MC-Rx

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Insights on the Drugs Pipeline

Exploring the changes in the drugs market.

August 2022

MC-Rx is dedicated to improved drug therapy vigilance, continuity of care, patient safety and effective formulary management. This edition is developed by our clinical team, which is comprised of registered clinical pharmacists, to provide you with continuous evaluation and insights of the drugs market and its impact as it evolves.

Here you will find

Drug pipeline

FDA drug approvals

New indications

Patent expirations

Generic approvals

FDA safety updates/ withdrawals/ recalls

Drug shortages/ discontinuations

Information last updated July 22, 2022.

Human Monkeypox Disease and Treatment

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Human Monkeypox Disease

Monkeypox is a rare disease caused by infection with the monkeypox virus. This virus is part of the same family of the virus that causes smallpox. Monkeypox symptoms are similar to smallpox symptoms, but milder, and monkeypox is rarely fatal. Monkeypox is not related to chickenpox.

Symptoms of monkeypox can include: fever, headache, muscle aches and backache, swollen lymph nodes, chills, exhaustion, and a rash that can look like pimples or blisters that appears on the face, inside the mouth, and on other parts of the body. The rash goes through different stages and can cause a lot of pain before healing completely. The illness typically lasts 2-4 weeks. Sometimes, people get a rash first, followed by other symptoms. Other people only experience a rash.

There are no treatments specifically for monkeypox virus infections. However, monkeypox and smallpox virus are genetically similar, which means that antiviral drugs and vaccines developed to protect against smallpox may be used to prevent and treat monkeypox virus infections. As of July 15, 2022, there have been reported a total of 1,814 cases of monkeypox/orthopox virus in the US/PR.

Human Monkeypox Disease Treatment

Tecovirimat

1. Indication and formulations

a. Tecovirimat (TPOXX) is indicated for the treatment of human smallpox disease caused by variola virus in adults and pediatric patients weighing at least 3 kg.

b. Recently the FDA approved an intravenous (IV) formulation of TPOXX (tecovirimat) to treat smallpox. The oral formulation of the drug was originally approved in 2018. The IV formulation is an option for those who are unable to swallow the oral capsule.

2. Clinical Studies

a. The effectiveness of TPOXX for treatment of smallpox disease has not been determined in humans because there are no human studies. Therefore, the effectiveness of TPOXX for treatment of smallpox disease was established based on results from animal efficacy studies of non-human primates and rabbits.

3. Healthcare providers accessibility

TPOXX is available through the Strategic National Stockpile, which has medicine and medical supplies to protect the American public if there is a public health emergency, including one involving smallpox. To request tecovirimat, clinicians and care facility pharmacists can contact

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their state/territorial health department or CDC. Treatment with TPOXX can begin upon receipt of the medication and after obtaining informed consent. No pre-registration is required for clinicians or facilities. Forms requested under the EA-IND can all be returned to CDC after treatment begins.

4. Patient accessibility

Because tecovirimat use for monkeypox is under an Expanded Access Investigational New Drug (EA-IND) protocol, certain documentation and return information related to tecovirimat treatment are required. The IND protocol will be provided to healthcare providers at the time of clinical consultation when tecovirimat therapy is indicated.

Minimally required forms to be completed and returned to CDC include:

1. Informed consent
2. FDA Form 1572
3. Patient intake form to provide the patient's baseline condition at the time of tecovirimat treatment decision.
4. Adverse event form to report whether any adverse event(s) ocurred during treatment with tecovirimat.
5. Clinical outcomes form to report tecovirimat treatment duration and patient's clinical outcome upon completion of treatment.
6. Photo of lesions, to the extent possible: at least 1 prior to tecovirimat treatment and 1 during treatment (between days 7 and 14) with dates of the photo(s) indicated.

Monkeypox Vaccines

Name	Overview
ACAM2000 (Vaccinia)	ACAM2000 is indicated for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection.
JYNNEOS	JYNNEOS is a vaccine indicated for prevention of smallpox and monkeypox disease in adults 18 years of age and older to be at high risk of smallpox or monkeypox infection.

The Advisory Committee on Immunization Practices (ACIP) recommends that people whose jobs may expose them to orthopoxvirus, such as monkeypox, get vaccinated with either ACAM2000 or JYNNEOS

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R&D | FDA Approval | In Market Brand | Generic Available | Off Market

to protect them if they are exposed to an orthopoxvirus. People who should get pre-exposure prophylaxis (PrEP) include:

1. Clinical laboratory personnel who perform testing to diagnose orthopoxvirus.
2. Research laboratory workers who directly handle cultures or animals contaminated or infected with orthopoxviruses that infect humans.
3. Certain healthcare and public health response team members designated by public health authorities to be vaccinated for preparedness purposes.

