

New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Jemperli™ (dostarlimab)* GlaxoSmithKline	PD-1 checkpoint inhibitor	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 treatments with a platinum-containing regimen	April 27, 2021
Kloxxado™ (naloxone) intranasal spray Hikma	Opioid antagonist	Emergency treatment of known or suspected opioid overdose, as manifested by respiratory and/or central nervous system depression, for adult and pediatric patients	2nd half of 2021
Nextstellis® (drospirenone/estetrol)* Mayne Pharma and Mithra Pharmaceuticals	Progestin/estrogen	Use by females of reproductive potential to prevent pregnancy	April 21, 2021
Qelbree™ (viloxazine)* Supernus	Selective norepinephrine reuptake inhibitor	Treatment of attention-deficit hyperactivity disorder in pediatric patients 6 to 17 years of age	April 14, 2021
Zynlonta™ (loncastuximab tesirine-lpyl)* ADC Therapeutics	Antibody drug conjugate	Treatment of adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, DLBCL arising from low grade lymphoma, and high-grade B-cell lymphoma	May 2, 2021

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

New generics

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Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Absorica® (isotretinoin) Sun	Teva ^{†¶} , Upsher-Smith ^{†§}	10 mg, 20 mg, 25 mg, 30 mg, 35 mg, and 40 mg capsules	Severe recalcitrant nodular acne	April 30, 2021*
Lyrica® CR (pregabalin) Pfizer	Novadoz/MSN [†] , Alvogen [†] , Apotex ^{†±} , Mylan/Viatris ^{†±} , and Sun [†]	82.5 mg, 165 mg, and 330 mg extended-release tablets	Neuropathic pain associated with diabetic peripheral neuropathy and postherpetic neuralgia	April 13, 2021 [‡]

†A-rated generic manufacturer
 ¶Granted 180 days of marketing exclusivity
 ±Apotex received approval for the 165 mg and 330 mg ER tablets; Mylan/Viatris received approval for the 82.5 mg ER tablet
 ‡ Launch date for Novadoz/MSN, Sun and Alvogen; other manufacturers are pending
 §Upsher-Smith received approval for the 40 mg capsule
 *Launch date for Upsher-Smith is pending

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New authorized brand alternatives

Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Absorica® (isotretinoin) Sun	Sun	10 mg, 20 mg, 25 mg, 30 mg, 35 mg, and 40 mg capsules	Severe recalcitrant nodular acne	May 4, 2021*

Indications/Label updates

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Drug name Manufacturer(s)	Type	Description
Bamlanivimab Eli Lilly	Revocation of emergency use authorization	The FDA revoked the emergency use authorization for bamlanivimab, when administered alone, to be used for the treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults and certain pediatric patients with positive results of direct SARS-CoV-2 vial testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization. Bamlanivimab should be administered with etesevimab.
Diovan® (valsartan) Novartis	Expanded indication	Treatment of hypertension, to lower blood pressure in adults and pediatric patients one year of age and older
Evekeo ODT™ (amphetamine sulfate) Arbor	Expanded indication, new strength	Treatment of attention deficit hyperactivity disorder in pediatric patients 3 to 17 years of age The FDA also approved a new strength (2.5 mg) of Evekeo ODT.
Farxiga® (dapagliflozin) AstraZeneca	New indication	To reduce the risk of sustained estimated glomerular filtration rate decline, end-stage kidney disease, cardiovascular death, and hospitalization for heart failure in adults with chronic kidney disease at risk of progression
Natroba® (spinosad) ParaPRO	New indication	Topical treatment of scabies infestations in adult and pediatric patients 4 years of age and older
Opdivo® (nivolumab) Bristol Myers Squibb	New indication	In combination with fluoropyrimidine- and platinum-containing chemotherapy, for the treatment of patients with advanced or metastatic gastric cancer, gastroesophageal junction cancer, and esophageal adenocarcinoma
Praluent® (alirocumab) Regeneron	New orphan indication	Adjunct to other low-density lipoprotein cholesterol (LDL-C)-lowering therapies in adult patients with homozygous familial hypercholesterolemia to reduce LDL-C
Ragwitek®	Expanded indication	Treatment of short ragweed pollen-induced allergic rhinitis, with or without conjunctivitis, confirmed by positive skin test or in vitro testing for pollen-specific IgE antibodies for

Drug name Manufacturer(s)	Type	Description
(short ragweed pollen allergen extract) ALK-Abelló		short ragweed pollen. Ragwitek is approved for use in persons 5 through 65 years of age
Trodelvy [®] (sacituzumab govitecan-hziy) Gilead	Expanded indication	Treatment of adult patients with unresectable locally advanced or metastatic triple negative breast cancer who have received two or more prior systemic therapies, at least one of them for metastatic disease
	New indication	Treatment of locally advanced or metastatic urothelial cancer in adult patients who have previously received platinum-containing chemotherapy and either a programmed death receptor-1 or a programmed death-ligand 1 inhibitor
Tyvaso [®] (treprostinil) United Therapeutics	New indication	Treatment of pulmonary hypertension associated with interstitial lung disease to improve exercise ability
Xolair [®] (omalizumab) Genentech	Dosing update	The FDA approved Xolair prefilled syringe for self-injection across all its approved indications. Xolair prefilled syringe was previously approved for administration by a healthcare professional only.

