MC-Rx

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Insights on the Drugs Pipeline

Exploring the changes in the drugs market.

December 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

Updated through December 8, 2022.

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

"Hot Topic"

The World Health Organization (WHO) recommended a new name for monkeypox that is intended to mitigate a rise in related racist and stigmatizing language associated with the ailment. The WHO's newly recommended preferred term is "mpox."

Mpox, similar to smallpox, is an illness caused by a viral zoonotic infection, meaning that it can spread from animals to humans. It can also spread from humans to other humans and from the environment to humans.

- The most common symptoms of mpox identified during the 2022 outbreak include fever, headache, muscle aches, back pain, low energy, swollen lymph nodes, and is followed by the development of a rash which may last for two to three weeks.
- Symptoms usually go away on their own or with supportive care, such as medications for pain or fever. People remain infectious until all the sores have crusted over, the scabs have fallen off and a new layer of skin has formed underneath.

People who live with or have close contact (including sexual contact) with someone who has mpox are most at risk. Some examples of techniques to prevent the spread of mpox include:

- Keep yourself informed about mpox in your area or social group and have open conversations with those you come into close contact (especially sexual contact) with about any symptoms you or they may have.
- Clean your hands frequently with soap and water or an alcohol-based hand rub.
- Frequently clean and disinfect commonly touched surfaces in the environments that could have been contaminated with the virus from someone who is infectious. Common household disinfectants or bleach products are enough to kill the mpox virus.
- If you think you might have mpox, you can act to protect others by seeking medical advice and isolating yourself from others until you have been evaluated and tested.
- If you have probable or confirmed mpox, you should isolate yourself from others until all of your sores have crusted over, the scabs have fallen off and a new layer of skin has formed underneath, and all the sores inside your body have also healed.

Some additional preventive measures include vaccination. There are two vaccines against mpox available in the US: ACAM2000 and JYNNEOS. Only people who are at risk (i.e. someone who has been in close contact with someone who has mpox) should be considered for vaccination.

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What's New

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

Vaccine	Indication	FDA Approval Date	Details
ACAM2000 (Smallpox (Vaccinia) Vaccine, Live)	Indicated for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection.	May 2, 2007	• Effectiveness of ACAM2000 against mpox is unknown, but it is suggested to have demonstrated protection against mpox in one study.
JYNNEOS (Smallpox and Mpox Vaccine, Live, Nonreplicating) suspension for subcutaneous injection (MVA-BN) Modified Vaccinia Ankara-Bavarian Nordic	JYNNEOS is a vaccine indicated for prevention of smallpox and mpox disease in adults 18 years of age and older determined to be at high risk for smallpox or mpox infection	September 24, 2019	• Jynneos will be available for those determined to be at high risk of either smallpox or mpox infection.

Currently, there is no specific treatment approved for mpox. However, there are several antiviral medications used to treat smallpox and other conditions that may help patients with mpox. These antivirals include: tecovirimat (TPOXX), brincidofovir (Tembexa, and cidofovir (Vistide). Additionally, intravenous vaccinia immune globulin (VIGIV), which is licensed for the treatment of complications from smallpox vaccination, may be authorized for use to treat mpox and other pox viruses during an outbreak.

Medication	Indication	FDA Approval Date	Formulation	Details
CNJ-016, Vaccinia Immune Globulin Intravenous (Human)	Indicated for the treatment of complications due to vaccinia vaccination (See package insert for additional information)	March 3, 2005	• Sterile solution available as 15 mL single-use vial containing a dose of ≥ 50,000 U/vial	CDC holds an expanded access IND protocol that allows the use of stockpiled VIGIV for the treatment of orthopoxviruses (including mpox) in an outbreak. VIGIV is not prepositioned by the US government. It is available upon clinician request to CDC on a case-by-case basis.
Tembexa (brincidofovir)	TEMBEXA is indicated for the treatment of human smallpox disease in adult and pediatric patients, including neonates	June 4, 2021	• Tablets: 100 mg • Oral Suspension: 10 mg/mL	Brincidofovir is made available from the SNS for treatment of mpox to clinicians who request and obtain an FDA-authorized single-patient emergency use IND (e-IND).

