

New drugs

[Learn more](#)

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Besremi [®] (ropeginterferon alfa-2b-njft) ^{†*} PharmaEssentia	Interferon alfa-2b	Treatment of adults with polycythemia vera	November 19, 2021
Purified Cortrophin [™] Gel (repository corticotropin) ANI Pharmaceuticals	Adrenocorticotrophic hormone	Treatment of certain chronic autoimmune disorders, including acute exacerbations of multiple sclerosis and rheumatoid arthritis, in addition to excess urinary protein due to nephrotic syndrome	First Quarter 2022
Dhivy [™] (carbidopa/levodopa) Riverside Pharmaceutical	Aromatic amino acid decarboxylation inhibitor/ aromatic amino acid	Treatment of Parkinson's disease, post-encephalitic parkinsonism, and symptomatic parkinsonism that may follow carbon monoxide intoxication or manganese intoxication	TBD
Dyanavel [®] XR (amphetamine) extended-release tablets Tris Pharma	CNS stimulant	Treatment of attention deficit hyperactivity disorder in patients 6 years and older	First Quarter 2022
Eprontia [™] (topiramate) oral solution Azurity	Anticonvulsant	Initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 2 years of age and older; as adjunctive therapy for the treatment of partial-onset seizures, primary generalized tonic-clonic seizures, and seizures associated with Lennox-Gastaut syndrome in patients 2 years of age and older; for the preventive treatment of migraine in patients 12 years and older	November 11, 2021
Fyarro [™]	mTOR kinase inhibitor	Treatment of adult patients with locally advanced unresectable or metastatic malignant perivascular epithelioid cell tumor	First Quarter 2022

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
(sirolimus protein-bound particles) (albumin-bound) [†] Aadi Bioscience			
Livtency [™] (maribavir) ^{†*} Takeda	Cytomegalovirus pUL97 kinase inhibitor	Treatment of adults and pediatric patients (12 years of age and older and weighing at least 35 kg) with post-transplant cytomegalovirus infection/disease that is refractory to treatment (with or without genotypic resistance) with ganciclovir, valganciclovir, cidofovir or foscarnet	November 29, 2021
Lyvispah [™] (baclofen) oral granules in packets Saol Therapeutics	Gamma-aminobutyric acid agonist	Treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity. Lyvispah may also be of some value in patients with spinal cord injuries and other spinal cord diseases	TBD
Voxzogo [™] (vosoritide) ^{†*} BioMarin	C-type natriuretic peptide analog	To increase linear growth in pediatric patients with achondroplasia who are 5 years of age and older with open epiphyses	Mid to late December 2021

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

New biosimilars

Learn more

Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Semglee [®] (insulin glargine-yfgh) [‡] Viatris	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	November 16, 2021

[‡]Interchangeable biosimilar to Lantus[®] (insulin glargine)

New generics

[Learn more](#)

Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Arranon [®] (nelarabine) Novartis	Zydus ^{†*}	250 mg/50 mL injection	T-cell acute lymphoblastic leukemia and T-cell lymphoblastic lymphoma	November 18, 2021

[†]A-rated generic manufacturer
*180-day Competitive Generic Therapy designation

New authorized brand alternatives

[Learn more](#)

Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Roszet [®] (rosuvastatin/ezetimibe) Althera	Althera	5 mg/10 mg, 10 mg/10 mg, 20 mg/10 mg, and 40 mg/10 mg tablets	Adjunct to diet in patients with primary non-familial hyperlipidemia to reduce low-density lipoprotein cholesterol (LDL-C). Alone or as an adjunct to other LDL-C-lowering therapies in patients with homozygous familial hypercholesterolemia to reduce LDL-C	November 15, 2021

Indications/Label updates

[Learn more](#)

