MC-Rx

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Insights on the Drugs Pipeline

Exploring the changes in the drugs market.

June 2023

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 June 2, 2023.

What Are The Changes After The End Of COVID-19?

The President of the United States declared a National Emergency concerning the Novel Coronavirus Disease (COVID-19) Outbreak on March 13, 2020. The United States has made several remarkable developments over the last three years, which include COVID-19 vaccines, organizing the largest global vaccination campaign, developing COVID-19 treatments, and distributing COVID-19 tests. In fact, COVID-19 was the third leading cause of death in 2021. However, during January 2023, according to the Department of Health, deaths due to COVID-19 have decreased by 97%. Thus, the federal COVID-19 Public Health Emergency (PHE) declaration ended on May 11, 2023. With this declaration, there are some changes in coverage and/or access to COVID-19 treatments, vaccines, and services.

What are some of the changes?

The areas most affected by the end of the COVID-19 PHE are COVID-19 vaccines and tests, treatments, telehealth services, and data sources. Overall, the federal government is no longer purchasing or distributing COVID-19 vaccines and treatments, which means patients must either go through their health insurance or pay out-of-pocket.

Vaccines approved under an Emergency Use Authorization (EUA) will continue to be available at no cost to the member. Once Vaccines approved by the Food & Drug Administration (FDA) (e.g. Spikevax, Comirnaty) are commercially available, members may have access through their insurance plans in accordance with their plan benefit and/or may incur an out-of-pocket cost depending on insurance coverage of vaccines.

Tests, specifically for the private commercial health plans, there may be out-of-pocket costs for members and/or limitations on the number of tests you can receive at any given time. However, COVID-19 PCRs and antigen tests will continue to be covered by Medicare Part B with a provider's order. Additionally, members with Medicaid will continue to have coverage for COVID-19 PCR and OTC tests without cost sharing through September 30, 2024. This will however, vary by state.

Treatments, since the federal government has stopped the purchasing of these treatments, out-of-pocket expenses for COVID-19 treatments may change after these products become commercially available and move to traditional healthcare models.

Telehealth Services & Data Sources, telemedicine flexibilities such as authorized prescribers being allowed to prescribe controlled substances, will be extended until November 11, 2023. Lastly, some states will no longer routinely report on COVID-19 statistics, however, the Centers for Disease Control and Prevention (CDC) continues to report on these metrics.

Because of the end of the public health emergency, COVID-19 treatments, vaccines, and services will continue to remain accessible to the public, but may have out-of-pocket costs to members. Contact your insurance provider for information regarding coverage and out-of-pocket costs for products and services.

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References:

- Assistant Secretary for Public Affairs (ASPA) (2023) *Fact sheet: COVID-19 public health emergency transition roadmap, HHS.gov*. Available at: https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html (Accessed: 20 May 2023).
- *"Coverage for Covid-19 Testing, Vaccinations, and Treatment." Center on Budget and Policy Priorities, 22 May 2023, www.cbpp.org/research/health/coverage-for-covid-19-testing-vaccinations-and-treatment*.
- *Covid-19 was third leading cause of death in U.S. (2022) Centers for Disease Control and Prevention*. Available at: https://www.cdc.gov/media/releases/2022/s0422-third-leading-cause.html (Accessed: 20 May 2023).
- DPH news release - end of the Public Health Emergency Declaration. Georgia Department of Public Health. May 11, 2023. Accessed May 20, 2023. https://dph.georgia.gov/press-releases/2023-05-11/dph-news-release-end-public-health-emergency-declaration#:~:text=Now%20that%20we%20have%20safe,longer%20a%20public%20health%20emergency.
- *Fact Sheet: Actions taken by the Biden-Harris Administration to ensure continued COVID-19 protections and surge preparedness after Public Health Emergency Transition (2023) The White House*. Available at: https://www.whitehouse.gov/briefing-room/statements-releases/2023/05/09/fact-sheet-actions-taken-by-the-biden-harris-administration-to-ensure-continued-covid-19-protections-and-surge-preparedness-after-public-health-emergency-transition/ (Accessed: 01 June 2023).
- *Fact Sheet: HHS Announces 'HHS Bridge Access Program For COVID-19 Vaccines and Treatments' to Maintain Access to COVID-19 Care for the Uninsured*. Available at: https://www.hhs.gov/about/news/2023/04/18/fact-sheet-hhs-announces-hhs-bridge-access-program-covid-19-vaccines-treatments-maintain-access-covid-19-care-uninsured.html

