OPTUMRx®

RxHighlights

December 2021

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New drugs

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Adbry™ (tralokinumab-ldrm)* Leo Pharma	Interleukin-13 inhibitor	Treatment of moderate-to-severe atopic dermatitis in adult patients whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable	February 2022
Apretude™ (cabotegravir) ViiV Healthcare	HIV integrase inhibitor	At-risk adults and adolescents weighing at least 35 kg for pre-exposure prophylaxis to reduce the risk of sexually acquired human immunodeficiency virus-1 infection	December 27, 2021
Bijuva® (estradiol and progesterone) TherapeuticsMD	Estrogen/ progesterone	Treatment of moderate to severe vasomotor symptoms due to menopause	TBD
Dartisla ODT™ (glycopyrrolate) Edenbridge Pharmaceuticals	Anticholinergic	To reduce symptoms of a peptic ulcer as an adjunct to treatment of peptic ulcer in adults	January 4, 2022
Entadfi™ (finasteride/tadalafil) Veru	5-alpha-reductase/ phosphodiesterase type 5 inhibitor	To initiate treatment of the signs and symptoms of benign prostatic hyperplasia in men with an enlarged prostate for up to 26 weeks	Early 2022
Lastacaft® (alcaftadine) 0.25% ophthalmic solution± Allergan	H1 histamine receptor antagonist	Temporarily relieve itchy eyes due to pollen, ragweed, grass, animal hair and dander	TBD
Lanreotide injection Cipla Limited	Somatostatin analog	Long-term treatment of acromegalic patients who have had an inadequate response to surgery and/or radiotherapy, or for whom surgery and/or radiotherapy is not an option; Treatment of adult patients with unresectable, well or moderately differentiated, locally	January 2022

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
		advanced or metastatic gastroenteropancreatic neuroendocrine tumors to improve progression-free survival	
Leqvio® (inclisiran)†* Norvartis	RNA interfering therapeutic targetting proprotein convertase subtilisin–kexin type 9	As an adjunct to diet and maximally tolerated statin therapy for the treatment of adults with heterozygous familial hypercholesterolemia or clinical atherosclerotic cardiovascular disease, who require additional lowering of low-density lipoprotein cholesterol	December 27, 2021
PreHevbrio™ (hepatitis B vaccine [recombinant]) VBI Vaccines	Vaccine	Prevention of infection caused by all known subtypes of hepatitis B virus	First Quarter of 2022
Recorlev® (levoketoconazole) Xeris Biopharma	Cortisol synthesis inhibitor	Treatment of endogenous hypercortisolemia in adult patients with Cushing's syndrome for whom surgery is not an option or has not been curative	First Quarter of 2022
Tascenso ODT™ (fingolimod) Handa Neuroscience	Sphingosine-1-phosphate receptor immunomodulator	Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in pediatric patients 10 years of age and older and weighing less than or equal to 40 kg	TBD
Tarpeyo™ (budesonide)† Calliditas Therapeutics	Corticosteroid	To 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	December 28, 2021
Tezspire™ (tezepelumab-ekko)* Amgen, AstraZeneca	Thymic stromal lymphopoietin antagonist	Add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma	January 5, 2022
Vyvgart™ (efgartigimod alfa-fcab)†* Argenx	Neonatal Fc receptor antibody	Treatment of generalized myasthenia gravis in adult patients who are anti-acetylcholine receptor antibody positive	December 22, 2021
Xaciato™ (clindamycin) Daré Bioscience	Lincosamide	Treatment of bacterial vaginosis in females 12 years and older	TBD

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

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New biosimilars

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Yusimry™ (adalimumab-aqvh) Coherus	Tumor necrosis factor	Rheumatoid arthritis, juvenile idiopathic arthritis, psoriatic arthritis, ankylosing spondylitis, adult and pediatric Crohn's disease, ulcerative colitis, and plaque psoriasis	July 1, 2023
Rezvoglar™ (insulin glargine-aglr) Eli Lilly	Long-acting insulin	To improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus	TBD

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New generics

Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Carbaglu® (carglumic acid) Recordati Rare Diseases	Eton/Novitium†	200 mg tablet for oral suspension	Acute and chronic hyperammonemia	December 1, 2021
Narcan® (naloxone) Emergent BioSolutions	Teva†	4 mg nasal spray	Emergency treatment of opioid overdose	December 22, 2021
Epiduo® Forte (adapalene/benzoyl peroxide) Galderma	Taro†	0.3%/2.5% gel	Acne vulgaris	December 6, 2021