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Medication	Indication	FDA Approval Date	Formulation	Details
TPOXX (tecovirimat) ST-246	Indicated for the treatment of human smallpox disease in adults and pediatric patients weighing at least 3 kg (See limitations of use)	July 13, 2018	• Capsules 200 mg of tecovirimat • Injection: A single-dose vial containing 200 mg of tecovirimat	CDC holds a non-research expanded access Investigational New Drug (EA-IND) protocol (sometimes called "compassionate use") that allows for the use of tecovirimat for primary or early empiric treatment of non-variola orthopoxvirus infections, including mpox, in adults and children of all ages.
Vistide (cidofovir)	For CMV retinitis in patients with acquired immunodeficiency syndrome (AIDS)	June, 1996	• Injection: 75 mg/mL for intravenous infusion, is supplied as a non-preserved solution in single-use clear glass vials	Data are not available on the effectiveness of cidofovir in treatment of mpox virus infection in people. However, it has shown to be effective against orthopoxviruses in in vitro and animal studies. Cidofovir should not be used simultaneously with brincidofovir.

CDC Content last reviewed on December 1, 2022

References:

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Biosimilar Pipeline

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

Biosimilars under FDA Review with Possible Near-Term Approval

Biosimilar	Manufacturer(s)	Reference Biologic	Possible FDA Approval Date	Potential Launch Date
adalimumab (Adalimumab)	Fresenius Kabi	Humira (adalimumab)	1Q 2023	Settlement: 09/30/2023
adalimumab HCF, CF (Hukyndra)	Teva /Alvotech	Humira (adalimumab)	Dec. 2022	Settlement: 07/01/2023
adalimumab, CF (Yuflyma)	Celltrion	Humira (adalimumab)	2022	Settlement: 07/01/2023
adalimumab-adaz (Hyrimoz HCF, CF)	Sandoz	Humira (adalimumab)	5/21/2023	Settlement: 07/01/2023
adalimumab-afzb, CF(Abrilada)	Pfizer	Humira (adalimumab)	4Q:2022	Settlement: 07/01/2023
aflibercept (Aflibercept)	Momenta/Viatris	Eylea (aflibercept)	Oct. 2022	TBD (2024)
bevacizumab (Vegzelma)	Actinium /Celltrion	Avastin (bevacizumab)	10/1/2022	TBD (Pending FDA Approval)
bevacizumab (Bevacizumab)	Biothera	Avastin (bevacizumab)	2022	TBD (Pending FDA Approval)
bevacizumab (Abevmy)	Viatris/Biocon	Avastin (bevacizumab)	2022	TBD (Pending FDA Approval)
bevacizumab (Aybintio)	Samsung Bioepis/ Merck	Avastin (bevacizumab)	2022	TBD (Pending FDA Approval)
filgrastim (Filgrastim)	Tanvex BioPharma	Neupogen (filgrastim)	2022	TBD (Pending FDA Approval)
natalizumab (Natalizumab)	Sandoz	Tysabri (natalizumab)	May 2023	TBD (Pending FDA Approval)
pegfilgrastim (Lupifil-P)	Lupin	Neulasta (pegfilgrastim)	2H:2022	TBD (Pending FDA Approval)
tocilizumab (Tocilizumab)	Fresenius Kabi/ Merck	Actemra (tocilizumab)	2Q:2023	TBD (Pending FDA Approval)
trastuzumab (Trastuzumab)	EirGenix/Sandoz	Herceptin (trastuzumab)	10/20/2022	TBD (Pending FDA Approval)
trastuzumab (Trastuzumab)	Tanvex BioPharma	Herceptin (trastuzumab)	2022	TBD (Pending FDA Approval)

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Specialty Pipeline

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December 2022

Pipeline Drug	Current Status	Anticipated Approval	What is this drug being developed for?
adagrasib (Mirati Therapeutics)	NDA Filed	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 (Miplyffa - Orphazyme)	Complete Response	2023	Molecular chaperone activator that stimulates the normal cellular protein repair pathway for the treatment of NiemannPick Disease Type C (NPC); oral
bimekizumab (Bimzelx - UCB)	Complete Response	2023	Monoclonal antibody that blocks the effects of IL-17A and IL17F for the treatment of moderate-to-severe plaque psoriasis; SC injection
lebrikizumab (Eli Lilly)	Phase 3	2023	Humanized monoclonal antibody targeting interleukin 13 (IL13) for the treatment of atopic dermatitis; SC
lenacapavir (Gilead)	NDA Filed	12/27/2022	Long-acting HIV-1 capsid inhibitor for the treatment of HIV-1 infection in heavily treatment-experienced (THE) people with multi-drug resistant (MDR) HIV-1 infection; SC (every 6 months by a HCP) after oral dosing on Days 1, 2 and 8
obeticholic acid (Intercept Pharmaceuticals)	Complete Response	2023	Farnesoid X receptor (FXR) agonist for the treatment of liver fibrosis due to nonalcoholic steatohepatitis (NASH); oral
trofinetide (Acadia Pharmaceuticals)	NDA Filed	03/12/2023	A novel synthetic analog of the amino-terminal tripeptide of IGF1 to reduce neuroinflammation and supporting synaptic function in patients with Rett syndrome; oral solution