Under these strategies, the US Government is rapidly expanding access to hundreds of thousands of doses of JYNNEOS vaccine for prophylactic use against monkeypox in areas with the highest transmission and need, using a tiered allocation system. Jurisdictions can also request shipment of the ACAM2000 vaccine, which is in much greater supply, but due to significant side effects is not recommended for everyone.

Vaccines Similarities and Differences

Vaccine	Indicated for Smallpox	Attenuated Vaccine	Live Vaccine	Multiple Puncture Technique	Indicated for Immunocompromised people	Number of doses
ACAM2000	X		X	X		1
JYNNEOS	X	X			X	2

Vaccine	Subcutaneous administration	Scarification administration	Fully vaccinated after 4 weeks	Fully vaccinated after 2 weeks from second dose
ACAM2000		X	X	
JYNNEOS	X			X

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Vaccine Strategies to Prevent Monkeypox - CDC Recommendations

Strategy	Overview
Monkeypox Vaccine Post-Exposure Prophylaxis (PEP)	CDC recommends that the vaccine be given within 4 days from the date of exposure for the best chance to prevent onset of the disease. If given between 4 and 14 days after the date of exposure, vaccination may reduce the symptoms of disease, but may not prevent the disease. However, when compiled with self-isolation and other prevention measures when symptoms first occur, PEP is important for controlling outbreaks and preventing further transmission of monkeypox.
Outbreak Response Monkeypox Vaccine Post-Exposure Prophylaxis (PEP++)	People with certain risk factors are more likely to have been recently exposed to monkeypox. The PEP++ approach aims to reach these people for post-exposure prophylaxis, even if they have not had documented exposure to someone with confirmed monkeypox. When coupled with self-isolation and other prevention measures when symptoms first occur, PEP++ may help slow the spread of the disease in areas with large numbers of monkeypox cases which would suggest a higher level of monkeypox virus transmission.
Monkeypox Vaccine Pre-exposure Prophylaxis (PrEP)	This approach refers to administering a vaccine to someone at high risk for monkeypox (for example. Laboratory workers who handle specimens that might contain monkeypox virus). At this time, most clinicians in the United States and laboratories not performing the orthopoxvirus generic test to diagnose orthopoxvirus, including monkeypox virus, are not advised to receive monkeypox vaccine PrEP.

Novavax COVID-19 Vaccine

The Novavax vaccine, as with all COVID-19 vaccines, is intended to reduce the risk of COVID-19, including the risk of severe illness and death among people who are fully vaccinated. This vaccine was granted an Emergency Use Authorization (EUA) by the FDA in mid-July, making it the fourth COVID-19 vaccine to be administered in the U.S. Novavax is already being used in 40 other countries and had a 90% efficacy in its clinical trial, performing almost as well as the mRNA vaccines in their early trials. Novavax is a vaccine based on protein subunits from the virus that cause COVID-19. While other vaccines trick the body's cells into creating parts of the virus that can trigger the immune system, the Novavax vaccine takes a different approach. It contains the spike protein of the coronavirus itself, but formulated as a nanoparticle, which cannot cause disease. In other words, after the immunization, the body will recognize the protein subunits and create antibodies that could fight the virus in an efficient manner. Although the company is studying the vaccine in children and teenagers ages 12 to 17, this vaccine is only approved for adults 18 years or older. To achieve full immunization each adult should receive two doses with a period of 3-8 weeks between each dose.

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In Conclusion

Monkeypox is an illness caused by the monkeypox virus. It is a viral zoonotic infection, meaning that it can spread from animals to humans. It can also spread from person to person. There are no treatments for Monkeypox, but antiviral drugs and vaccines developed to protect against smallpox may be used. In addition, to prevent an outbreak, the CDC recommends that people with high risk of monkeypox disease get vaccinated to help prevent illness. Also, they are aiming to reach people for post-exposure prophylaxis, even if they have not had documented exposure to someone with confirmed monkeypox disease.

In other topics, the COVID-19 is still a very serious disease that is endangering the lives of the most vulnerable. The development of new ways to confront this crisis, such as vaccines, is crucial for the well-being of our communities. By doing this, we are creating various approaches to the upcoming health-related issues.

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Specialty Pipeline

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

There is a growing trend of specialty drugs in the market. Therapeutic areas where the specialty drug pipeline could yield new approvals in the coming years include treatments for dermatologic conditions, hemophilia, genetic disorders, among others.

