MC-Rx

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Insights on the Drugs Pipeline

Exploring the changes in the drugs market.

October 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/recalls

Drug shortages

Updated through September 28, 2023.

Immunization Updates for the 2023-2024 Season: It's not just the flu!

As many viruses are constantly changing, so too change the immunization practices to keep ourselves and those close to us safe. Getting vaccinated not only reduces the chance of getting sick, but also reduces the severity of the disease, if acquired. Vaccines are a cornerstone of public safety, helping reduce incidence of diseases and the complications that could stem from those diseases like hospitalizations, pneumonia and others. At MC-Rx, we want you to be informed on the latest immunization updates.

In February 2023, the CDC published their vaccination schedules.

General changes in the vaccination schedule of Children and Adolescents

Vaccines added:

- COVID-19 (20232024 Formula)
- Priorix® – new measles, mumps, and rubella vaccine
- Pneumococcal 15-valent conjugate vaccine (PCV15)
- Dengue vaccine is recommended for HIV-positive children living in endemic areas, NOT for children traveling to or visiting dengue endemic areas

General Information: Vaccination Schedule for Adults

Vaccines added:

- COVID-19 (20232024 Formula)
- PreHevbrio™ – Hepatitis B virus infection prevention
- Priorix® – new measles, mumps, and rubella vaccine

For more information on schedules for Children, Adolescents and Adults, please visit the CDC website: https://www.cdc.gov/vaccines

Influenza Vaccine Updates

There are several influenza vaccines available for the 2023-2024 season. Talk to your pharmacist or provider about getting your flu shot this fall season.

COVID Vaccine Updates

COVID-19 vaccines were added to the regular vaccination schedule

- The FDA's Vaccines and Related Biological Products Advisory Committee (VRBPAC) updated its recommendation for COVID-19 vaccines from a bivalent composition to a monovalent composition that targets the XBB sub-lineage.
- Both Moderna and Pfizer have developed vaccines to target the XBB.1.5 subvariant.
- Both Moderna and Pfizer have stated that the vaccines demonstrate a strong antibody response to the XBB.1.5 subvariant and are effective against the EG.5 and BA.2.86 subvariants, which have recently surfaced.
- Updated vaccines are available and at least one (1) dose of the (20232024 Formula) mRNA COVID-19 vaccine is recommended.
- Talk to your pharmacist or provider to know which vaccine is appropriate for you.

Updates on Respiratory Syncytial Virus (RSV)

- RSV is a virus that mostly affects the lower respiratory tract
- It mainly affects young children (< 5 years) and elderly (> 65 years)
- Main cause of bronchiolitis and pneumonia in children under 1 year
- Seasonal virus (peak in autumn-winter)

Strategies approved for the immunization against Respiratory Syncytial Virus (RSV)

- Vaccines against RSV for Adults > 60 years: Arexvy® and Abrysvo®
  - The CDC recommends that adults 60 years or older receive the vaccine against RSV, after consulting your healthcare provider and reaching a joint decision after assessing the risks vs. benefits of receiving the vaccine.
- Vaccines against RSV for infants: Beyfortus™ and Abrysvo®
  - The FDA approved Abrysvo® for use in pregnant individuals at 32 to 36 weeks' gestational age

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to prevent lower respiratory tract disease (LRTD) and severe LRTD caused by RSV in infants from birth through 6 months of age.

- CDC recommends administering a single dose of Beyfortus™ to all infants <8 months of age born during or facing their first season of RSV. It is also recommended for a select group of children between the ages 8-19 months who are at risk of severe illness from RSV during their second season of RSV (e.g., immunocompromised)
- Beyfortus™ has been shown to reduce the risk of hospitalizations and visits to health institutions in infants
- The ACIP clarified that either Abrysvo® or Beyfortus™ should be used for protection against RSV in infants. The use of both Abrysvo® and Beyfortus™ would not offer added protection for most infants.