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New Molecular Entity

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NME	Details
Bevacizumab-adcd (Vegzelma) biosimilar* to AVASTIN	**Dosage form:** Injection: 100 mg/4 mL (25 mg/mL) or 400 mg/16 mL (25 mg/mL) in a single-dose vial. **Indication:** Is a vascular endothelial growth factor inhibitor indicated for the treatment of: • Metastatic colorectal cancer, in combination with intravenous fluorouracil based chemotherapy for first- or second-line treatment. • Metastatic colorectal cancer, in combination with pyrimidine irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen. **Comparables:** Avastin and biosimilars
Elivaldogene autotemcel (Skysona)	**Dosage form:** Is a cell suspension for intravenous infusion. **Indication:** Formerly known as eli-cel: Is indicated to slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy (CALD). Early, active CALD refers to asymptomatic or mildly symptomatic (neurologic function score, NFS ≤ 1) boys who have adolinium enhancement on brain magnetic resonance imaging (MRI) and Loes scores of 0.5-9. **Guidelines:** • https://rarediseases.org/rare-diseases/adrenoleukodystrophy/
Omidenepag isopropyl (Omlonti)	**Dosage form:** Ophthalmic solution containing 0.002% (0.02 mg/mL) of omidenepag isopropyl. **Indication:** Is a relatively selective prostaglandin E2 (EP2) receptor agonist, indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. **Guidelines:** • https://www.aafp.org/pubs/afp/issues/2016/0415/p668.html • https://www.nice.org.uk/guidance/ng81 **Comparables:** Prostaglandins: Bimatoprost, Latanoprost, Latanoprostene bunod, Tafluprost, Travoprost

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In-Market Brand

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

In-Market brand	Details
Futibatinib (Lytgobi)	**Dosage form:** Tablets: 4 mg. **Indication:** FDA granted accelerated approval. Is a kinase inhibitor indicated for the treatment of adult patients with previously treated, unresectable, locally advanced or metastatic intrahepatic cholangiocarcinoma harboring fibroblast growth factor receptor 2 (FGFR2) gene fusions or other rearrangements. This indication is approved under accelerated approval. **Guidelines:** ● https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf **Comparables:** Pemigatinib (Pemazyre), Infigratinib (Truseltiq)
Sodium phenylbutyrate and taurursodiol (Relyvrio)	**Dosage form:** For oral suspension: 3 g sodium phenylbutyrate and 1 g taurursodiol in single dose packets. **Indication:** Is indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults. **Guidelines:** ● American Academy of Neurology (AAN): Guideline on the care of the patient with amyotrophic lateral sclerosis – Drug, nutritional, and respiratory therapies, update (2009, reaffirmed 2020) ● AAN: Guideline on the care of the patient with amyotrophic lateral sclerosis – Multidisciplinary care, symptom management, and cognitive/behavioral impairment, update (2009, reaffirmed 2020)
Teclistamab-cqyv (Tecvayli)	**Dosage form:** Injection • 30 mg/3 mL (10 mg/mL) in a single-dose vial • 153 mg/1.7 mL (90 mg/mL) in a single-dose vial. **Indication:** Is a bispecific B-cell maturation antigen (BCMA)-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody. **Guidelines:** ● https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf
Tremelimumab-actl (lmjudo)	**Dosage form:** injection for intravenous infusion. **Indication:** Is indicated in combination with durvalumab, for the treatment of adult patients with unresectable hepatocellular carcinoma. **Guidelines:** ● https://www.nccn.org/professionals/physician_gls/pdf/hepatobiliary.pdf **Comparables:** ● Bevacizumab plus atezolizumab ● Sintilimab plus bevacizumab ● Cabozantinib plus atezolizumab

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New Drug Formulations

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

NDF	Details
Amifampridine (Firdapse)	**New Dosage Form:** Tablets: 10 mg, functionally scored. **Indication:** For the addition of the treatment of pediatric patients with Lambert-Eaton myasthenic syndrome age 6 to less than 17 years to the prescribing information. **Guidelines:** • https://rarediseases.org/rare-diseases/lambert-eaton-myasthenic-syndrome/ **Comparable:** Ruzurgi (amifampridine)
Aprepitant (Aponvie)	**New Dosage Form:** Emulsion; Intravenous: Injectable emulsion: 32 mg/4.4 mL (7.2 mg/mL) in single-dose vial. **Indication:** Is a substance P/neurokinin-1 (NK1) receptor antagonist, indicated for the prevention of postoperative nausea and vomiting (PONV) in adults. **Guidelines:** • https://www.nccn.org/professionals/physician_gls/pdf/antiemesis.pdf **Comparables:** Cinvanti, Emend, Fosaprepitant
Furosemide (Furoscix)	**New Dosage Form:** Injection: 80 mg per 10 mL in a single-dose prefilled cartridge co-packaged with a single-use on-body infusor. **Indication:** Is indicated for the treatment of congestion due to fluid overload in adults with NYHA Class II/III chronic heart failure. **Guidelines:** • 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines **Comparable:** Furosemide