Pipeline Drug	Current Status	Anticipated Approval	Indication
Adagrasib	NDA Filled	12/14/2022	KRAS G12C specific inhibitor for the treatment of KRAS G12C- mutated locally advanced or metastatic non-small cell lung cancer (NSCLC); oral.
Arimoclomol	Complete Response	2023	Molecular chaperone activator that stimulates the normal cellular protein repair pathway for the treatment of NiemannPick Disease Type C (NPC); oral.
Betibeglogene autotemcel	BLA Filed	08/19/2022	Gene therapy for the treatment of β-globin gene therapy for the treatment of transfusion-dependent β thalassemia; IV infusion.
Bimekizumab	Complete Response	2023	Monoclonal antibody that blocks the effects of IL-17A and IL-treatment of transfusion-dependent β thalassemia; IV infusion.
Cipaglucosidase alfa	BLA Filed	10/29/2022	Recombinant human acid α-glucosidase (rhGAA) enzyme replacement therapy/chaperone therapy for the treatment of late-onset Pompe disease; IV infusion.
Deucravacitinib	NDA Filed	09/10/2022	Tyrosine Kinase 2 (TYK2) inhibitor for use in patients with moderate to severe plaque psoriasis.
Donanemab	Phase 2	2023	Antibody that targets a modified form of beta amyloid called N3pG for the treatment of patients with early symptomatic Alzheimer's disease; IV infusion.
Eladocagene exuparvovec	Phase 3	2022	Recombinant, adeno-associated virus, containing the human cDNA encoding the AADC enzyme for the treatment of AADC deficiency; intracerebral infusion.
Etranacogene dezaparvovec	BLA Filed	11/24/2022	Gene therapy in patients with severe hemophilia B. *Single IV infusion*
Futibatinib	NDA Filed	09/30/2022	Fibroblast growth factor (FGFR) 1-4 inhibitor for the treatment of patients with previously treated locally advanced or metastatic cholangiocarcinoma harboring FGFR2 gene rearrangements, including gene fusions; oral.

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Specialty Pipeline

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Pipeline Drug	Current Status	Anticipated Approval	Indication
Lecanemab	Rolling Submission	01/09/2023	Humanized IgG1 monoclonal antibody that binds selectively to large, soluble Aß protofibrils and is thought to lead to their clearance or neutralize their toxicity for treatment of Alzheimer's Disease; IV infusion.
Mirikizumab	BLA Filed	04/28/023	Monoclonal antibody targeting IL-23p19 for the treatment of moderate-severe ulcerative colitis (UC); IV infusion and SC injection.
Obeticholic acid	Complete Response	2023	Farnesoid X receptor (FXR) agonist for the treatment of nonalcoholic steatohepatitis (NASH); oral.
Olipudase alfa	BLA Filed	07/03/2022	Enzyme (acid sphingomyelinase) replacement therapy for the long-term treatment of non-central nervous system (CNS) manifestations of acid sphingomyelinase deficiency (ASMD); IV.
Pegunigalsidase alfa	Complete Response	2023	Plant cell-expressed, recombinant alpha-galactosidase-A enzyme for the treatment of Fabry disease; IV infusion (monthly).
Spesolimab	BLA Filed	09/01/2022	Humanized monoclonal antibody that blocks activation of the interleukin-36 receptor for the treatment of generalized pustular psoriasis (GPP) flares; IV.
Teclistamab	BLA Filed	08/29/2022	BCMA/CD3 bispecific antibody for the treatment of relapsed or refractory multiple myeloma; SC.
Teplizumab	BLA Filed	08/17/2022	Humanized monoclonal antibody engineered to alter the function of the T lymphocytes that mediate the destruction of the insulin-producing beta cells of the islets of the pancreas to delay or prevent the onset of type 1 diabetes in at-risk individuals; IV.
Valoctocogene roxaparvovec	Complete Response	2023	Adenovirus-associated virus vector-mediated the transfer of Human Factor VIII gene in patients with severe hemophilia A; IV Infusion.
Vutrisiran	NDA Filed	07/14/2022	Therapeutic targeting transthyretin (TTR) for the treatment of the polyneuropathy of hereditary transthyretin-mediated (hATTR) amyloidosis in adults; SC.

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Biosimilar Pipeline

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Below is a list of biosimilars that are currently under FDA review. Approval of a biosimilar does not imply availability and allocation in the market. Additional patent, exclusivities, settlement agreements, etc. may result in a delay in launch of a biosimilar.