†A-rated generic manufacturer

New authorized brand alternatives

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Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Dexilant® (dexlansoprazole) Takeda	TWi Pharmaceuticals	30 mg and 60 mg delayed-release capsules	Erosive esophagitis, relief of heartburn, and treatment of symptomatic non-erosive gastroesophageal reflux disease	December 17, 2021
Epiduo® Forte (adapalene/benzoyl peroxide) Galderma	Teva	0.3%/2.5% gel	Acne vulgaris	December 1, 2021
Narcan® (naloxone) Emergent BioSolutions	Sandoz	4 mg nasal spray	Emergency treatment of opioid overdose	December 22, 2021

Indications/Label updates

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Drug name Manufacturer(s)	Type	Description
Caplyta® (lumateperone) Intra-Cellular Therapies	New indication	Treatment of depressive episodes associated with bipolar I or II disorder (bipolar depression) in adults, as monotherapy and as adjunctive therapy with lithium or valproate
Pfizer/BioNTech COVID-19 Vaccine	Expanded Emergency use authorization (EUA)	A single booster dose to individuals 16 years of age and older who have completed a primary series with Pfizer-BioNTech COVID-19 vaccine or Comirnaty®
Cosentyx® (secukinumab) Novartis	New indication	Treatment of active enthesitis-related arthritis in patients 4 years of age and older
	Expanded indication	Treatment of active psoriatic arthritis (PsA) in patients 2 years of age and older

Drug name Manufacturer(s)	Type	Description
Darzalex Faspro® (daratumumab/hyaluronidase-fihj), Janssen	Expanded indication	In combination with dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy
Kyprolis® (carfilzomib) Amgen	Expanded indication	In combination with dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received one to three prior lines of therapy
Evusheld™ (tixagevimab/cilgavimab) AstraZeneca	New and Expanded EUA	For pre-exposure prophylaxis of COVID-19 in adults and pediatric individuals: who are not currently infected with SARS-CoV-2 and who have not had a known recent exposure to an individual infected with SARS- CoV-2 and who have moderate to severe immune compromise due to a medical condition or receipt of immunosuppressive medications or treatments and may not mount an adequate immune response to COVID-19 vaccination; or for whom vaccination with any available COVID-19 vaccine, according to the approved or authorized schedule, is not recommended due to a history of severe adverse reaction (eg, severe allergic reaction) to a COVID-19 vaccine(s) and/or COVID-19 vaccine component(s)
Kisqali® (ribociclib) and **Kisqali Femara® Co-Pack** Novartis	Expanded indication	Treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy; or Fulvestrant as initial endocrine-based therapy or following disease progression on endocrine therapy in postmenopausal women or in men
Molnupiravir Merck	Emergency use authorization	Treatment of mild-to-moderate COVID-19 in adults with positive results of direct SARS-CoV-2 viral testing who are at high risk for progressing to severe COVID-19, including hospitalization or death, and for whom alternative COVID-19 treatment options authorized by FDA are not accessible or clinically appropriate
Oral JAK Inhibitors (Xeljanz®/XR, Olumiant®, Rinvoq®) Pfizer, AbbVie, Eli Lilly	Label update	*Boxed Warnings and Warnings and Precautions* section updated with additional information about the risks of malignancy and thrombosis, and the addition of mortality and major adverse cardiovascular events (defined as cardiovascular death, myocardial infarction, and stroke) risks
Orencia® (abatacept) Bristol-Myers Squibb	New orphan indication	Prophylaxis of acute graft versus host disease, in combination with a calcineurin inhibitor and methotrexate, in adults and pediatric patients 2 years of age and older undergoing hematopoietic stem cell transplantation from a matched or 1 allele-mismatched unrelated-donor