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Specialty Pipeline

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

Drug Name (Brand Name Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Arimoclomol (Miplyffa - Orphazyme)	Complete Response	2023	Molecular chaperone activator that stimulates the normal cellular protein repair pathway for the treatment of Niemann-Pick Disease Type C (NPC); oral
Avacincaptad pegol (ACP- Iveric Bio)	BLA Filed	08/19/2023	Inhibitor of complement component 5 (C5) for treating geographic atrophy secondary to age-related macular degeneration (AMD); intravitreal injection
Bimekizumab (Bimzelx - UCB)	BLA Filed	2023	Monoclonal antibody that blocks the effects of IL-17A and IL-17F for the treatment of moderate-to-severe plaque psoriasis; SC injection
Cipaglucosidase alfa (Amicus Therapeutics)	BLA Filed	2023	Recombinant human acid α-glucosidase (rhGAA) enzyme replacement therapy/ chaperone therapy for the treatment of late-onset Pompe disease; IV infusion
Delandistrogene moxeparvovec (Sarepta/ Genentech)	BLA Filed	05/29/2023	A unique, engineered micro-dystrophin gene therapy, using an AAV vector, for the treatment of Duchenne Muscular Dystrophy (DMD); IV infusion (one time)
Donanemab (Eli Lilly)	Complete Response	2024	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 (Upstaza PTC Therapeutics)	Phase 3	2023	Recombinant, adeno-associated virus, containing the human cDNA encoding the AADC enzyme for the treatment of AADC deficiency; intracerebral infusion
Exagamglogene autotemcel (Vertex Pharmaceuticals/ CRISPR Therapeutics)	Phase 3	2023	Gene edited therapy utilizing CRISPR-Cas9 of primary human hematopoietic stem and progenitor CD34+ cells that have undergone ex vivo editing of the erythroid specific enhancer region of BCL11A, for the treatment of sickle cell disease and transfusion dependent beta thalassemia; intravenous (single dose)
Lebrikizumab (Eli Lilly)	BLA Filed	09/2023	Humanized monoclonal antibody targeting interleukin 13 (IL-13) for the treatment of atopic dermatitis; SC

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Specialty Pipeline

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

Drug Name (Brand Name Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Leniolisib (Pharming)	Approved	03/24/2023	Phosphoinositide 3-kinase delta (PI3Kδ) inhibitor for the treatment of activated phosphoinositide 3-kinase delta (APDS) syndrome in patients 12 years of age and older; oral
Lovotibeglogene autotemcel (lovocel - bluebird bio)	Phase 3	2024	Lenti-D gene therapy for the treatment of sickle cell disease; IV infusion
Mirikizumab (Eli Lilly)	BLA Filed	2023	Monoclonal antibody targeting IL-23p19 for the treatment of moderate-to-severe ulcerative colitis; administered via IV infusion and SC injection
Nedosiran (Novo Nordisk)	NDA Filed	09/2023	RNA interference therapeutic designed to inhibit hepatic lactate dehydrogenase (LDH; encoded by LDHA), the enzyme responsible for oxalate overproduction for the treatment of primary hyperoxaluria type 1; SC injection
Obeticholic acid (Intercept Pharmaceuticals)	NDA Filed	06/23/2023	Farnesoid X receptor (FXR) agonist for the treatment of liver fibrosis due to nonalcoholic steatohepatitis (NASH); oral
Resmetirom (Madrigal Pharmaceuticals)	Phase 3	2024	Thyroid hormone receptor (THR) ß-selective agonist for the treatment of nonalcoholic steatohepatitis (NASH); oral
Ritlecitinib (Pfizer)	NDA Filed	2023	JAK3/TEC inhibitor for the treatment of adults and adolescents aged 12 years and older with alopecia areata; oral
Talquetamab (Janssen/ Genmab)	BLA Filed	08/09/2023	First in class; bispecific antibody that targets both GPRC5D, a novel multiple myeloma target, and CD3 on T-cells for the treatment of adult patients with relapsed or refractory multiple myeloma, who have previously received at least 3 prior lines of therapy; SC
Valoctocogene roxaparvovec (Roctavian – BioMarin Pharmaceuticals)	BLA Filed	06/30/2023	Adenoviral vector-mediated transfer of the Human Factor VIII gene to treat severe hemophilia A; IV infusion

