Optum Rx®

RxHighlights

February 2023

New drugs

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Drug name manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Altuviiio™ (antihemophilic factor [recombinant], Fc-VWF-XTEN fusion protein-ehtl)† Bioverativ Therapeutics and Sanofi	Recombinant factor VIII	Use in adults and children with hemophilia A (congenital factor VIII deficiency) for routine prophylaxis to reduce the frequency of bleeding episodes; on-demand treatment and control of bleeding episodes; and perioperative management of bleeding	TBD
Atorvaliq® (atorvastatin) oral suspension CMP Pharma	HMG-CoA reductase inhibitor	To reduce the risk of myocardial infarction (MI), stroke, revascularization procedures, and angina in adults with multiple risk factors for coronary heart disease (CHD) but without clinically evident CHD; MI and stroke in adults with type 2 diabetes mellitus with multiple risk factors for CHD but without clinically evident CHD; non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for congestive heart failure, and angina in adults with clinically evident CHD. Adjunct to diet to reduce low-density lipoprotein cholesterol (LDL-C) in adults with primary hyperlipidemia or adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia. Adjunct to other LDL-C lowering therapies, or alone if such treatments are unavailable, to reduce LDL-C in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia. Adjunct to diet for the treatment of adults with primary dysbetalipoproteinemia or hypertriglyceridemia	March 3, 2023
Austedo® XR (deutetrabenazine) 6 mg, 12 mg and 24 mg extended-release tablets Teva	Vesicular monoamine transporter-2 inhibitor	In adults for the treatment of chorea associated with Huntington's disease and tardive dyskinesia	TBD

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Filspari™ (sparsentan)†* Travere Therapeutics	Dual endothelin angiotensin receptor antagonist	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	February 22, 2023
Jesduvroq (daprodustat)* GSK	Hypoxia-inducible factor-prolyl hydroxylase inhibitor	Treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least four months	TBD
Lamzede® (velmanase alfa-tycv)†* Chiesi Global Rare Diseases	Enzyme replacement therapy	Treatment of non-central nervous system manifestations of alpha mannosidosis in adult and pediatric patients	TBD
Skyclarys™ (omaveloxolone)†* Reata Pharmaceuticals	Nrf2 pathway activator	Treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older	Second quarter of 2023
Syfovre™ (pegcetacoplan) Apellis	Compliment C3 inhibitor	Treatment of geographic atrophy secondary to age-related macular degeneration	February 21,2023
Tezspire® (teplizumab-ekko) solution in a single-dose pre-filled pen AstraZeneca and Amgen	Thymic stromal lymphopoietin antagonist	Add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma	February 13, 2023

*New molecular entity; †Orphan drug

New generics

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Drug name manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Latuda® (lurasidone) Sunovion	Accord†, Amneal†, Dr. Reddy's†, MSN/Novadoz†, Sun†, Alkem/Ascend†, Zydus†, and Lupin†	20 mg, 40 mg, 60 mg, 80 mg and 120 mg tablets	Schizophrenia; major depressive episode associated with bipolar I disorder; adjunctive treatment with lithium or valproate in adults with major depressive episode associated with bipolar I disorder	February 20, 2023

†A-rated generic manufacturer

Indications/Label updates

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Drug name manufacturer(s)	Type	Description
Cibinqo® (abrocitinib) Pfizer	Expanded indication	Treatment of adults and pediatric patients 12 years of age and older with refractory, moderate-to-severe atopic dermatitis whose disease is not adequately controlled with other systemic drug products, including biologics, or when use of those therapies is inadvisable
Eylea® (aflibercept) Regeneron	New orphan indication	Treatment of retinopathy of prematurity
Jemperli® (dostarlimab-gxly) GSK	Updated indication	Treatment of adult patients with mismatch repair deficient recurrent or advanced endometrial cancer, as determined by an FDA-approved test, that has progressed on or following prior treatment with a platinum-containing regimen in any setting and are not candidates for curative surgery or radiation
Kevzara® (sarilumab) Regeneron and Sanofi	New indication	Treatment of adult patients with polymyalgia rheumatica who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper

Drug name manufacturer(s)	Type	Description
Opdivo® (nivolumab) Bristol Myers Squibb	Expanded indications	Treatment of adult and pediatric patients 12 years and older with unresectable or metastatic melanoma and adjuvant treatment of adult and pediatric patients 12 years and older with melanoma with involvement of lymph nodes or metastatic disease who have undergone complete resection
Revatio® (sildenafil) Viatris	Expanded indication	In pediatric patients 1 to 17 years old, for the treatment of pulmonary arterial hypertension to improve exercise ability and, in pediatric patients too young to perform standardized exercise testing, pulmonary hemodynamics thought to underly improvements in exercise
Takhzyro® (lanadelumab-flyo) Takeda	Expanded indication	Prophylaxis to prevent attacks of hereditary angioedema in adult and pediatric patients aged 2 years and older
Trodelvy® (sacituzumab govitecan-hziy) Gilead	New indication	Treatment of adult patients with unresectable locally advanced or metastatic hormone receptor positive, human epidermal growth factor receptor 2 negative (IHC 0, IHC 1+ or IHC 2+/ISH–) breast cancer who have received endocrine-based therapy and at least two additional systemic therapies in the metastatic setting
Yervoy® (ipilimumab) Bristol Myers Squibb	Expanded indication	Treatment of unresectable or metastatic melanoma in adult and pediatric patients 12 years and older

Drug safety news / Drug updates

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Drug name manufacturer(s)	Description
Bivalent mRNA COVID-19 vaccines Pfizer/BioNTech	The Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP) supported (they did not vote) harmonizing the vaccine strain composition for mRNA COVID-19 vaccines across both the primary series and booster doses. The current recommendation for people ages 6 months and older is a primary series of two monovalent vaccines followed by a bivalent booster dose (in most ages). For children 6 months to 4 years of age who start a Pfizer/BioNTech primary series, the third dose in a 3-dose primary series is a bivalent dose. The future proposed recommendation for people ages 6 months and older is a primary series of two bivalent vaccines followed by a bivalent booster dose (in most ages).

