

New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Aduhelm™ (aducanumab)* Biogen	Amyloid beta-protein inhibitor	Treatment of Alzheimer's disease	June 14, 2021
Astepro® Allergy and Children's Astepro Allergy (azelastine) 0.15% nasal spray [‡] Bayer	Antihistamine	Temporary relief of nasal congestion, runny nose, sneezing and itchy nose due to hay fever or other upper respiratory allergies in adults and children 6 years of age and older	First quarter of 2022
Brexafemme® (ibrexafungerp)* SCYNEXIS	Triterpenoid	Treatment of adult and post-menarchal pediatric females with vulvovaginal candidiasis	July 1, 2021
Dupixent® (dupilumab) 200 mg (175 mg/mL) auto-injector Regeneron	Interleukin-4/13 inhibitor	Treatment of atopic dermatitis, asthma, and chronic rhinosinusitis with nasal polyps	TBD
Lybalvi™ (olanzapine/samidorphan)* Alkermes	Dopamine receptor antagonist/ opioid receptor antagonist	Treatment of schizophrenia in adults and bipolar I disorder in adults as acute treatment of manic or mixed episodes as monotherapy and as adjunct to lithium or valproate or maintenance monotherapy treatment	4th quarter 2021
Pevnar 20™ (pneumococcal 20-valent conjugate vaccine) Pfizer	Vaccine	Active immunization for the prevention of pneumonia and invasive disease caused by <i>Streptococcus pneumoniae</i> serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F, and 33F in adults 18 years of age and older	TBD

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Rylaze™ (asparaginase erwinia chrysanthemi [recombinant]-rywn) [†] Jazz Pharmaceuticals	Asparaginase	A component of a multi-agent chemotherapeutic regimen for the treatment of acute lymphoblastic leukemia (ALL) and lymphoblastic lymphoma (LBL) in adult and pediatric patients 1 month or older who have developed hypersensitivity to E. coli-derived asparaginase	Mid-July 2021
Ryplazim® (plasminogen, human-tvmh) [†] Liminal BioSciences	Plasminogen	Treatment of patients with plasminogen deficiency type 1 (hypoplasminogenemia)	TBD
Soanz® (torsemide) Sarfez Pharmaceuticals	Loop diuretic	In adults for the treatment of edema associated with heart failure or renal disease	TBD
StrataGraft® (allogeneic cultured keratinocytes and dermal fibroblasts in murine collagen-dsat) ^{†*} Mallinckrodt	Allogeneic cellularized scaffold product	Treatment of adults with thermal burns containing intact dermal elements for which surgical intervention is clinically indicated	TBD
Verkazia® (cyclosporine) ophthalmic emulsion 0.1% [†] Santen Pharmaceutical	Immunosuppressant	Treatment of vernal keratoconjunctivitis in children and adults	TBD
Wegovy™ (semaglutide) Novo Nordisk	Glucagon-like peptide-1 receptor agonist	Adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index of 30 kg/m ² or greater or 27 kg/m ² or greater in the presence of at least one weight-related comorbid condition (eg, hypertension, type 2 diabetes mellitus, or dyslipidemia)	June 8, 2021

*New molecular entity; † Orphan drug; ±Over-the-counter approval; TBD: To be determined

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New generics

Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Banzel [®] (rufinamide) Eisai	Hikma [†] , Mylan [†] , Glenmark [†] , Camber/Hetero [†]	200 mg and 400 mg tablets	Seizures associated with Lennox-Gastaut syndrome	June 1, 2021
Bepreve [®] (bepotastine) Bausch Health	Mylan [†]	1.5% ophthalmic solution	Itching associated with signs and symptoms of allergic conjunctivitis	June 1, 2021
Intelence [®] (etravirine) Janssen	Amneal [†]	25 mg, 100 mg, and 200 mg tablets	Human immunodeficiency virus type 1 (HIV- 1) infection	June 15, 2021
Kaletra [®] (lopinavir/ritonavir) AbbVie	Camber [†]	100 mg/25 mg and 200 mg/50mg tablets	HIV-1 infection	June 7, 2021
Perforomist [®] (formoterol fumarate) Mylan Specialty	Teva [†]	0.02 mg/2 mL inhalation solution	Maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease	June 22, 2021

[†]A-rated generic manufacturer

[Learn more](#)**New authorized brand alternatives**

Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Bepreve [®] (bepotastine) Bausch Health	Bausch and Lomb	1.5% ophthalmic solution	Itching associated with signs and symptoms of allergic conjunctivitis	June 1, 2021
Perforomist [®] (formoterol fumarate) Mylan Specialty	Mylan/Viatris	0.02 mg/2 mL inhalation solution	Maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease	June 22, 2021

Indications/Label updates[Learn more](#)

Drug name Manufacturer(s)	Type	Description
Actemra [®] (tocilizumab) Genentech	Emergency use authorization approval	Treatment of COVID-19 in hospitalized adults and pediatric patients (2 years of age and older) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation
Ayvakit [™] (avapritinib) Blueprint Medicines	New indication	Treatment of adult patients with advanced systemic mastocytosis
Epclusa [®] (sofosbuvir/velpatasvir) Gilead	Expanded indication, new formulation approval	Treatment of adults and pediatric patients 3 years of age and older with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection: without cirrhosis or with compensated cirrhosis and with decompensated cirrhosis for use in combination with ribavirin An oral pellet formulation of Epclusa (200 mg/50 mg and 150 mg/37.5 mg strengths) was also approved to support the expanded indication.