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Biosimilar Pipeline

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

Biosimilar	Manufacturer(s)	Reference Biologic	Possible FDA Approval Date	Potential Launch Date
Adalimumab (Simlandi)	Teva/Alvotech	Humira (adalimumab)	4/13/2023	Settlement: 07/01/2023
Adalimumab (Yuflyma)	Celltrion	Humira (adalimumab)	2023	Settlement: 07/01/2023
Adalimumab-Afzb (Abrilada)	Pfizer	Humira (adalimumab)	2023	Settlement: 07/01/2023
Aflibercept	Momenta/Biocon	Eylea (aflibercept)	Mid 2023	TBD (2024?)
Bevacizumab	Biothera/Sandoz	Avastin (bevacizumab)	2023	TBD (Pending FDA Approval)
Bevacizumab (Equidacent)	Centus	Avastin (bevacizumab)	2023	TBD (Pending FDA Approval)
Bevacizumab (Abevmy)	Biocon	Avastin (bevacizumab)	2024	TBD (Pending FDA Approval)
Bevacizumab (Aybintio)	Samsung Bioepis/ Organon	Avastin (bevacizumab)	2023	TBD (Pending FDA Approval)
Denosumab	Sandoz	Prolia (denosumab)	12/6/2023	TBD (Feb 2025?)
Filgrastim	Tanvex BioPharma	Neupogen (filgrastim)	2023	TBD (Pending FDA Approval)
Infliximab	Celltrion	Remicade (infliximab)	10/22/2023	TBD (Pending FDA Approval)
Natalizumab	Sandoz	Tysabri (natalizumab)	May 2023	TBD (Pending FDA Approval)
Pegfilgrastim (Lupifil-P)	Lupin	Neulasta (pegfilgrastim)	2023	TBD (Pending FDA Approval)
Pegfilgrastim-Cbqv (Udenyca OBI)	Coherus Biosciences	Neulasta (pegfilgrastim)	Oct. 2023	TBD. New on-body device
Tocilizumab	Fresenius Kabi/Merck KGaA	Actemra (tocilizumab)	2Q:2023	TBD (Settlement agreement. Terms not disclosed)
Tocilizumab	Biothera/Biogen	Actemra (tocilizumab)	10/9/2023	TBD (Pending FDA Approval)
Trastuzumab	Henlius/Accorda	Herceptin (trastuzumab)	12/14/2023	TBD (Pending FDA Approval)
Trastuzumab	EirGenix/Sandoz	Herceptin (trastuzumab)	2023	TBD (Pending FDA Approval)

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Biosimilar Pipeline

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

Biosimilar	Manufacturer(s)	Reference Biologic	Possible FDA Approval Date	Potential Launch Date
Trastuzumab	Tanvex BioPharma	Herceptin (trastuzumab)	2024	TBD (Pending FDA Approval)
Ustekinumab	Amgen	Stelara (ustekinumab)	2H 2023	TBD (Pending FDA Approval)
Ustekinumab	Alvotech/Teva	Stelara (ustekinumab)	2H:2023	TBD (Pending FDA Approval)