Drug name Manufacturer(s)	Type	Description
Otezla® (apremilast) Amgen	Expanded indication	Treatment of adult patients with plaque psoriasis who are candidates for phototherapy or systemic therapy
Oxbryta® (voxelotor) Global Blood Therapeutics	Expanded indication, new formulation approval	Treatment of sickle cell disease in adults and pediatric patients 4 years of age and older To support the expanded indication, a 300 mg tablet for oral suspension formulation of Oxbryta was also approved.
Paxlovid™ (nirmatrelvir/ritonavir) Pfizer	Emergency use authorization	Treatment of mild-to-moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progression to severe COVID-19, including hospitalization or death
Rexulti® (brexpiprazole) Otsuka Pharmaceutical	Expanded indication	Treatment of schizophrenia in adults and pediatric patients ages 13 years and older
Rinvoq® (upadacitinib) AbbVie	New indication	Treatment of adults with active psoriatic arthritis who have had an inadequate response or intolerance to one or more tumor necrosis factor blockers
Siklos® (hydroxyurea) Medunik	Expanded indication	To reduce the frequency of painful crises and to reduce the need for blood transfusions in adult and pediatric patients, 2 years of age and older, with sickle cell anemia with recurrent moderate to severe painful crises
Vocabria® (cabotegravir) ViiV Healthcare	New indication	For in at-risk adults and adolescents weighing at least 35 kg for short-term pre-exposure prophylaxis (PrEP) to reduce the risk of sexually acquired HIV-1 infection.
Xarelto® (rivaroxaban) Janssen	New indications, new formulation approval	Treatment of venous thromboembolism (VTE) and the reduction in the risk of recurrent VTE in pediatric patients from birth to less than 18 years after at least 5 days of initial parenteral anticoagulant treatment; and thromboprophylaxis in pediatric patients aged 2 years and older with congenital heart disease who have undergone the Fontan procedure

Drug name Manufacturer(s)	Type	Description
Xeljanz® (tofacitinib) and **Xeljanz XR** (tofacitinib) Pfizer	New indication	Treatment of adult patients with active ankylosing spondylitis who have had an inadequate response or intolerance to one or more tumor necrosis factor blockers
Zepatier® (elbasvir/grazoprevir) Merck	Expanded indication	Treatment of chronic hepatitis C virus genotype 1 or 4 infection in adult and pediatric patients 12 years of age and older or weighing at least 30 kg
Zynrelef® (bupivacaine and meloxicam) Heron Therapeutics	Expanded indication	In adults for soft tissue or periarticular instillation to produce postsurgical analgesia for up to 72 hours after foot and ankle, small-to-medium open abdominal, and lower extremity total joint arthroplasty surgical procedures

Drug safety news / Drug updates

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Drug name Manufacturer(s)	Description
Farydak® (panobinostat) Secura Bio	Secura Bio announced, based on discussions with the FDA, that they have submitted for the withdrawal of the approval of Farydak, for use in combination with bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least two prior regimens, including bortezomib and an immunomodulatory agent. Secura Bio noted that it was not feasible for the company to complete the required post-approval clinical studies as designed as part of the accelerated approval process. The clinical benefit of Farydak has not been confirmed as part of the accelerated approval process.
Oral JAK Inhibitors - **Xeljanz®/XR** (tofacitinib), **Olumiant®** (baracitinib), **Rinvoq®** (upadacitinib) Pfizer, AbbVie, Eli Lilly	The FDA approved a class-wide update to the labeling for the oral JAK inhibitors to include additional information about the risks of malignancy and thrombosis, and the addition of mortality and major adverse cardiovascular events (MACE) (defined as cardiovascular death, myocardial infarction, and stroke) risks within the *Boxed Warnings* and *Warnings and Precautions* sections.
COVID-19 Vaccine Janssen	The ACIP voted unanimously in favor of a statement indicating that mRNA COVID-19 vaccines are clinically preferred over Janssen's COVID-19 vaccine to prevent COVID-19 among people aged 18 years and older. The CDC also approved this recommendation.

