment of schizophrenia in adults; and for the treatment of schizoaffective disorder in adults as monotherapy and as an adjunct to mood stabilizers or antidepressants | TBD |
| **Kisunla™** (donanemab-azbt)*<br>Eli Lilly | Beta-amyloid monoclonal antibody | Treatment of Alzheimer's disease. Treatment with Kisunla should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials | July 8, 2024 |
| **Leqselvi™** (deuruxolitinib)<br>Sun Pharma | Janus kinase inhibitor | Treatment of adults with severe alopecia areata | TBD |
| **Zunveyl®** (benzgalantamine)<br>Alpha Cognition | Acetylcholinesterase inhibitor | Treatment of adults with mild to moderate dementia of the Alzheimer's type | Q1 2025 |

*New molecular entity; TBD: To be determined

## New biosimilars

Learn more

| Drug name manufacturer(s) | Therapeutic category | Indication(s) | Launch information |
|---|---|---|---|
| **Ahzantive**™ (aflibercept-mrbb)<br>Formycon | Vascular endothelial growth factor (VEGF) inhibitor | Biosimilar to Eylea (aflibercept). Ahzantive and Eylea share indications for the treatment of<br>1.) Neovascular (wet) age-related macular degeneration<br>2.) Macular edema following retinal vein occlusion<br>3.) Diabetic macular edema<br>4.) Diabetic retinopathy | TBD |
| **Epysqli**® (eculizumab-aagh)<br>Samsung Bioepis | Monoclonal antibody (MAb) complement protein C5 inhibitor | Biosimilar to Soliris. Epysqli and Soliris share indications for the treatment of<br>1.) Patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis<br>2.) Patients with atypical hemolytic uremic syndrome to inhibit complement-mediated thrombotic microangiopathy | TBD |
| **Pyzchiva**® (ustekinumab-ttwe)<br>Samsung Bioepis and Sandoz | Human interleukin-12 and -23 antagonist | Biosimilar to Stelara. Pyzchiva and Stelara share indications for treatment of<br>1.) Adults and pediatric patients 6 years and older with moderate to severe plaque psoriasis (PsO), who are candidates for phototherapy or systemic therapy<br>2.) Adults and pediatric patients 6 years and older with active psoriatic arthritis (PsA)<br>3.) Adult patients with moderately to severely active Crohn's disease (CD)<br>4.) Adult patients with moderately to severely active ulcerative colitis (UC). | February 2025 |
| **Tyenne**® (tocilizumab-aazg)<br>Fresenius Kabi | Anti-interleukin-6 (anti-IL-6) receptor monoclonal antibody (MAb) | Biosimilar to Actemra. Tyenne and Actemra share the indication in<br>1.) Adult patients for moderately to severely active rheumatoid arthritis who have had an inadequate | July 2, 2024 |

| Drug name manufacturer(s) | Therapeutic category | Indication(s) | Launch information |
|---|---|---|---|
| | | response to one or more disease-modifying anti-rheumatic drugs<br>2.) Adult patients for giant cell arteritis<br>3.) Patients 2 years of age and older for active polyarticular juvenile idiopathic arthritis and active systemic juvenile idiopathic arthritis. | |

TBD: To be determined

## New generics

Learn more

| Drug name manufacturer(s) | Generic manufacturer(s) | Strength(s) & dosage form(s) | Therapeutic use | Launch information |
|---|---|---|---|---|
| **Corlanor®** (ivabradine)<br>Amgen | Ingenus, Camber, and Zydus* | 5 mg ivabradine film-coated tablets;<br>7.5 mg ivabradine film-coated tablets;<br>5 mg/5 mL (1 mg/mL) oral solution 5 mL ampules | 1.) To reduce the risk of hospitalization for worsening heart failure in adult patients with stable, symptomatic chronic heart failure with left ventricular ejection fraction ≤ 35%, who are in sinus rhythm with resting heart rate ≥ 70 beats per minute and either are on maximally tolerated doses of beta-blockers or have a contraindication to beta-blocker use.<br>2.) For the treatment of stable symptomatic heart failure due to dilated cardiomyopathy in pediatric patients aged 6 months and older, who are in sinus rhythm with an elevated heart rate. | July 15, 2024 |
| **Endari™** (L-glutamine oral powder)<br>Emmaus Medical | ANI Pharmaceuticals† | 60 Packets (5 grams/ packet) | To reduce the acute complications of sickle cell disease in adult and pediatric patients 5 years of age and older | July 15, 2024 |