Drug name Manufacturer(s)	Type	Description
Mavyret® (glecaprevir/pibrentasvir) AbbVie	Expanded indication, new formulation approval	<p>Treatment of adult and pediatric patients 3 years and older with HCV genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis; and HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both</p> <p>An oral pellet formulation and strength (50 mg/20 mg) of Mavyret was also approved to support the expanded indication.</p>
Pradaxa® (dabigatran etexilate) Boehringer Ingelheim	New indication, new formulation approval	<p>Pradaxa capsules were approved for the treatment of VTE in pediatric patients 8 to less than 18 years of age who have been treated with a parenteral anticoagulant for at least 5 days and to reduce the risk of recurrence of VTE in pediatric patients 8 to less than 18 years of age who have been previously treated</p> <p>Pradaxa oral pellets are a new formulation and were approved for the treatment of venous thromboembolic events (VTE) in pediatric patients aged 3 months to less than 12 years of age who have been treated with a parenteral anticoagulant for at least 5 days and to reduce the risk of recurrence of VTE in pediatric patients aged 3 months to less than 12 years of age who have been previously treated</p>
Solosec® (secnidazole) Lupin	New indication	Treatment of trichomoniasis caused by <i>Trichomonas vaginalis</i> in adults
Toviaz® (fesoterodine fumarate) Pfizer	New indication	Treatment of neurogenic detrusor overactivity in pediatric patients 6 years of age and older with a body weight greater than 25 kg
Trikafta® (elexacaftor/tezacaftor/ivacaftor; ivacaftor) Vertex	Expanded indication, new strength	<p>Treatment of cystic fibrosis in patients aged 6 years and older who have at least one <i>F508del</i> mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene or a mutation in the CFTR gene that is responsive based on <i>in vitro</i> data</p> <p>A new strength of Trikafta (fixed-dose combination containing elexacaftor 50 mg, tezacaftor 25 mg and ivacaftor 37.5 mg co-packaged with ivacaftor 75 mg) was also approved to support the expanded indication.</p>
Ultomiris® (ravulizumab-cwvz) Alexion	Expanded indication	Treatment of adult and pediatric patients one month of age and older with paroxysmal nocturnal hemoglobinuria

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Drug recalls/Withdrawals/Shortages/Discontinuations

Drug name Manufacturer(s)	Strength(s) and dosage form(s)	Type	Description
Chantix® (varenicline) Pfizer	0.5 mg and 1 mg tablets	Pause on distribution, warehouse level recall	Pfizer suspended distribution of Chantix and announced a warehouse level recall of nine lots due to the discovery of nitrosamine impurities that were found in some of the tablets during product testing. Chantix is indicated for use as an aid to smoking cessation treatment.
Gamunex-C® (immune globulin [human]) Grifols Therapeutics	10% injection	Withdrawal	Grifols announced a voluntary, consumer-level withdrawal of one lot of Gamunex-C injection due to a higher rate of allergic/hypersensitivity type reactions, a small number of which were considered medically significant
UltiCare® Pen Needles UltiMed	6 mm x 31 G mini pen needles	Withdrawal	UltiMed announced a consumer-level withdrawal of one lot of UltiCare pen needles 6 mm x 31G due to a report received that the inner box and case label expiration date is incorrectly labeled as February 28, 2006; the correct expiration date is February 28, 2026

Key guideline/Literature updates

Topic	Reference
American Academy of Dermatology - Actinic Keratosis Guidelines	<i>Journal of the American Academy of Dermatology</i> . April 2021
American College of Rheumatology - Treatment of Rheumatoid Arthritis	<i>Arthritis Care & Research</i> . June 2021
American Gastroenterological Association - Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease	<i>Gastroenterology</i> . June 2021
American Heart Association/American Stroke Association - Prevention of Stroke in Patients with Stroke and Transient Ischemic Attack	<i>Stroke</i> . May 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Anal Carcinoma - Version 2.2021	<i>NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma</i> . June 2021

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Breast Cancer - Version 5.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Breast Cancer.</u> June 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Central Nervous System Cancers - Version 1.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Central Nervous System Cancers.</u> June 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers - Version 3.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Esophageal and Esophagogastric Junction Cancers.</u> June 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Gastric Cancer - Version 3.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Gastric Cancer.</u> June 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers - Version 3.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Hepatobiliary Cancers.</u> June 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Kaposi Sarcoma - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Kaposi Sarcoma.</u> June 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Melanoma: Uveal - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Melanoma: Uveal.</u> June 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Neuroendocrine and Adrenal Tumors.</u> June 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer - Version 5.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Non-Small Cell Lung Cancer.</u> June 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Pediatric Aggressive Mature B-Cell Lymphomas - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Pediatric Aggressive Mature B-Cell Lymphomas.</u>

Topic	Reference
	June 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Penile Cancer - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Penile Cancer.</u> June 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Systemic Light Chain Amyloidosis - Version 1.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Systemic Light Chain Amyloidosis.</u> June 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Systemic Mastocytosis - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Systemic Mastocytosis.</u> June 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Uterine Neoplasms - Version 3.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Uterine Neoplasms.</u> June 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma - Version 1.2022	<u>NCCN Clinical Practice Guidelines in Oncology: Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma.</u> June 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Wilms Tumor (Nephroblastoma) - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Wilms Tumor (Nephroblastoma).</u> June 2021
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adult Cancer Pain - Version 2.2021	<u>NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain.</u> June 2021



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