Drug recalls/Withdrawals/Shortages/Discontinuations

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Drug name Manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Clobetasol ointment Taro	0.05% ointment	Recall	The FDA announced a consumer level recall of one lot of clobetasol 0.05% ointment due to the presence of *Ralstonia pickettii* bacteria. Clobetasol ointment is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid responsive dermatoses.
Enoxaparin injection Sandoz	40 mg/0.4 mL single-dose syringes	Recall	Sandoz announced a voluntary, consumer-level recall of one lot of enoxaparin because a portion of the recalled lot experienced a temperature excursion during shipment. Enoxaparin is indicated for the prophylaxis and treatment of deep vein thrombosis, prophylaxis of ischemic complications of unstable angina and non-Q-wave myocardial infarction (MI), and for the treatment of acute ST-segment elevation MI.
Hizentra® [immune globulin subcutaneous (human)] CSL Behring	20% liquid, 50 mL vial containing 10 g of protein	Withdrawal	CSL Behring announced a patient-level withdrawal of one lot of Hizentra due to an increased frequency of reports of injection-site reactions and local hypersensitivity-type of events after administration.
Losartan and **losartan/hydrochlorothiazide (HCTZ)**	Losartan: 25 mg, 50 mg and100 mg tablets Losartan/HCTZ: 50 mg/12.5 mg, 100 mg/12.5 mg, and 100 mg/25 mg tablets	Shortage	There is currently a supply disruption of generic losartan and losartan/HCTZ products. Due to increased FDA testing requirements for impurities, the active pharmaceutical ingredient is in short supply leading to market-wide supply constraints. Losartan is used to treat high blood pressure, to decrease the risk of stroke in people with high blood pressure and left ventricular hypertrophy and to slow the worsening of diabetic kidney disease in people with type 2 diabetes.
Lidocaine Teligent Pharma	4% topical solution	Recall	Teligent Pharma announced a voluntary, patient-level recall of two lots of lidocaine because testing has found it to be super potent. Lidocaine topical solution is indicated for the production of topical anesthesia of accessible mucous membranes of the oral and nasal cavities and proximal portions of the digestive tract.

Drug name Manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Methyldopa Accord, Mylan	250 mg and 500 mg tablets	Shortage	The drug shortage of methyldopa tablets is ongoing. Accord has temporarily discontinued methyldopa tablets and there is no information as to when or if the product will be available at a future date. Mylan discontinued methyldopa tablets on October 8, 2021. The shortage of methyldopa was originally posted on the FDA Drug Shortage site in August 2018. Methyldopa is indicated for the treatment of hypertension.
Nitroglycerin lingual spray Padagis	400 mcg/spray	Recall	Padagis announced a consumer level recall of three lots of nitroglycerin lingual spray because of possible failure of the product to properly dispense medication; some units may contain a disassembled pump, affecting the ability to dispense medication. Nitroglycerin lingual spray is indicated for acute relief of an attack or prophylaxis of angina pectoris due to coronary artery disease.
Veklury® (remdesivir) Gilead	100 mg injection	Recall	Gilead announced a voluntary, consumer-level recall of two lots of Veklury due to the presence of glass particulates. Veklury is indicated for the treatment of adults and pediatric patients ≥ 12 years old and weighing ≥ 40 kg requiring hospitalization for COVID-19.

Key guideline/Literature updates

Topic	Reference
National Institutes of Health - COVID-19 Treatment	COVID-19 Treatment Guidelines. January 2022
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia - Version 3.2021	NCCN Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia. December 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer - Version 6.2021	NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer. December 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer - Version 2.2022	NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. December 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers - Version 1.2022	NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers. December 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastric Cancer - Version 1.2022	NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer. December 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Head and Neck Cancers - Version 1.2022	NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers. December 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kidney Cancer - Version 4.2022	NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer. December 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Malignant Peritoneal Mesothelioma - Version 1.2022	NCCN Clinical Practice Guidelines in Oncology: Malignant Peritoneal Mesothelioma. December 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Malignant Pleural Mesothelioma - Version 1.2022	NCCN Clinical Practice Guidelines in Oncology: Malignant Pleural Mesothelioma. December 2021

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma - Version 4.2022	*NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma*. December 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors - Version 4.2021	*NCCN Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors*. December 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer - Version 1.2022	*NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer*. December 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Penile Cancer - Version 1.2022	*NCCN Clinical Practice Guidelines in Oncology: Penile Cancer*. December 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: T-Cell Lymphomas - Version 1.2022	*NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas*. December 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thymomas and Thymic Carcinomas - Version 1.2022	*NCCN Clinical Practice Guidelines in Oncology: Thymomas and Thymic Carcinomas*. December 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma - Version 2.2022	*NCCN Clinical Practice Guidelines in Oncology: Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma*. December 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors - Version 1.2022	*NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Growth Factors*. December 2021

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