Drug recalls/Withdrawals/Shortages/Discontinuations

Learn more

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Artificial Eye Ointment Global Pharma Healthcare	mineral oil 15%, white petrolatum 83%	Recall	Global Pharma Healthcare announced a consumer-level recall of one batch of Artificial Eye Ointment due to possible microbial contamination and some product packaging is leaking or may otherwise be compromised. Artificial eye ointment is used as a lubricant to prevent further irritation or to relieve dryness of the eyes.
Artificial Tears Lubricant Eye Drops Global Pharma Healthcare	Ezricare Artificial Tears (carboxymethylcellulose sodium) Lubricant Eye Drops Delsam Pharma's Artificial Tears (carboxymethylcellulose	Recall	Global Pharma Healthcare announced a consumer-level recall of all lots within expiry of their Artificial Tears Lubricant Eye Drops, distributed by EzriCare and Delsam Pharma due to possible contamination. Artificial Tears (are used as a protectant against further irritation or to relieve dryness of the eye for the temporary relief of discomfort due to minor irritations of the eye, or to exposure to wind or sun.

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
	sodium) Lubricant Eye Drops		
BD Insulin Syringes with the BD Micro-Fine™ IV Needle BD	1 mL syringe with 12.7 mm, 28 G needles and 0.5 mL syringe with 12.7 mm, 28 G needles	Recall	BD announced a consumer-level recall of some lots of BD Insulin Syringes with the BD Micro-Fine IV Needle because of manufacturing issues that can result in unsealed packaging for the individual syringes and the products may no longer be sterile.
Enfamil® Prosobee® Simply Plant-Based Infant Formula Reckitt	12.9 oz. container	Recall	Reckitt announced a consumer level recall of two batches of ProSobee Simply Plant-Based Infant Formula due to a possibility of cross-contamination with *Cronobacter sakazakii*.
Ferrous sulfate tablets Nationwide Pharmaceutical	324 mg tablets	Recall	Nationwide Pharmaceutical announced a consumer-level recall of four lots of ferrous sulfate 324 mg tablets because of a lack of child safety caps on product containers. Ferrous sulfate tablets are dietary supplements.
Heparin sodium injection Sagent	20,000 units/mL	Recall	Sagent announced a consumer-level recall of one lot of heparin injection due to mislabeling. The incorrect labeling omits the preservative and states the incorrect concentration, showing “each mL contains: 1,000 USP units heparin sodium; 9 mg sodium chloride” instead of the correct labeling, which should state, “each mL contains: 20,000 USP units heparin sodium; 0.01 mL benzyl alcohol (as preservative).” Heparin injection is indicated for the prophylaxis and treatment of venous thrombosis and pulmonary embolism; prevention of postoperative deep venous thrombosis and pulmonary embolism in patients undergoing major abdominothoracic surgery or who, for other reasons, are at risk of developing thromboembolic disease; atrial fibrillation with embolization; treatment of acute and chronic consumptive coagulopathies; prevention of clotting in arterial and

Drug name manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
			cardiac surgery; prophylaxis and treatment of peripheral arterial embolism; anticoagulant use in blood transfusions, extracorporeal circulation, and dialysis procedures.
Sodium chloride injection B. Braun Medical	0.9% sodium chloride injection in EXCEL plus IV container	Recall	B. Braun Medical announced a consumer-level recall of some lots of sodium chloride 0.9% injection due to the possibility of an incomplete seal that may cause leakage. The recalled lots may exhibit microscopic channel leaks near the port assembly of the product. Sodium chloride injection is indicated for use as sources of electrolytes and water for hydration; extracellular fluid replacement, treatment of metabolic alkalosis in the presence of fluid loss and mild sodium depletion; use as a priming solution in hemodialysis procedures and may be used to initiate and terminate blood transfusions without hemolyzing red blood cells; uase as pharmaceutic aids and diluents for the infusion of compatible drug additives
TIROSINT®-SOL (levothyroxine sodium) oral solution IBSA Pharma	All strengths of TIROSINT-SOL oral solution	Recall	IBSA Pharma recalled 27 lots of TIROSINT-SOL oral solution because they may be subpotent. TIROSINT-SOL is indicated as a replacement therapy for hypothyroidism. It is also indicated as adjunct to surgery and radioiodine therapy in the management of thyrotropin-dependent well-differentiated thyroid cancer.

Key guideline/Literature updates

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: B-Cell Lymphomas - Version 2.2023	*NCCN Clinical Practice Guidelines in Oncology: Cell Lymphomas*. February 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer - Version 1.2023	*NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer*. February 2023

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer - Version 3.2023	*NCCN Clinical Practice Guidelines in Oncology: Breast Cancer*. February 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers - Version 1.2023	*NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers*. February 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer - Version 2.2023	*NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer*. February 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic - Version 3.2023	*NCCN Clinical Practice Guidelines in Oncology: Genetic/Familial High-Risk Assessment: Breast, Ovarian, and Pancreatic*. February 2023
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Older Adult Oncology - Version 1.2023	*NCCN Clinical Practice Guidelines in Oncology: Older Adult Oncology*. February 2023

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