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

## Indications/Label updates

Learn more

| Drug name manufacturer(s) | Type | Description |
|---|---|---|
| **Brineura®** (cerliponase alfa) BioMarin | Expanded Indication | Slow the loss of ambulation in pediatric patients with neuronal ceroid lipofuscinosis type 2, also known as tripeptidyl peptidase 1 deficiency |
| **Fibryga®** (fibrinogen [human]) Octapharma | New Indication | Treatment of acute bleeding episodes in patients with acquired fibrinogen deficiency |
| **Darzalex Faspro®** (daratumumab/hyaluronidase-fihj) Johnson & Johnson | New Indication | Treatment of adult patients with multiple myeloma in combination with bortezomib, lenalidomide, and dexamethasone for induction and consolidation in newly diagnosed patients who are eligible for autologous stem cell transplant |
| **Kisqali®** (ribociclib) Novartis | Updated indication | Treatment of adults with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with fulvestrant as initial endocrine-based therapy or with disease progression following endocrine therapy. |
| **Livmarli®** (maralixibat) Mirum Pharmaceuticals | Expanded indication | Treatment of cholestatic pruritus in patients 12 months of age and older with progressive familial intrahepatic cholestasis (previously only for symptomatic patients 5 years and older) |
| | New strength | The FDA approved a new 19 mg/mL oral solution strength of Livmarli |
| **Palforzia®** (peanut [Arachis hypogaea] allergen powder-dnfp) Aimmune Therapeutics | Expanded indication | Mitigation of allergic reactions, including anaphylaxis, that may occur with accidental exposure to peanut. Palforzia is approved for use in patients with a confirmed diagnosis of peanut allergy. Initial dose escalation may be administered to patients aged 1 through 17 years. Up-dosing and maintenance may be continued in patients 1 year of age and older |
| **Tezruly™ (terazosin)** Novitium | New formulation | The FDA approved an oral solution formulation of terazosin, for the treatment of signs and symptoms of benign prostatic hyperplasia (BPH), and for the treatment of hypertension alone or with other antihypertensive agents. |

| Drug name manufacturer(s) | Type | Description |
|---|---|---|
| **Velphoro®** (sucroferric oxyhydroxide)<br>Fresenius | Expanded indication | Control of serum phosphorus levels in adults and pediatric patients 9 years of age and older with chronic kidney disease on dialysis (pediatric population is new). |
| **Voquezna®** (vonoprazan)<br>Phathom Pharmaceuticals | New indication | Relief of heartburn associated with non-erosive gastroesophageal reflux disease in adults. |
| **Zoryve®** (roflumilast)<br>Arcutis Biotherapeutics | New indication | Treatment of mild to moderate atopic dermatitis in adult and pediatric patients 6 years of age and older.<br>Topical treatment of plaque psoriasis, including intertriginous areas, in adult and pediatric patients 6 years of age and older. |
| | New strength | The FDA approved a new 0.15% strength of Zoryve |

## Drug recalls/Withdrawals/Shortages/Discontinuations

Learn more

| Drug name manufacturer(s) | Strength(s) and dosage form(s) | Type | Description |
|---|---|---|---|
| **Acetaminophen**<br>Hikma | 1,000 mg per 100 mL (10 mg/mL) injection | Recall | Hikma announced a consumer level recall of one lot of acetaminophen injection 1000 mg/100 mL (10 mg/mL) due to the potential presence of a bag labelled dexmedetomidine injection (400 mcg/100 mL) inside the overwrap that is labeled acetaminophen injection, 1000 mg/100 mL, (10 mg/mL).<br>Acetaminophen injection is indicated for the management of mild to moderate pain in adult and pediatric patients 2 years and older, the management of moderate to severe pain with adjunctive opioid analgesics in adult and pediatric patients 2 years and older and the reduction of fever in adult and pediatric patients. |

| Drug name manufacturer(s) | Strength(s) and dosage form(s) | Type | Description |
|---|---|---|---|
| | | | Dexmedetomidine is indicated for intensive care unit sedation and procedural sedation. |
| **Clonazepam**<br>Endo | 0.25 mg orally disintegrating tablets; 0.125 mg orally disintegrating tablets | Recall | Endo announced a consumer level recall of one lot of clonazepam orally disintegrating 0.25 mg tablets because they may have been packaged in a carton labelled as 0.125 mg.<br>Clonazepam orally disintegrating tablet is used for the treatment of the Lennox-Gastaut syndrome (petit mal variant), akinetic and myoclonic seizures, absence seizures (petit mal), and for the treatment of panic disorder, with or without agoraphobia, as defined in DSM-V. |
| **Sodium Chloride Injection**<br>B. Braun Medical | 0.9% injection, 1000 mL | Recall | B. Braun Medical announced a consumer level recall of two lots of sodium chloride 0.9% injection due to the potential for particulate matter and leakage.<br>Sodium chloride injection is indicated for use as a source of electrolytes and water for hydration; fluid replacement; treatment of metabolic alkalosis; and as a diluent for the infusion of compatible drug additives. |
| **FreeStyle Libre 3 Sensors**<br>Abbott | N/A | Recall | Abbott announced a consumer level recall of three lots of FreeStyle Libre 3 sensors because the sensors may provide incorrect high glucose readings.<br>FreeStyle Libre 3 sensors provide continuous glucose monitoring levels for patients with diabetes.<br>The FreeStyle Libre 3 system includes a sensor, reader and app. This recall impacts the sensor only. The FreeStyle Libre 3 reader and app are not impacted. |

## Key guideline/Literature updates – July 2024

| Topic | Reference |
|---|---|
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia - Version 2.2024 | https://www.nccn.org/guidelines/recently-published-guidelines |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Central Nervous System Cancers - Version 2.2024 | |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers - Version 4.2025 | |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastrointestinal Stromal Tumors - Version 2.2024 | |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Histiocytic Neoplasms - Version 2.2024 | |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes - Version 3.2024 | |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal - Version 3.2024 | |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Acute Lymphoblastic Leukemia - Version 6.2024 | |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma - Version 2.2024 | |
| National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Wilms Tumor (Nephroblastoma) - Version 1.2024 | |