In Conclusion:

We should all value the role of the pharmacy staff in immunization efforts. This season getting vaccinated isn't just a recommendation; it's a crucial step in protecting yourself and those around you. At MC-Rx, we promote vaccinations as a simple, yet effective way to stay healthy, keep the community safe, and reduce the burden on healthcare systems. So, roll up your sleeve and get vaccinated. It's a small action that can make a big difference in the battle against respiratory illness.

References

- Vaccine Recommendations and Guidelines of the ACIP. (2017). Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/intro.html
- Vaccines & Immunizations. (2021). Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/
- Recommended updated (2023–2024 Formula) mRNA COVID-19 vaccines for people who are not moderately or severely immunocompromised. Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/covid-19/downloads/COVID19-vaccination-recommendations-most-people.pdf
- Use of COVID-19 Vaccines in the United States. Centers for Disease Control and Prevention. https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html

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Specialty Pipeline

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

Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Arimoclomol (Miplyffa - Orphazyme)	Complete response	2024	Molecular chaperone activator that stimulates the normal cellular protein repair pathway for the treatment of Niemann-Pick Disease Type C (NPC); oral
bimekizumab (Bimzelx - UCB)	BLA Filed	3Q 2023	Monoclonal antibody that blocks the effects of IL-17A and IL-17F for the treatment of moderate-to-severe plaque psoriasis; subcutaneous injection
cipaglucosidase alfa (Amicus Therapeutics)	BLA Filed	3Q 2023	Recombinant human acid α-glucosidase (rhGAA) enzyme replacement therapy/chaperone therapy for the treatment of late-onset Pompe disease; IV infusion
danicopan (AstraZeneca)	NDA Filed	07/27/2024	Complement factor D (CFD) inhibitor for treatment-naïve paroxysmal nocturnal hemoglobinuria (PNH) patients; oral
Donanemab (Eli Lilly)	BLA Filed	December 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 (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
Eplontersen (Ionis Pharmaceuticals/ AstraZeneca)	BLA Filed	12/22/2023	Antisense medicine designed to inhibit production of transthyretin (TTR) for the treatment of hereditary transthyretinmediated amyloid polyneuropathy (hATTR-PN); subcutaneous injection
etrasimod (Pfizer)	NDA Filed	10/21/2023	Selective sphingosine-1-phosphate (S1P) receptor modulator for the treatment of moderate-to-severe ulcerative colitis; oral
exagamglogene autotemcel (Vertex Pharmaceuticals/ CRISPR Therapeutics)	BLA Filed	12/08/2023	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)

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Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
fidanacogene elaparvovec (Pfizer)	BLA Filed	04/27/2024	Bio-engineered adeno-associated virus (AAV) capsid expressing a codon-optimized, high-activity human factor IX variant for the treatment of hemophilia B; IV infusion (one time)
garadacimab (CSL Behring)	Phase 3	2024	Fully human recombinant FXIIa antagonist monoclonal antibody for the prevention and treatment of hereditary angioedema (HAE); subcutaneous injection
iptacopan (Novartis)	NDA Filed	12/23/2023	Low molecular weight factor B inhibitor for the treatment of paroxysmal nocturnal hemoglobinuria; oral
lebrikizumab (Eli Lilly)	BLA Filed	September 2023	Humanized monoclonal antibody targeting interleukin 13 (IL-13) for the treatment of atopic dermatitis; subcutaneous injection
lovotibeglogene autotemcel (lovocel - bluebird bio)	BLA Filed	12/20/2023	Lenti-D gene therapy for the treatment of sickle cell disease (SCD) in patients 12 years of age and older with history of vaso-occlusive events; IV infusion
mirikizumab (Eli Lilly)	BLA Filed	4Q 2023	Monoclonal antibody targeting IL-23p19 for the treatment of moderate-to-severe ulcerative colitis; IV infusion and subcutaneous injection.
nedosiran (Novo Nordisk)	NDA Filed	September 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; subcutaneous injection
repotrectinib (Bristol Myers Squibb)	NDA Filed	11/27/2023	Tyrosine kinase inhibitor (TKI) for the treatment of ROS1-positive locally advanced or metastatic non-small cell lung cancer (NSCLC); oral
resmetirom (Madrigal Pharmaceuticals)	NDA Filed	03/17/2024	Thyroid hormone receptor (THR) ß -selective agonist for the treatment of nonalcoholic steatohepatitis (NASH) with liver fibrosis; oral
sotatercept (Merck)	BLA Filed	08/01/2024	Soluble receptor fusion protein comprised of extracellular domain of the human activin receptor type IIA (ActRIIA) fused to human immunoglobulin for the treatment of pulmonary arterial hypertension; subcutaneous injection