Pipeline Biosimilar	Manufacturer	Reference Biologic	Posible FDA Approval Date	Potential Launch Date
Bevacizumab (Aybintio)	Samsung Bioepis/ Merck	Avastin (bevacizumab)	2022	TBD (Pending FDA Approval)
Pegfilgrastim (Lupifil-P)	Lupin	Neulasta (pegfilgrastim)	4/2/2022	TBD (Pending FDA Approval)
Ranibizumab-ranq (Cimerli)	Bioeq/Coherus	Lucentis (ranibizumab)	8/2/2022	TBD (Pending FDA Approval)
Adalimumab-bwwd (Hadlima)	Biogen/Samsung Bioepis	Humira (adalimumab)	8/31/2022	Settlement: 06/30/2023
Trastuzumab	EirGenix/Sandoz	Herceptin (trastuzumab)	10/20/2022	TBD (Pending FDA Approval)
Aflibercept	Momenta/Viatris	Eylea (aflibercept)	Oct. 2022	TBD (2024?)
Bevacizumab (Abevmy)	Viatris/Biocon	Avastin (bevacizumab)	2022	TBD (Pending FDA Approval)
Adalimumab (Hukyndra)	Cipla/Alvotech	Humira (adalimumab)	2022	Settlement: 07/01/2023
Pegfilgrastim (Stimufend)	Fresenius Kabi	Neulasta (pegfilgrastim)	2022	TBD (Pending FDA Approval)
Filgrastim	Tanvex BioPharma	Neupogen (filgrastim)	2022	TBD (Pending FDA Approval)
Pegfilgrastim (Lupifil-P)	Lupin	Neulasta (pegfilgrastim)	2Q 2022	TBD (Pending FDA Approval)
Bevacizumab	Biothera	Avastin (bevacizumab)	2022	TBD (Pending FDA Approval
Adalimumab-afzd (Abrilada)	Pfizer	Humira (adalimumab)	4Q 2022	Settlement: 07/01/2023
Trastuzumab	Tanvex BioPharma	Herceptin (trastuzumab)	2022	TBD (Pending FDA Approval

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New Drug Entities

R&D | **FDA Approval** | In Market Brand | Generic Available | Off Market

Drug Name	Information
Tapinarof (Vtama)	**Dose:** Cream, 1%. Each gram of VTAMA cream contains 10 mg of tapinarof. **Indication:** An aryl hydrocarbon receptor agonist indicated for the topical treatment of plaque psoriasis in adults. **Comparables:** None. Vtama is a First-in-class Aryl hydrocarbon receptor (AhR) agonist. **Guidelines:** Joint AAD-NPF guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures.
Pegfilgrastim-pbbk (Fylnetra)	**Dose:** Injection: 6 mg/0.6 mL solution in a single-dose prefilled syringe for manual use only **Indication:** A leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anticancer drugs associated with a clinically significant incidence of febrile neutropenia. **Comparables:** Fulphila, Neulasta, Neulasta Onpro, Nyvepria, Udenyca, Ziextenzo **Guidelines:** https://www.nccn.org/professionals/physician_gls/pdf/growthfactors.pdf
Vutrisiran (Amvuttra)	**Dose:** Injection: 25 mg/0.5 mL in a single-dose prefilled syringe. **Indication:** Is a transthyretin-directed small interfering RNA indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults. **Comparables:** Onpattro (Patisiran)

This information is up-to-date as of May 17th, 2022.

New Drug Formulations

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Drug Name	Information
Tecovirimat (Tpoxx)	**Dose:** A single -dose vial containing 200mg injection **Indications:** TPOXX is an inhibitor of the orthopoxvirus VP37 envelope wrapping protein and is indicated for the treatment of human smallpox disease in adults and pediatric patients weighing at least 3 kg. **Comparables:** None **Guidelines:** https://www.cdc.gov/smallpox/prevention-treatment/index.html
Treprostinil (Tyvaso DPI)	**Dose:** Inhalation powder: Single-dose plastic cartridges containing 16, 32, 48, or 64 mcg of treprostinil as a dry powder formulation. **Indication:** • Pulmonary arterial hypertension (PAH; WHO Group 1) to improve exercise ability. Studies with Tyvaso establishing effectiveness predominately included patients with NYHA Functional Class III symptoms and etiologies of idiopathic or heritable PAH (56%) or PAH associated with connective tissue diseases (33%). • Pulmonary hypertension associated with interstitial lung disease (PH-ILD; WHO Group 3) to improve exercise ability. The study with Tyvaso establishing effectiveness predominately included patients with etiologies of idiopathic interstitial pneumonia (IIP) (45%) inclusive of idiopathic pulmonary fibrosis (IPF), combined pulmonary fibrosis and emphysema (CPFE) (25%), and WHO Group 3 connective tissue disease (22%). **Comparables:** Tyvaso inhalation for nebulizer **Guidelines:** CHEST: Guideline and expert panel report on therapy for pulmonary arterial hypertension in adults, update (2019)
Sodium Phenylbutyrate (Pheburane)	**Dose:** Oral pellets: 84 g of sodium phenylbutyrate per bottle. **Indication:** Is a nitrogen-binding agent indicated as adjunctive therapy to standard of care, which includes dietary management, for the chronic management of adult and pediatric patients with urea cycle disorders (UCDs), involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC) or argininosuccinic acid synthetase (AS). **Comparables:** Sodium phenylbutyrate (Buphenyl), oral glycerol phenylbutyrate (Ravicti), Citrulline (OTC), carglumic acid (Carbaglu) **Guidelines:** https://rarediseases.org/?s=urea+cycle+disorders+&submit=