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New Drug Entities

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

New Drug Entities	Details
Tofersen (Qalsody)	**Dosage form:** Injection: 100 mg/15 mL (6.7 mg/mL) solution in a single-dose vial. **Indication:** PRIORITY; Orphan: An antisense oligonucleotide indicated for the treatment of amyotrophic lateral sclerosis (ALS) in adults who have a mutation in the superoxide dismutase 1 (SOD1) gene. **Comparables:** None **Guidelines:** American Academy of Neurology (AAN)
Beremagene geperpavec-svdt (Vyjuvek)	**Dosage form:** single-use vial. Vyjuvek is a genetically modified (engineered in a laboratory) herpes-simplex virus used to deliver normal copies of the COL7A1 gene to the wounds. COL7 molecules arrange themselves into long, thin bundles that form anchoring fibrils that hold the epidermis (skin) and dermis together, which is essential for maintaining the integrity of the skin. Vyjuvek has also been modified to eliminate its ability to replicate in normal cells. Vyjuvek is mixed into an excipient (non-active ingredient) gel prior to topical application. A healthcare professional evenly applies Vyjuvek gel in droplets to a patient's wounds once a week. **Indication:** Off-the-shelf gene therapy for the treatment of wounds in patients 6 months of age and older with dystrophic epidermolysis bullosa (DEB) with mutation(s) in the collagen type VII alpha 1 chain (COL7A1) gene. **Comparables:** None **Guidelines:** https://rarediseases.org/rare-diseases/epidermolysis-bullosa/
Epcoritamab-bysp (Epkinly)	**Dosage form:** Injection: 4 mg/0.8 mL in a single-dose vial. Dilute prior to use. Injection: 48 mg/0.8 mL in a single-dose vial. **Indication:** Is a bispecific CD20-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy. *the first and only subcutaneous, bispecific antibody for patients with diffuse large B-cell lymphoma in the third line or later. **Comparables:** None **Guidelines:** National Comprehensive Cancer Network (NCCN)
Nirmatrelvir tablets; Ritonavir tablets (Paxlovid)	**Dosage form:** Tablets: nirmatrelvir 150 mg (3) • Tablets: ritonavir 100 mg (3) **Indication:** Treatment of mild-to-moderate coronavirus disease 2019 (COVID-19) in adults who are at high risk for progression to severe COVID-19, including hospitalization or death. **Comparables:** Molnupiravir (EUA) **Guidelines:** https://www.covid19treatmentguidelines.nih.gov/

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New Drug Entities

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

New Drug Entities	Details
Perfluorohexyloctane (Miebo)	**Dosage form:** Ophthalmic solution: 100% perfluorohexyloctane. **Indication:** Semifluorinated alkane indicated for treatment of the signs and symptoms of dry-eye disease. **Comparables:** Restasis generics, Xiidra (lifitegrast ophthalmic solution), and Tyrvaya (varenicline solution) nasal spray. **Guidelines:** https://www.aao.org/education/preferred-practice-pattern/dry-eye-syndrome-ppp-2018
Rezafungin (Rezzayo)	**Dosage form:** For injection: 200 mg as a solid (cake or powder) in a single-dose vial for reconstitution. **Indication:** An echinocandin antifungal indicated in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. **Comparables:** The echinocandins include caspofungin, anidulafungin, and micafungin **Guidelines:** IDSA: Clinical practice guideline for the management of candidiasis, update (2016)

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New Drug Formulations

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

New Drug Formulations	Details
Gabapentin (Gralise)	**New Dosage form:** NDF Tablets: 450 mg, 600 mg, 750 mg, and 900 mg; Other Tablets 300 mg. For the addition of new dosage strengths (450 mg, 750 mg and 900 mg) **Indications:** For the management of postherpetic neuralgia **Comparables:** Gabapentin
Lacosamide extended-release (Motpoly XR)	**New Dosage form:** 100 mg, 150 mg, 200 mg extended-release capsules **Indication:** The treatment of partial-onset seizures in adults and in pediatric patients weighing at least 50 kg. **Comparables:** Lacosamide, Vimpat **Guidelines:** AAN and AES Guidelines (2018)
Tropicamide and phenylephrine hydrochloride (Mydcombi)	**New Dosage form:** Ophthalmic spray containing tropicamide 1% and phenylephrine hydrochloride 2.5%. Each metered spray delivers 0.008 mL which contains 0.08 mg tropicamide and 0.2 mg phenylephrine HCl **Indication:** A combination of tropicamide, an anticholinergic, and phenylephrine hydrochloride, an alpha-1 adrenergic receptor agonist indicated to induce mydriasis for diagnostic procedures and in conditions where short-term pupil dilation is desired. **Comparables:** Other Ophthalmic Diagnostics
Zolpidem Tartrate	**New Dosage form:** Capsules: 7.5 mg **Indication:** A gamma-aminobutyric acid (GABA) A receptor positive modulator, is indicated for the short-term treatment of transient insomnia characterized by difficulties with sleep initiation in adults younger than age 65 years of age. **Comparables:** Generic Zolpidem **Guidelines:** AASM: Clinical practice guideline for the pharmacologic treatment of chronic insomnia in adults (2017)