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Biosimilar Pipeline

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

Generic Name Investigational Name	Manufacturer(s)	Reference Biological	Possible FDA approval date	Potential launch date
adalimumab biosimilar (Simlandi)	Teva/Alvotech	Humira (adalimumab)	2024	TBD
adalimumab-afzb (Abrilada)	Pfizer	Humira (adalimumab)	2023	November 2023
aflibercept biosimilar	Celltrion	Eylea (aflibercept)	4/29/2024	TBD (2024)
aflibercept biosimilar	Coherus Biosciences	Eylea (aflibercept)	6/29/2024	TBD (2024)
aflibercept biosimilar (Yesafili)	Momenta/Biocon	Eylea (aflibercept)	2023	TBD (2024)
bevacizumab biosimilar	Biothera/Sandoz	Avastin (bevacizumab)	2023	TBD (Pending FDA Approval)
bevacizumab biosimilar (Abevmy)	Biocon	Avastin (bevacizumab)	2024	TBD (Pending FDA Approval)
bevacizumab biosimilar (Aybintio)	Samsung Bioepis/ Organon	Avastin (bevacizumab)	2023	TBD (Pending FDA Approval)
bevacizumab biosimilar (Equidacent)	Centus	Avastin (bevacizumab)	2023-2024	TBD (Pending FDA Approval)
denosumab biosimilar	Sandoz	Prolia (denosumab)	12/6/2023	TBD (Feb 2025)
eculizumab biosimilar	Amgen/Daiichi Sankyo	Soliris (eculizumab)	2/28/2024	Settlement: March 1, 2025
filgrastim biosimilar	Tanvex BioPharma	Neupogen (filgrastim)	2023	TBD (Pending FDA Approval)
insulin glargine biosimilar (Basalin)	Sandoz/Gan & Lee	Lantus (insulin glargine)	4/3/2024	TBD

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Biosimilar Pipeline

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

Generic Name Investigational Name	Manufacturer(s)	Reference Biological	Possible FDA approval date	Potential launch date
pegfilgrastim biosimilar (Lupifil-P)	Lupin	Neulasta (pegfilgrastim)	2023	TBD (Pending FDA Approval)
pegfilgrastim-cbqv (Udenyca OBI)	Coherus Biosciences	Neulasta Onpro (pegfilgrastim)	Oct. 2023	TBD. New on-body device
ranibizumab biosimilar (Xlucane)	Xbrane Biopharma	Lucentis (ranibizumab)	4/21/2024	TBD (upon approval?)
rituximab biosimilar	Dr. Reddy's/Fresenius	Rituxan (rituximab)	7/12/2024	TBD (Pending FDA Approval)
tocilizumab biosimilar	Biothera/Biogen	Actemra (tocilizumab)	10/9/2023	TBD (Pending Approval/ resolution of litigation)
tocilizumab biosimilar (Tyenne)	Fresenius/Merck KGaA	Actemra (tocilizumab)	2H 2023	TBD (Settlement agreement. Terms not disclosed)
trastuzumab biosimilar	Tanvex BioPharma	Herceptin (trastuzumab)	2024	TBD (Pending FDA Approval)
trastuzumab biosimilar (Zercepac)	Henlius/Accorda	Herceptin (trastuzumab)	12/14/2023	TBD (Pending FDA Approval)
ustekinumab biosimilar	Alvotech/Teva	Stelara (ustekinumab)	10/11/2023	Settlement: Feb. 21, 2025
ustekinumab biosimilar	Amgen	Stelara (ustekinumab)	2H 2023	Settlement: Jan. 1, 2025