Drug safety news

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Drug name Manufacturer(s)	Description
COVID-19 Vaccine Johnson & Johnson	The CDC's Advisory Committee on Immunization Practices (ACIP) convened an emergency meeting to reassess the risk benefit profile of the Johnson & Johnson (J&J) coronavirus vaccine. After reviewing the current data, hearing from J&J, and deliberating on different options, the CDC decided to reaffirm their original recommendations for the vaccine for ages and genders. The J&J COVID-19 vaccine is recommended for persons 18 years of age and older in the U.S. population under the FDA's Emergency Use Authorization.

Drug recalls/Withdrawals/Shortages/Discontinuations

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Drug name Manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
ChloroPrep™ Hi-Lite Orange™ (chlorhexidine gluconate/isopropyl alcohol) BD	26 mL applicator	Recall	BD announced a voluntary, user-level recall of specific lots of ChloroPrep Hi-Lite Orange 26 mL applicator due to a defective applicator. ChloroPrep Hi-Lite is used as an antiseptic for the preparation of the patient's skin prior to surgery to help reduce bacteria that potentially can cause skin infection.
Cystaran® (cysteamine) Leadiant	0.44% ophthalmic solution	Shortage	The long-term drug shortage of Leadiant's Cystaran 0.44% ophthalmic solution is ongoing. Cystaran has been unavailable due to an independent manufacturer declaring bankruptcy. Leadiant is working with a different manufacturer to restart production and they do not have an estimated date of availability.

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			Cysteamine ophthalmic solution is a cystine-depleting agent indicated for the treatment of corneal cystine crystal accumulation in patients with cystinosis, a rare genetic disorder.
Gamunex-C® (immune globulin [human]) Grifols	10% injection	Withdrawal	<p>Grifols announced a voluntary, consumer-level withdrawal of two lots of Gamunex-C injection due to a higher rate of allergic/hypersensitivity type reactions, a small number of which were considered medically significant.</p> <p>Gamunex-C is indicated for the treatment of primary humoral immunodeficiency; idiopathic thrombocytopenic purpura; and chronic inflammatory demyelinating polyneuropathy.</p>
Nefazodone Teva	50 mg, 100 mg, 150mg, 200 mg, and 250 mg tablets	Shortage	<p>The long-term drug shortage of Teva's nefazodone tablets is ongoing. Nefazodone has been unavailable due to raw ingredient supply issues. Teva is the sole supplier of nefazodone tablets and does not have an estimate as to when supply will be available.</p> <p>Nefazodone is indicated for the treatment of depression.</p>
NP Thyroid® (thyroid) Acella	15 mg, 30 mg, 60 mg, 90 mg and 120 mg tablets	Recall	<p>Acella announced a voluntary, consumer-level recall of 35 lots of NP Thyroid tablets because testing has found these lots to be subpotent. The products contain less than 90% of the labeled amount of liothyronine and/or levothyroxine.</p> <p>NP Thyroid is indicated as replacement or supplemental therapy in patients with hypothyroidism; as pituitary TSH suppressants, in the treatment or prevention of various types of euthyroid goiters, including thyroid nodules, subacute or chronic lymphocytic thyroiditis (Hashimoto's), multinodular goiter, and in the management of thyroid cancer.</p>
Zerbaxa® (ceftolozane/tazobactam) Merck	1.5 g (ceftolozane/tazobactam) for injection is supplied in single-dose vials containing ceftolozane 1 g and	Shortage	<p>The long-term drug shortage of Zerbaxa injection is ongoing. Zerbaxa has been unavailable due to requirements related to complying with good manufacturing practices.</p> <p>Zerbaxa is indicated for the treatment of complicated intra-abdominal infections, complicated urinary tract infections and</p>

Drug name Manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
	tazobactam 0.5 g per vial		for hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia.

Key guideline/Literature updates

Topic	Reference
Management of Blood Pressure in Chronic Kidney Disease – Kidney Disease: Improving Global Outcomes	<i>Kidney International</i> . March 2021
Prevention, Diagnosis, and Treatment of Lyme Disease – Infectious Diseases of Society of America, American Academy of Neurology and American College of Rheumatology	<i>Neurology</i> . February 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia - Version 1.2021	<i>NCCN Clinical Practice Guidelines in Oncology: Acute Lymphoblastic Leukemia</i> . April 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer - Version 3.2021	<i>NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer</i> . April 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer - Version 4.2021	<i>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer</i> . April 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Central Nervous System Cancers- Version 5.2021	<i>NCCN Clinical Practice Guidelines in Oncology: Central Nervous System Cancers</i> . April 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma - Version 4.2021	<i>NCCN Clinical Practice Guidelines in Oncology: Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma</i> . April 2021

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Head and Neck Cancers - Version 3.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Head and Neck Cancers.</u> April 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers.</u> April 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma - Version 4.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Hodgkin Lymphoma.</u> April 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kidney Cancer - Version 4.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Kidney Cancer.</u> April 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Melanoma: Uveal - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Melanoma: Uveal.</u> April 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Multiple Myeloma - Version 7.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Multiple Myeloma.</u> April 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Myeloproliferative Neoplasms.</u> April 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors.</u> April 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Soft Tissue Sarcoma.</u> April 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Systemic Mastocytosis - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Systemic Mastocytosis.</u> April 2021

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Testicular Cancer - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Testicular Cancer.</u> April 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thyroid Carcinoma - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Thyroid Carcinoma.</u> April 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Vulvar Cancer - Version 3.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Vulvar Cancer.</u> April 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Colorectal Cancer Screening.</u> April 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Hematopoietic Cell Transplantation.</u> April 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer in People with HIV - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Cancer in People with HIV.</u> April 2021



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