Drug name Manufacturer(s)	Type	Description
Cutaquig® [immune globulin subcutaneous (human) - hipp] Octapharma	Expanded indication	Replacement therapy for primary humoral immunodeficiency in adults and pediatric patients 2 years of age and older
COVID-19 Vaccines Moderna, Pfizer	Emergency use authorization (EUA) expansion	The FDA announced an expanded EUA for Pfizer/BioNTech and Moderna COVID-19 vaccines authorizing use of a single booster dose for all individuals 18 years of age and older at least six-months after completion of primary vaccination with any FDA-authorized or approved COVID-19 vaccine. This new approval expands the patient population eligible for booster doses.
Injectafer® (ferric carboxymaltose) American Regent	New indication	Treatment of iron deficiency anemia in adults and pediatric patients 1 year of age and older who have either intolerance to oral iron or an unsatisfactory response to oral iron
Keytruda® (pembrolizumab) Merck	Expanded indication	Adjuvant treatment of patients with renal cell carcinoma at intermediate-high or high risk of recurrence following nephrectomy, or following nephrectomy and resection of metastatic lesions

Drug recalls/Withdrawals/Shortages/Discontinuations

[Learn more](#)

Drug name Manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Levetiracetam injection Sagent	500 mg/5 mL injection	Recall	The FDA announced a voluntary, user-level recall of four lots of levetiracetam injection because of a lack of container closure integrity found in reserve sample vials which may result in a non-sterile product. Levetiracetam injection is used to treat partial-onset seizures, myoclonic seizures in patients with juvenile myoclonic epilepsy, and primary generalized tonic-clonic seizures.

Drug name Manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Nefazodone Teva	50 mg, 100 mg, 150 mg, 200 mg, and 250 mg tablets	Shortage	The drug shortage of Teva's nefazodone tablets is ongoing. Nefazodone has been unavailable due to raw ingredient supply issues. Teva estimates that product will be available in the fourth quarter of 2021 to first quarter of 2021. Nefazodone is indicated for the treatment of depression.

Key guideline/Literature updates

Topic	Reference
American Academy of Orthopaedic Surgeons – Management of Osteoarthritis of the Knee (Non-Arthroplasty)	<i>American Academy of Orthopaedic Surgeons</i> . August 2021
American College of Gastroenterology – Benign Anorectal Disorders	<i>American Journal of Gastroenterology</i> . October 2021
American Society of Hematology – Sickle Cell Disease: Stem Cell Transplantation	<i>Blood Advances</i> . September 2021
Infectious Diseases Society of America and Society for Healthcare Epidemiology of America – Management of <i>Clostridioides difficile</i> Infection in Adults	<i>Clinical Infectious Diseases</i> . September 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer - Version 1.2022	<i>NCCN Clinical Practice Guidelines in Oncology: Basal Cell Skin Cancer</i> . November 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer - Version 1.2022	<i>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer</i> . November 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia - Version 2.2022	<i>NCCN Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia</i> . November 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Dermatofibrosarcoma Protuberans - Version 1.2022	<i>NCCN Clinical Practice Guidelines in Oncology: Dermatofibrosarcoma Protuberans</i> .

Topic	Reference
	November 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma - Version 1.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma.</u> November 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kidney Cancer - Version 3.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer.</u> November 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Merkel Cell Carcinoma - Version 1.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Merkel Cell Carcinoma.</u> November 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Myelodysplastic Syndromes.</u> November 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Prostate Cancer - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Prostate Cancer.</u> November 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer.</u> November 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Squamous Cell Skin Cancer - Version 1.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Squamous Cell Skin Cancer.</u> November 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer-Associated Venous Thromboembolic Disease - Version 3.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Cancer-Associated Venous Thromboembolic Disease.</u> November 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adolescent and Young Adult (AYA) Oncology - Version 2.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Adolescent and Young Adult (AYA) Oncology.</u> November 2021



optum.com/optumrx

OptumRx specializes in the delivery, clinical management and affordability of prescription medications and consumer health products. We are an Optum® company — a leading provider of integrated health services. Learn more at optum.com.

All Optum® trademarks and logos are owned by Optum, Inc. All other brand or product names are trademarks or registered marks of their respective owners. This document contains information that is considered proprietary to OptumRx and should not be reproduced without the express written consent of OptumRx.

RxHighlights is published by the OptumRx Clinical Services Department.

© 2021 Optum, Inc. All rights reserved.