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New Drug Entities	Details
Natalizumab-sztn (Tyruko)- Biosimilar	**Dosage form:** Injection 300 mg infused intravenously **Indications:** Is indicated as monotherapy for the treatment of relapsing forms of multiple sclerosis, to include clinically isolated syndrome, relapsing remitting disease, and active secondary progressive disease, in adults. Also indicated for inducing and maintaining clinical response and remission in adult patients with moderately to severely active Crohn's disease with evidence of inflammation who have had an inadequate response to, or are unable to tolerate, conventional CD therapies and inhibitors of TNF-α **Comparables:** Tysabri (natalizumab) **Guidelines:** • Rae-Grant, A., Day, G. S., Marrie, R. A., Rabinstein, A., Cree, B. A. C., Gronseth, G. S., Haboubi, M., Halper, J., Hosey, J. P., Jones, D. E., Lisak, R., Pelletier, D., Potrebic, S., Sitcov, C., Sommers, R., Stachowiak, J., Getchius, T. S. D., Merillat, S. A., & Pringsheim, T. (2018). Practice guideline recommendations summary: Disease-modifying therapies for adults with multiple sclerosis. Neurology, 90(17), 777–788. https://doi.org/10.1212/wnl.0000000000005347 • Lichtenstein, G. R. Loftus, E. V., Isaacs, K. L., Regueiro, M.D., Gerson, L. B., Sands, B. E. ACG Clinical Guideline: Management of Crohn's Disease in Adults. (2018). American Journal of Gastroenterology 113(4): p481-517. DOI: 10.1038/ajg.2018.27

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New Drug Formulations

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

New Drug Formulations	Details
Fosaprepitant (Focinvez)	**New Dosage form:** Injection: 150 mg/50 mL (3 mg/mL) of fosaprepitant, in a single-dose vial. **Indication:** Is a substance P/neurokinin-1 (NK1) receptor antagonist, indicated in adults and pediatric patients 6 months of age and older, in combination with other antiemetic agents, for the prevention of (1): acute and delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy (HEC) including high-dose cisplatin and (2) delayed nausea and vomiting associated with initial and repeat courses of moderately emetogenic cancer chemotherapy (MEC). **Comparables:** Fosaprepitant, aprepitant **Guidelines:** • National Comprehensive Cancer Network Guidelines. Treatment by Cancer Type. https://www.nccn.org/guidelines
Melphalan (Hepzato kit)	**New Dosage form:** Hepzato includes 50 mg freeze-dried (lyophilized) melphalan powder per vial in five (5) single-dose vials, intended for reconstitution with the supplied diluents. Intra-arterial administration. **Indication:** Orphan drug: Is an alkylating drug indicated as a liver-directed treatment for adult patients with uveal melanoma with unresectable hepatic metastases affecting less than 50% of the liver and no extrahepatic disease, or extrahepatic disease limited to the bone, lymph nodes, subcutaneous tissues, or lung that is amenable to resection or radiation. **Comparables:** Other melphalan formulations **Guidelines:** • Melanoma: Uveal, Version 1.2023. National Comprehensive Cancer Network. https://www.nccn.org/professionals/physician_gls/pdf/uveal.pdf
Methotrexate (Jylamvo)	**New Dosage form:** Oral Solution **Indication:** Treatment of adults with rheumatoid arthritis, Treatment of adults with severe psoriasis, Treatment of adults with acute lymphoblastic leukemia (ALL) as part of a combination chemotherapy maintenance regimen, Treatment of adults with mycosis fungoides; treatment of adults with relapsed or refractory non-Hodgkin lymphoma as part of a metronomic combination regimen. **Comparables:** Other methotrexate formulations, including oral solution (Xatmep) **Guidelines:** • National Comprehensive Cancer Network Guidelines. Treatment by Cancer Type. https://www.nccn.org/guidelines • Rheumatoid Arthritis Guideline (2021). American College of Rheumatology. https://rheumatology.org/rheumatoid-arthritis-guideline