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New Drug Formulations

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Drug Name	Information
Methylphenidate HCL Osmotic Release (Relexxii)	**Dose:** Extended-release tablets:18 mg, 27 mg, 36 mg, 45 mg, 54 mg, 63 mg, and 72 mg **Indication:** Is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in adults (up to the age of 65 years) and pediatric patients 6 years of age and older. **Comparables:** Methylphenidate and Amphetamines (dextroamphetamine and mixed dextroamphetamine-amphetamine salts). **Guidelines:** https://www.aafp.org/family-physician/patient-care/clinical-recommendations/all-clinical-recommendations/ADHD.html
Venlafaxine Extended-release (Venbysi XR)	**Dose:** Extended-Release tablets: 112.5 mg **Indication:** A serotonin and norepinephrine reuptake inhibitor (SNRI) indicated in adults for the treatment of: • Major Depressive Disorder (MDD), • Generalized Anxiety Disorder (GAD). **Comparables:** Effexor XR **Guidelines:** • APA Clinical Practice Guideline for the Treatment of MDD across three age cohorts chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.apa.org/depression-guideline/guideline.pdf • Diagnosis and Management of Generalized Anxiety Disorder and Panic Disorder in Adults https://www.aafp.org/pubs/afp/issues/2015/0501/p617.html
Zonisamide oral suspension (Zonisade)	**Dose:** Suspension; Oral 100 mg/5 mL Indication: As adjunctive therapy for the treatment of partial onset seizures in adults and pediatric patients 16 years of age and older **Comparables:** Zonegran, Zonisamide **Guidelines:** • Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new-onset epilepsy 2018 https://doi.org/10.5698%2F1535-7597.18.4.260 • Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment-resistant epilepsy https://doi.org/10.5698%2F1535-7597.18.4.269

Information last updated July 22, 2022.

New Drug Indications

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Drug Name	Information
Azacitidine (Vidaza)	**Dose:** Lyophilized powder in 100 mg single-dose vials. **New Indication:** For the treatment of pediatric patients aged one month and older with newly diagnosed juvenile myelomonocytic leukemia (JMML) based on the results from Study AZA-JMML-001 for VIDAZA (azacitidine for injection). **Guidelines:** https://rarediseases.org/rare-diseases/juvenile-myelomonocytic-leukemia/
Ivosidenib (Tibsovo)	**Dose:** Tablets: 250 mg **New Indication:** Is indicated in combination with azacitidine or as monotherapy for the treatment of newly diagnosed acute myeloid leukemia (AML) with a susceptible isocitrate dehydrogenase-1 (IDH1) mutation as detected by an FDA-approved test in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy. **Guidelines:** https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf
Risdiplam (Evrysdi)	**Dose:** For Oral Solution: 60 mg of risdiplam as a powder for constitution to provide 0.75 mg/mL solution. **New Indication:** New Patient Population: Less than 2 months of age 0.15 mg/kg. For the treatment of spinal muscular atrophy (SMA) in pediatric and adult patients. **Guidelines:** • Treatment algorithm for infants diagnosed with spinal muscular atrophy through newborn screening (2018) • https://rarediseases.org/rare-diseases/spinal-muscular-atrophy/
Brolucizumab-dbll (Beovu)	**Dose:** Intravitreal injection: 6 mg/0.05 mL solution in a single-dose pre-filled syringe. Intravitreal injection: 6 mg/0.05 mL solution in a single-dose vial. **New Indication:** FDA approval to treat diabetic macular edema (DME). **Guidelines:** American Society of Retina Specialists Evidence based guidelines for management of diabetic macular edema chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://www.asrs.org/content/documents/evidence-based-guidelines-for-management-of-diabetic-macular-edema.pdf