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New Drug Indications

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

New Drug Indications	Details
Adalimumab-adaz (Hyrimoz)	For the addition of the indication of treatment of moderate-to-severe hidradenitis suppurativa in adult patients.
Brexpiprazole (Rexulti)	For the addition of the indication of treatment of agitation associated with dementia due to Alzheimer's disease.
Dapagliflozin (Farxiga)	For the following new indication: to reduce the risk of cardiovascular death, hospitalization for heart failure and urgent heart failure visit in adults with heart failure.
Escitalopram (Lexapro)	For the expansion of the indication for generalized anxiety disorder (GAD) to include patients 7 to 17 years of age
Fluticasone furoate and vilanterol (Breo Ellipta)	For the expansion of indication for Breo Ellipta (fluticasone furoate and vilanterol) 100/25 mcg to include maintenance treatment of asthma for patients aged 12 to 17 years, AND For the expansion of indication for Breo Ellipta (fluticasone furoate and vilanterol) to include maintenance treatment of asthma in patients 5 to 11 years.
Immune Globulin (Human) with Recombinant Human Hyaluronidase (Hyqvia)	For the expansion of the indication of Primary Immunodeficiency Diseases to pediatric patients from 2 years of age ≤ 16 years of age .
Ivacaftor (Kalydeco)	For the expansion of indication for treatment of cystic fibrosis (CF) in patients 1 month to less than 4 months of age who have at least one mutation in the CFTR gene that is responsive to Ivacaftor.
Levonorgestrel-releasing (Skyla)	For the expansion of the indication to prevent pregnancy for up to 3 years.
Polatuzumab vedotin-piiq (Polivy)	For the expansion of the indication to use in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone (R-CHP) for the treatment of adult patients who have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) or high-grade B-cell ymphoma (HGBL) and who have an International Prognostic Index score of 2 or greater.
Somapacitan-beco (Sogroya)	For the expansion of indication for the treatment of pediatric patients who have growth failure due to inadequate secretion of endogenous growth hormone (GH)
Teprotumumab-trbw (Tepezza)	To specify that it is now indicated for use in all patients with thyroid eye disease (TED) rather than just those patients with acute cases of the disease.
Upadacitinib (Rinvoq)	For the treatment of adult patients with moderately-to-severely active Crohn's disease who have had an inadequate response or intolerance to one or more TNF blockers.