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New Indications

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New Indications	Details
Adalimumab-afzb (Abrilada)	For the addition of the indication for treatment of non-infectious intermediate, posterior, and panuveitis in adult patients.
Adalimumab-fkjp (Hulio)	For the addition of the indication for treatment of non-infectious intermediate, posterior, and panuveitis in adult patients.
Avelumab (Bavencio)	For the addition of the indication for treatment of adults and pediatric patients 12 years and older with metastatic Merkel Cell Carcinoma (MCC)
Canakinumab (Ilaris)	For the addition of the indication for treatment of gout flares in adults in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate
COVID-19 Vaccine, mRNA (Spikevax)	For the expansion of the indication for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 12 years of age and older.
Dostarlimab-gxly (Jemperli)	For the addition of the indication, in combination with carboplatin and paclitaxel, followed as a single agent for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR), as determined by an FDA-approved test, or microsatellite instability-high (MSI-H).
Dabrafenib (Tafinlar)	For the addition of the indication for the treatment of adult and pediatric patients 1 year 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.
Respiratory Syncytial Virus Vaccine (Abrysvo)	For the addition of the indication for active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age.
Rosuvastatin (Ezallor Sprinkle)	For the addition and revision of the indications for (1) treatment to reduce the risk of stroke, myocardial infarction, and arterial revascularization procedures in adults without established coronary heart disease who are at increased risk of cardiovascular (CV) disease based on age, hsCRP ≥2 mg/L, and at least one additional CV risk factor; (2) as an adjunct to diet to reduce LDL-C in adults and pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia (HeFH); (3) as an adjunct to diet to reduce low-density lipoprotein cholesterol (LDLC) and slow the progression of atherosclerosis in adults.
Temozolomide (Temodar)	For the addition of the indication as adjuvant treatment of adults with newly diagnosed anaplastic astrocytoma or treatment of adults with refractory anaplastic astrocytoma.

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New Indications

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New Indications	Details
Tifluridine/tipiracil (Lonsurf)	For the expansion of the indication for treatment of metastatic colorectal cancer as a single agent or in combination with bevacizumab who have been previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy, an anti-VEGF biological therapy, and if RAS wild-type, an anti-EGFR therapy.
Trametinib (Mekinist)	For the addition of the indication for the treatment of adult and pediatric patients 1 year 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.
Valbenazine (Ingrezza)	For the addition of the indications of treatment of adults with chorea associated with Huntington's disease.

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In Market Brand

In-Market-Brands	Details
Cantharidin (Ycanth)	**Dosage form:** Topical solution: 0.7% cantharidin. **Indication:** Is indicated for the topical treatment of molluscum contagiosum in adult and pediatric patients 2 years of age and older **Comparables:** None **Guidelines:** • Badri T, Gandhi GR. Molluscum Contagiosum. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK441898/ • Molluscum Contagiosum. (2015). Centers for Disease Control and Prevention. https://www.cdc.gov/poxvirus/molluscum-contagiosum/index.html
Elranatamab-bcmm (Elrexfio)	**Dosage form:** Injection: 76 mg/1.9 mL (40 mg/mL) in a single-dose vial, 44 mg/1.1 mL (40 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. **Comparables:** Tecvayli (teclistamab-cqyv), Abecma (idecabtagene vicleucel), Carvykti (ciltacabtagene autoleucel), Talvey (talquetamab-tgvs) **Guidelines:** • Multiple Myeloma, Version 1.2024. National Comprehensive Cancer Network (NCCN). https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf
Lotilaner (Xdemvy)	**Dosage form:** ophthalmic solution containing lotilaner 0.25% **Indication:** Is an ectoparasiticide (anti-parasitic) indicated for the treatment of Demodex blepharitis. **Comparables:** None **Guidelines:** • The Evolving Landscape of Demodex Blepharitis Management. (2022). The American Journal of Managed Care. https://ajmc.com/demodex-blepharitis-perspectives