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New Drug Indications

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Drug Name	Information
Lisocabtagene Maraleucel (Breyanzi)	**Dose:** Suspension for infusion A single dose. **Indication:** For adult patients with large B-cell lymphoma (LBCL) who have refractory disease to first-line chemoimmunotherapy or relapse within 12 months of first-line chemoimmunotherapy; or refractory disease to first-line chemoimmunotherapy or relapse after first-line chemoimmunotherapy and are not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age. It is not indicated for the treatment of patients with primary central nervous system lymphoma. **Guidelines:** https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf
Tisagenlecleucel (Kymriah)	**Dose:** For autologous use only. For intravenous use only **Indication:** Accelerated approval for adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy. **Guidelines:** https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf
Nivolumab (Opdivo)	**Dose:** Injection: 40 mg/4 mL, 100 mg/10 mL, 120 mg/12 mL, and 240 mg/24 mL solution in a single-dose vial. **Indication:** In patients with unresectable advanced or metastatic esophageal squamous cell carcinoma as first-line treatment in combination with fluoropyrimidine- and platinum-containing chemotherapy. **Guidelines:** https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf
Ipilimumab (Yervoy)	**Dose:** Injection: 50 mg/10 mL (5 mg/mL) and 200 mg/40 mL (5 mg/mL) in a single-dose vial. **Indication:** Use in combination with nivolumab, is indicated for the first-line treatment of patients with unresectable advanced or metastatic esophageal squamous cell carcinoma. **Guidelines:** https://www.nccn.org/professionals/physician_gls/pdf/esophageal.pdf
Rituximab-arrx (Riabni)	**Dose:** injection, 100 mg/10 mL (10 mg/mL) and 500 mg/50 mL (10 mg/mL). **Indication:** To be used in combination with methotrexate for treating adult patients who have rheumatoid arthritis (RA) that is not responsive to treatment with a tumor necrosis factor (TNF) antagonist. **Guidelines:** https://www.rheumatology.org/Portals/0/Files/2021-ACR-Guideline-for-Treatment-Rheumatoid-Arthritis-Early-View.pdf

Information last updated July 22, 2022.

New Drug Indications

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Drug Name	Information
Mycophenolate mofetil (CellCept)	**Dose:** Capsules: 250 mg • Tablets: 500 mg • For Oral Suspension: 35 g mycophenolate mofetil, powder for reconstitution (200 mg/mL upon reconstitution) • For Injection: 500 mg mycophenolate mofetil in a single-dose vial for reconstitution. **Indication:** For expanding the current use of CellCept in the prophylaxis of organ rejection to pediatric recipients of allogenic heart and liver transplants, respectively. New Patient Population **Guidelines:** An Overview of Immunosuppression in Solid Organ TransplantationJanuary 31, 2015 https://www.ajmc.com/view/ace022_jan15_enderby
Baricitinib (Olumiant)	**Dose:** Tablets: 4 mg, 2 mg, 1 mg **Indication:** For the addition of the indication for the treatment of adult patients with severe alopecia areata. **Guidelines:** British Association of Dermatologists (BAD): Guidelines for the management of alopecia areata (2012) https://onlinelibrary.wiley.com/doi/pdf/10.1111/j.1365-2133.2012.10955.x
Setmelanotid (Imcivree)	**Dose:** Injection: 10 mg/mL solution in a 1 mL multiple-dose vial. **Indication:** For addition of an indication for chronic weight management in adult and pediatric patients 6 years of age and older with Bardet-Biedl Syndrome (BBS) to the prescribing information. **Guidelines:** https://rarediseases.org/rare-diseases/bardet-biedl-syndrome/
Brexanolone (Zulresso)	**Dose:** Injection: 100 mg/20 mL (5 mg/mL) single-dose vial. **Indication:** For expansion of the indication to include patients 15 years and older diagnosed with postpartum depression and addition of corresponding study information to applicable sections of the package insert, medication guide, and REMS. **Guidelines:** Postpartum Major Depression Am Fam Physician. 2010;82(8):926-933 https://www.aafp.org/pubs/afp/issues/2010/1015/p926.html

Information last updated July 22, 2022.

New Drug Indications

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Drug Name	Information
Risankizumab-rzaa (Skyrizi)	**Dose:** Injection: 600 mg/10 mL (60 mg/mL) in each single-dose vial & Injection: 360 mg/2.4 mL (150 mg/mL) in each single-dose prefilled cartridge. Other Dosage: Injection: 150 mg/mL in each single-dose prefilled pen. • Injection: 150 mg/mL in each single-dose prefilled syringe. • Injection: 75 mg/0.83 mL in each single-dose prefilled syringe. **Indication:** Moderately to severely active Crohn's disease in adults. **Guidelines:** AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn's Disease https://www.gastrojournal.org/article/S0016-5085(21)00645-4/fulltext
Trametinib (Mekinist)	**Dose:** Tablets: 0.5 mg, 2 mg **Indication:** Use in combination with dabrafenib is indicated for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. This indication is approved under accelerated approval based on overall response rate and duration of response. **Guidelines:** https://www.targetedonc.com/view/nccn-guidelines-updates-solid-tumors
Dabrafenib (Tafinlar)	**Dose:** Capsules: 50 mg, 75 mg **Indication:** Is indicated, in combination with trametinib, for the treatment of adult and pediatric patients 6 years of age and older with unresectable or metastatic solid tumors with BRAF V600E mutation who have progressed following prior treatment and have no satisfactory alternative treatment options. This indication is approved under accelerated approval based on overall response rate and duration of response. **Guidelines:** https://www.targetedonc.com/view/nccn-guidelines-updates-solid-tumors