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In Market Brand

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

In-Market Brands	Details
Aripiprazole (Abilify Asimtufii)	**New Dosage form:** Abilify Asimtufii: Extended-release injectable suspension: 960 mg/3.2 mL and 720 mg/2.4 mL single-dose pre-filled syringes. **Indication:** For the treatment of schizophrenia in adults and as maintenance monotherapy treatment of bipolar I disorder in adults. **Comparables:** Abilify Maintena, Risperdal Consta, Aristada, Invega Sustena/ Hayfera/etc.
Chloroprocaine hydrochloride (Iheezo)	**New Dosage form:** Ophthalmic gel 3% contains 24 mg of chloroprocaine hydrochloride per vial (800 mg). Clear, colorless to light yellow gel in single, patient-use vial. **Indication:** An ester anesthetic indicated for ocular surface anesthesia. **Comparables:** Akten 3.5% Gel Drops, Alcaine 0.5% Eye Drops, Altacaine 0.5% Eye Drop, Proparacaine 0.5% Eye Drops, Tetracaine 0.5% Eye Drop **Guidelines:** • Mafi JN, Godoy-Travieso P, Wei E, et al. Evaluation of an Intervention to Reduce Low-Value Preoperative Care for Patients Undergoing Cataract Surgery at a Safety-Net Health System. JAMA Intern Med 2019; 179:648. • McGoldrick KE, Gayer SI. Anesthesia for Ophthalmologic Surgery. In: Clinical Anesthesia, 8, Barash PG (Ed), Lippincott Williams & Wilkins, Philadelphia 2017. p.1373. • Sweitzer B, Rajan N, Schell D, et al. Preoperative Care for Cataract Surgery: The Society for Ambulatory Anesthesia Position Statement. Anesth Analg 2021; 133:1431.
Fecal microbiota spores, live-brpk (Vowst)	**New Dosage form:** Capsule. A single dose is 4 capsules. **Indication:** To prevent the recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older following antibacterial treatment for recurrent CDI (rCDI). **Comparables:** Fecal Microbiota Transplantation (FMT) and Rebyota
Fezolinetant (Veozah)	**Dosage form:** Tablets: 45 mg **Indication:** A neurokinin 3 (NK3) receptor antagonist indicated for the treatment of moderate to severe vasomotor symptoms due to menopause. **Comparables:** Paroxetine 7.5-mg capsules **Guidelines:** ACOG: Practice bulletin on the management of menopausal symptoms (2014)
Omidubicel-onlv (Omisirge)	**Dosage form:** A single dose of OMISIRGE consists of • a Cultured Fraction (CF): a minimum of 8.0 × 108 total viable cells of which a minimum of 8.7% is CD34+ cells and a minimum of 9.2 × 107 CD34+ cells, and • a Non-cultured Fraction (NF): a minimum of 4.0 × 108 total viable cells with a minimum of 2.4 × 107 CD3+ cells **Indication:** A nicotinamide modified allogeneic hematopoietic progenitor cell therapy derived from cord blood indicated for use in adults and pediatric patients 12 years and older with hematologic malignancies who are planned for umbilical cord blood transplantation following myeloablative conditioning to reduce the time to neutrophil recovery and the incidence of infection. **Comparables:** None **Guidelines:** National Comprehensive Cancer Network (NCCN)

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In Market Brand

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In-Market Brands	Details
Pegunigalsidase alfa-iwxj (Elfabrio)	**Dosage form:** Injection: 20 mg/10 mL (2 mg/mL) solution in a single-dose vial. **Indication:** A hydrolytic lysosomal neutral glycosphingolipid-specific enzyme indicated for the treatment of adults with confirmed Fabry disease. **Comparables:** Fabrazyme (agalsidase beta), Galafold (migalastat hydrochloride) **Guidelines:** https://rarediseases.org/rare-diseases/fabry-disease/#therapies
Risperidone extended-release (Uzedy)	**New Dosage form** Uzedy (risperidone): Extended-release injectable suspension: 50 mg/0.14 mL, 75 mg/0.21 mL, 100 mg/0.28 mL, 125 mg/0.35 mL, 150 mg/0.42 mL, 200 mg/0.56 mL, and 250 mg/0.7 mL single-dose prefilled syringes. **Indication:** For the treatment of schizophrenia in adults and as maintenance monotherapy treatment of Bipolar I disorder in adults. **Comparables:** Abilify Maintena, Risperdal Consta, Aristada, Invega Sustena/ Hayfera/etc.
Sildenafil (Liqrev)	**New Dosage form:** Oral Suspension: 10 mg/mL (3) Each 1 mL of oral suspension. Contains 10 mg sildenafil (equivalent to 14 mg sildenafil citrate). **Indication:** For the treatment of pulmonary arterial hypertension (PAH) in adults to improve exercise ability and delay clinical worsening **Comparables:** Suspension (reconstituted) (Revatio Oral) 10 mg/mL, Suspension (reconstituted) (generic Sildenafil Citrate Oral) 10 mg/mL
Sodium oxybate (Lumryz)	**New Dosage form:** Extended-release oral suspension: Pkts of 4.5 g, 6 g, 7.5 g, or 9 g **Indication:** A central nervous system depressant indicated for the treatment of cataplexy or excessive daytime sleepiness (EDS) in adults with narcolepsy. **Comparables:** Xyrem and Xywav **Guidelines:** American Academy of Sleep Medicine (AASM): Clinical practice guideline for the management of REM sleep behavior disorder (2022)