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In Market Brand

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In-Market-Brands	Details
Motixafortide (Aphexda)	**Dosage form:** For Injection: 62 mg as a lyophilized powder in a single-dose vial for reconstitution **Indication:** In combination with filgrastim (G-CSF) to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with multiple myeloma. **Comparables:** Tecvayli (teclistamab-cqyv), Abecma (idecabtagene vicleucel), Carvykti (ciltacabtagene autoleucel), Talvey (talquetamab-tgvs), Elrexfio (elranatamab-bcmm) **Guidelines:** • Multiple Myeloma, Version 1.2024. National Comprehensive Cancer Network (NCCN). https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf
Niraparib and abiraterone acetate (Akeega)	**New Dosage form:** Tablets: 50 mg niraparib/500 mg abiraterone acetate, 100 mg niraparib/500 mg abiraterone acetate. **Indication:** New Combination: is a combination of niraparib, a poly (ADP-ribose) polymerase (PARP) inhibitor, and abiraterone acetate, a CYP17 inhibitor indicated with prednisone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC). **Comparables:** Lynparza (olaparib) in combination with abiraterone, Talzenna (talazoparib) in combination with Xtandi (enzalutamide). **Guidelines:** • Prostate Cancer, Version 4.2023. National Comprehensive Cancer Network. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf
Nirsevimab-alip (Beyfortus)	**Dosage form:** Injection 50 mg/0.5 mL in a single-dose prefilled syringe. **Indication:** Is a respiratory syncytial virus (RSV) F protein-directed fusion inhibitor indicated for the prevention of RSV lower respiratory tract disease in: Neonates and infants born during or entering their first RSV season. Children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season. **Comparables:** Abrysvo **Guidelines:** • U.S. Centers for Disease Control and Prevention. Respiratory syncytial virus infection (RSV). RSV surveillance & research. https://www.cdc.gov/rsv/research/index.htm

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In Market Brand

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In-Market-Brands	Details
Palovarotene (Sohonos)	**Dosage form:** Capsules: 1, 1.5, 2.5, 5, 10 mg. **Indication:** Orphan drug: is a retinoid indicated for reduction in the volume of new heterotopic ossification in adults and children aged 8 years and older for females and 10 years and older for males with fibrodysplasia ossificans progressiva (FOP). **Comparables:** None. **Guidelines:** • Fibrodysplasia Ossificans Progressiva (2023). National Organization of Rare Disorders. https://rarediseases.org/rare-diseases/fibrodysplasia-ossificans-progressiva/#therapies
Pozelimab-bbfg (Veopoz)	**Dosage form:** Injection: 400 mg/2 mL (200 mg/mL) in a single-dose vial. **Indication:** Orphan drug: Is a complement inhibitor indicated for the treatment of adult and pediatric patients 1 year of age and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease. **Comparables:** None. **Guidelines:** • Yu, C. Y., & Ardoin, S. P. (2021). Complement inhibitor for therapy of CHAPLE. Nature immunology, 22(2), 106-108. https://doi.org/10.1038/s41590-020-00842-9
Prothrombin complex concentrate, human-lans (Balfaxar)	**New Dosage form:** lyophilized powder for reconstitution for intravenous use in a single-dose vial (500 Factor IX units in 20 mL) **Indication:** is a blood coagulation factor replacement product indicated for the urgent reversal of acquired coagulation factor deficiency induced by Vitamin K antagonist (VKA, e.g., warfarin) therapy in adult patients with need for an urgent surgery/invasive procedure. **Comparables:** Kcentra (prothrombin complex concentrate (human)), Fresh Frozen Plasma (FFP) Vitamin K **Guidelines:** • Garcia, D. A. & Crowther, M. A. (2012). Reversal of Warfarin. Circulation, 125(23). pp. 2944-2947 doi:10.1161/circulationaha.111.081489