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Drug Name	Information
Phentermine and Topiramate extended-release (Qsymia)	**Dose:** Extended-release capsules: (phentermine mg/topiramate mg) • 3.75 mg/23 mg • 7.5 mg/46 mg • 11.25 mg/69 mg • 15 mg/92 mg **Indication:** Indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in: Pediatric patients aged 12 years and older with BMI in the 5th percentile or greater standardized for age and sex. **Guidelines:** • Department of Veteran Affairs (VA)/Department of Defense (DoD): Clinical practice guideline for management of adult overweight and obesity (OBE) (2020) https://www.healthquality.va.gov/guidelines/CD/obesity/ • Academy of Nutrition and Dietetics (AND): Position on interventions for the treatment of overweight and obesity in adults (2016) https://www.jandonline.org/article/S2212-2672(15)01636-6/pdf
Secukinumab (Cosentyx)	**Dose:** Injection: 150 mg/mL solution in a single-dose Sensoready® pen and in a single-dose prefilled syringe. • Injection: 75 mg/0.5 mL solution in a single-dose prefilled syringe (for pediatric patients). • For Injection: 150 mg, lyophilized powder in a single-dose vial for reconstitution (for healthcare professional use only). **Indication:** Has expanded approval alone or with methotrexate, to include patients six years and older with enthesitis-related arthritis (ERA) and juvenile psoriatic arthritis (JPsA) who have not responded adequately to conventional therapy. **Guidelines:** • ACR/AF: Guideline for the treatment of juvenile idiopathic arthritis – Therapeutic approaches for non-systemic polyarthritis, sacroiliitis, and enthesitis (2019) • American College of Rheumatology (ACR)/National Psoriasis Foundation (NPF): Joint guideline for the treatment of psoriatic arthritis (2018).
Measles, mumps, and rubella (MMR) live vaccine (Priorix)	**Dose:** subcutaneous (SC) injections **Indication:** Indicated for active immunization for the prevention of measles, mumps, and rubella in individuals 12 months of age and older. **Guidelines:** https://www.cdc.gov/vaccines/vpd/mmr/public/index.html#:~:text=CDC%20recommends%20all%20children%20get,days%20after%20the%20first%20dose.

Information last updated July 22, 2022.

New Drug Indications

R&D | **FDA Approval** | In Market Brand | Generic Available | Off Market

Drug Name	Information
Pneumococcal 15-valent conjugate vaccine (Vaxneuvance)	**Dose:** Intramuscular injection: 0.5 mL as a single dose. **Indication:** New Patient Population. Its approval was extended to children as young as six weeks old. is a vaccine indicated for active immunization for the prevention of invasive disease caused by Streptococcus pneumoniae serotypes 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F in individuals 6 weeks of age and older. **Guidelines:** https://www.cdc.gov/pneumococcal/clinicians/prevention.html#:~:text=Vaccines%20are%20the%20best%20way,chemoprophylaxis%20is%20not%20recommended%20generally.
COVID-19 mRNA vaccine (Comirnaty)	**Dose:** Vaccine Intramuscular Suspension for injection. After preparation, a single dose is 0.3 mL. **Indication:** Under an Emergency Use Authorization (EUA), to include use in adolescents 12 through 15 years of age for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV 2). **Guidelines:** https://www.cdc.gov/coronavirus/2019-ncov/vaccines/index.html
Carfilzomib (Kyprolis)	**Dose:** For injection: 10 mg, 30 mg or 60 mg lyophilized powder in single-dose vial for reconstitution. **Indication:** Kyprolis in combination with Sarclisa (isatuximab-irfc) and dexamethasone (Isa-Kd) for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received one to three lines of therapy. **Guidelines:** https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf

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R&D | FDA Approval | In Market Brand | Generic Available | Off Market