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New Generics

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First Time Generic Drug Approvals

ANDA Number	Generic Name	ANDA Applicant	Brand Names	ANDA Approval Date	ANDA Indication
202073	Darunavir Tablets, 600 mg and 800 mg	Lupin Limited	Prezista (Darunavir) Tablets	9/29/2022	For the treatment of HIV-1 infection in adult and pediatric patients 3 years of age and older
209485	Mirabegron Extended-Release Tablets, 25 mg and 50 mg	Lupin Limited	Myrbetriq (Mirabegron) Extended-Release Tablets	9/29/2022	For the treatment of overactive bladder in adult patients with symptoms of urge urinary incontinence, urgency, and urinary frequency

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FDA Drug Shortages

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Posting Date	Generic Name	Dosage Forms	Reason for Shortage
10/25/2022	Albuterol Sulfate Inhalational Solution	0.5%; 20mL	Other
10/18/2022	Alprostadil (Muse) Suppository	Multiple Strengths	Multiple Reasons for Shortage
10/28/2022	Amoxicillin Oral Powder for Suspension	Multiple Strengths	Multiple Reasons for Shortage
10/12/2022	Amphetamine Aspartate; Amphetamine Sulfate; Dextroamphetamine Saccharate; Dextroamphetamine Sulfate Tablets	Multiple Strengths	Multiple Reasons for Shortage
10/27/2022	Bosentan Tablets	Multiple Strengths	
11/2/2022	Butenafine Hydrochloride Cream	Multiple Strengths	
10/26/2022	Clobetasol Propionate Ointment	Multiple Strengths	
11/21/2022	Collagenase Ointment	Multiple Strengths	Multiple Reasons for Shortage
10/14/2022	Glipizide XL Tablets	Multiple Strengths	
11/18/2022	Glucagon Injection	Multiple Strengths	
11/8/2022	Hydrochlorothiazide and Spironolactone (Aldactazide) Tablets	25 mg tablet; bottle of 100	
10/27/2022	Lamivudine Oral Solution	5 mg/mL 240 mL bottle	
10/27/2022	Lamivudine Tablets	100 mg tablets	
10/11/2022	Memantine Hydrochloride Extended-Release Capsules	Multiple Strengths	
11/28/2022	Metronidazole Vaginal Gel	0.75%, 70g tube	
10/7/2022	Nateglinide Tablets	Multiple Strengths	
11/16/2022	Neomycin Sulfate Tablets	Multiple Strengths	Multiple Reasons for Shortage
11/23/2022	Paliperidone Extended Release Tablets	Multiple Strengths	

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New Drug Entities

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Posting Date	Generic Name	Dosage Forms	Reason for Shortage
11/23/2022	Pregabalin Capsules	Multiple Strengths	
10/14/2022	Verapamil Hydrochloride Tablets	120 mg: Bottle of 100 caplets	
11/14/2022	Voriconazole Tablets	Multiple Strengths	

FDA Recalls & Safety Alerts

Date	Manufacturer	Product Description	Recall Reason Description	Company Name
09/29/2022	Golden State Medical Supply	Clopidogrel 75mg Tablets, Atenolol 25mg Tablets	Due to Label Mix-up	Golden State Medical Supply, Incorporated
10/25/2022	Mylan Institutional LLC	Octreotide Acetate Injection, 500 mcg/mL	Due to glass particulates	Mylan Institutional LLC, a Viatris company
10/25/2022	Aurobindo Pharma USA, Inc.	Quinapril and Hydrochlorothiazide Tablets USP, 20mg / 12.5mg, 90's HDPE bottle	Due to presence of Nitrosamine Drug Substance Related Impurity (NDSRI), N-Nitroso-Quinapril	Aurobindo Pharma USA, Inc.

Manufacturer Withdrawals

Date	Manufacturer	Product Description	Recall Reason Description
11/22/2022	GlaxoSmithKline	Belantamab mafodotin-blmf (Blenrep)	Blenrep fell short of its primary efficacy measure in the Phase III confirmatory trial DREAMM-3

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