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New Generics

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Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indication
Acetaminophen and Ibuprofen Tablets	L. Perrigo Company	Advil Dual Action with Acetaminophen (OTC)	2/28/2023	Temporarily relieves minor aches and pains due to headache, toothache, backache, menstrual cramps, muscular aches, minor pain of arthritis
Bismuth Subcitrate Potassium, Metronidazole and Tetracycline Hydrochloride Capsules	Par Pharmaceutical, Inc.	Pylera	3/6/2023	For the treatment of patients with Helicobacter pylori infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate H. pylori
Calcipotriene & Betamethasone Dipropionate Foam	Glenmark Pharmaceuticals Limited	Enstilar	3/21/2023	For the topical treatment of plaque psoriasis in patients 12 years and older
Doxepin Hydrochloride Cream	Teva Pharmaceuticals Development, Inc.	Zonalon	2/17/2023	For the short-term (up to 8 days) management of moderate pruritus in adult patients with atopic dermatitis or lichen simplex chronicus
Nitisinone Capsules	Torrent Pharma Inc.	Orfadin	1/9/2023	For the treatment of adult and pediatric patients with hereditary tyrosinemia type 1 (HT-1) in combination with dietary restriction of tyrosine and phenyl
Tiopronin Delayed-Release Tablets	Par Pharmaceutical, Inc.	Thiola	2/24/2023	For the prevention of cystine stone formation in adults and pediatric patients 9 years of age and older with severe homozygous cystinuria, who are not responsive to these measures alone
Tofacitinib Tablets	Micro Labs Limited	Xeljanz	3/13/2023	For the treatment of adult patients with moderately-to-severely active rheumatoid arthritis; active psoriatic arthritis; moderately to severely active ulcerative colitis

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Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indication
Topiramate Extended-Release Capsules	Zydus Pharmaceuticals (USA) Inc.	Trokendi XR	2/9/2023	Initial monotherapy for the treatment of partial-onset or primary generalized tonic-clonic seizures in patients 6 years of age and older; adjunctive therapy for the treatment of partial-onset, primary generalized tonic-clonic seizures or seizures associated with Lennox-Gastaut syndrome (LGS) in patients 6 years of age and older; preventive treatment of migraine in patients 12 years of age and older

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Recall Notifications

Date	Drug Name	Reason for Recall	Company Name
03/31/2023	Atovaquone Oral Suspension (Camber)	Potential Bacillus cereus Contamination	Camber Pharmaceuticals, Inc.
03/02/2023	Brimonidine Tartrate Ophthalmic Solution, 0.15% (Apotex)	Potential lack of sterility	Apotex Corp
03/22/2023	Dabigatran Etexilate Capsules, USP (Ascend Laboratories)	Detection of N-nitroso-dabigatran (NDAB) Impurity	Ascend Laboratories LLC.
04/28/2023	FENTANYL Buccal Tablets CII (Mayne Pharma Inc.)	Safety updates were omitted in the Product Insert/ Medication Guide (MG)	Teva Pharmaceuticals USA

Safety Notifications

- FDA updating warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions
  - To address continuing concerns of misuse, abuse, addiction, and overdose of prescription stimulants, the U.S. Food and Drug Administration (FDA) is requiring updates to the Boxed Warning and other information to ensure the prescribing information is made consistent across the entire class of these medicines
- FDA updates prescribing information for all opioid pain medicines to provide additional guidance for safe use
  - As part of its ongoing efforts to address the nation's opioid crisis, the U.S. Food and Drug Administration (FDA) is making several updates to the prescribing information of opioid pain medicines to provide additional guidance on the use of these powerful medicines

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CONTACT INFORMATION:

Toll-free 1-877-741-7470
www.mc-rx.com

Headquarters
U.S. Corporate Park
1267 Professional Pkwy
Gainesville, GA 30507

Puerto Rico
Road #1 Km. 33.3 Lot #4
Angora Industrial Park
Bo. Bairoa Caguas, P.R. 00725

Call Box 4908, Caguas, P.R. 00726

druginfo@mc-rx.com

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