First-Time Generic Approval

Generic Name	Applicant	Brand Name	Approval Date	Indication
Abiraterone Acetate Tablets USP, 125 mg	Teva Pharmaceuticals USA, Inc.	Yonsa (Abiraterone Acetate) Tablets	6/24/2022	In combination with methylprednisolone for the treatment of patients with metastatic castration-resistant prostate cancer
Cabazitaxel Injection, 60 mg/1.5 mL (40 mg/mL)	Breckenridge Pharmaceutical, Inc.	Jevtana (Cabazitaxel) Injection	6/23/2022	In combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer previously treated with a docetaxel-containing treatment regimen
Brivaracetam Tablets, 10 mg, 25 mg,50 mg, 75 mg, and 100 mg	Sunshine Lake Pharma Co. Limited	Briviact (Brivaracetam) Tablets	6/9/2022	For the treatment of partial-onset seizures in patients 4 years of age and older
Pemetrexed for Injection USP, 100 mg/vial, 500 mg/vial, 1 gram/vial	Zydus Pharmaceuticals (Usa) Inc.	Alimta (Pemetrexed for Injection)	5/25/2022	For the treatment of non-squamous non-small cell lung cancer and mesothelioma
Posaconazole Injection, 300 mg/16.7 mL (18 mg/mL) Single-Dose vial	Par Sterile Products, LLC	Noxafil (Posaconazole) IV solution	5/25/2022	For the prophylaxis of invasive Aspergillus and Candida infections in patients who are at high risk of developing these infections due to being severely immunocompromised
Lacosamide Oral Solution USP, 10 mg/mL	Alkem Laboratories Limited	Vimpat (Lacosamide) Oral Solution	5/19/2022	For the treatment of partial-onset seizures in patients 4 years of age and older

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Recall

R&D | FDA Approval | In Market Brand | Generic Available | Off Market

Date	Brand Name(s)	Product Description	Recall Reason Description	Company Name
07/21/2022	Multiple brands	Multiple OTC Medical Products	Products stored outside of temperature requirements	Family Dollar
07/15/2022	Multiple brand names	Magnesium Citrate Saline Laxative Oral Solution, Lemon Flavor	Microbial contamination with Gluconacetobacter liquefaciens	Vi-Jon, LLC
07/06/2022	Mylan Pharmaceuticals Inc.	Insulin Glargine (Insulin glargine-yfgn) Injection Pens	Potential for the label to be missing on some pens.	Mylan Pharmaceuticals Inc.
06/30/2022	Launch Sequence	Launch Sequence Aphrodisia and Euphoria Capsules	Contain Tadalafil	Loud Muscle Science, LLC
06/29/2022	Bryant Ranch Prepack Inc.	Morphine Sulfate 30 mg Extended-Release tablets	Incorrect labeling	Bryant Ranch Prepack Inc.
06/14/2022	Arti King	Artri King Reforzado con Ortiga y Omega 3	Undeclared Diclofenac and Dexamethasone	Latin Foods Market
06/09/2022	SnoreStop	Nasal spray	Due to microbial contamination identified as Providencia rettgeri.	Green Pharmaceuticals Inc.
06/08/2022	Major	Milk of Magnesia, Magnisium Hydroxide/ Aluminum Hydroxide/ Simethicone Oral Suspension	Due to microbial contamination	Plastikon Healthcare, LLC
06/07/2022	Allergy Bee Gone for Kids	Nasal Swab Remedy	Product contains elevated levels of Bacillus cereus	Buzzagogo Inc.
05/28/2022	Artri Ajo King	Joint supplements	Contains diclofenac	Walmart Inc.
05/23/2022	Teva	Anagrelide Capsules	Dissolution Test Failure	Teva Pharmaceuticals USA

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New Safety Communications	Date
FDA warns about possible increased risk of death and serious side effects with cancer drug Copiktra (duvelisib)	06/30/2022
FDA approval of lymphoma medicine Ukoniq (umbralisib) is withdrawn due to safety concerns	06/01/2022

Shortages (New)

Date	Drug Name (Shortage Reason)
07/20/2022	Adenosine Injection (Discontinuation)
07/20/2022	Alprostadil Injection (Discontinuation)
07/20/2022	Amikacin Sulfate Injection (Discontinuation)
07/20/2022	Bleomycin Injection (Discontinuation)
07/20/2022	Dacarbazine Injection (Discontinuation)
07/20/2022	Daunorubicin Hydrochloride Injection (Discontinuation)
07/20/2022	Desmopressin Acetate Injection (Discontinuation)
07/20/2022	Epoprostenol Sodium for Injection and Sterile Diluent for Epoprostenol Sodium for Injection (Discontinuation)
07/20/2022	Haloperidol Decanoate Injection (Discontinuation)
07/19/2022	Bumetanide Injection (Discontinuation)
07/14/2022	Iomeprol Injection (Currently in Shortage)
07/13/2022	Vandetanib Tablets (Currently in Shortage)
07/12/2022	Bivalirudin in 0.9% Sodium Chloride Injection (Discontinuation)
07/12/2022	Streptozocin (Zanosar) Sterile Powder (Currently in Shortage)

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References

For the most up to date list of drug shortages visit:

- https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm
- https://www.ashp.org/Coronavirus

Sources

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- https://www.cdc.gov/media/releases/2021/s-07082021.html t
- https://www.cdc.gov/mmwr/volumes/70/wr/mm7020e2.htm t
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- https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-newtherapeutic-biological-products/novel-drug-approvals-2021 t
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- https://www.accessdata.fda.gov/scripts/drugshortages/

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