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In-Market-Brands	Details
Quizartinib (Vanflyta)	**Dosage form:** Tablets: 17.7 mg or 26.5 mg. **Indication:** Is a kinase inhibitor indicated in combination with standard cytarabine and anthracycline induction and cytarabine consolidation, and as maintenance monotherapy following consolidation chemotherapy, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is FLT3 internal tandem duplication (ITD)-positive as detected by an FDA-approved test. **Comparables:** none **Guidelines:** • Acute Myeloid Leukemia, Version 4.2023. National Comprehensive Cancer Network (NCCN). https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf
Talquetamab-tgvs (Talvey)	**Dosage form:** Injection 3 mg/1.5 mL (2 mg/mL) in a single-dose vial, 40 mg/mL in a single-dose vial **Indication:** is a bispecific GPRC5D-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. **Comparables:** Tecvayli (teclistamab-cqyv), Abecma (idecabtagene vicleucel), Carvykti (ciltacabtagene autoleucel), Elrexfio (elranatamab-bcmm) **Guidelines:** • Multiple Myeloma, Version 1.2024. National Comprehensive Cancer Network (NCCN). https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf

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New Generics

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Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indications
Ertugliflozin Tablets, 5 mg and 15 mg Although approved, no generic is commercially available.	Aurobindo Pharma Limited	Steglatro (Ertugliflozin) Tablets	7/13/2023	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus
Naltrexone for Extended-Release Injectable Suspension, 380 mg/vial, Single-Dose Vial	Teva Pharmaceuticals USA, Inc.	Vivitrol (Naltrexone) for Extended-Release Injectable Suspension	7/6/2023	For the prevention of relapse to opioid dependence, following opioid detoxification
Oxcarbazepine Extended-Release Tablets, 150 mg, 300 mg, and 600 mg	Apotex Inc.	Oxtellar XR (Oxcarbazepine) Extended-Release Tablets	7/13/2023	For the treatment of partial-onset seizures in patients 6 years of age and older
Plerixafor Injection, 24 mg/1.2 mL (20 mg/mL) Single-Dose Vial	Zydus Pharmaceuticals (USA) Inc., Kindos Pharmaceuticals Co., Ltd., Amneal EU, Limited, Eugia Pharma Specialities Limited Eugia Pharma Specialities Limited, MSN Laboratories Private Limited, Teva Pharmaceuticals USA, Inc., Dr. Reddy's Laboratories Limited	Mozobil (Plerixafor) Injection	7/24/2023	In combination with granulocyte-colony stimulating factor to mobilize hematopoietic stem cells to the peripheral blood for collection and subsequent autologous transplantation in patients with non-Hodgkin's lymphoma or multiple myeloma

Updated through September 28, 2023.

New Generics

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

Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indications
Ponatinib Tablets, 15 mg and 45 mg	Apotex Inc.	Iclusig (Ponatinib) Tablets	7/14/2023	For the treatment of adult patients with chronic phase chronic myeloid leukemia (CML); accelerated phase or blast phase CML or Philadelphia chromosome positive acute lymphoblastic leukemia ; T315I-positive CML or T315I-positive Ph+ ALL
Saxagliptin and Metformin Hydrochloride Extended-Release Tablets, 5 mg/500 mg, 2.5 mg/1,000 mg, and 5 mg/1,000 mg	Sun Pharmaceutical Industries Limited, Mylan Pharmaceuticals Inc.	Kombiglyze XR (Saxagliptin and Metformin Hydrochloride) Extended-Release Tablets	7/31/2023	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus when treatment with both saxagliptin and metformin is appropriate
Saxagliptin Tablets, 2.5 mg and 5 mg	Sun Pharmaceutical Industries Limited, Glenmark Pharmaceuticals Limited, Mylan Pharmaceuticals Inc., Aurobindo Pharma Limited, Amneal Pharmaceuticals of NY, LLC	Onglyza (Saxagliptin) Tablets	7/31/2023	As an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus

Updated through September 28, 2023.

Recall Notifications

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

Date	Drug Name	Reason for Recall	Company name
9/22/2023	Sucralfate Oral Suspension 1g/10mL	Potential contamination with Bacillus cereus	VistaPharm
9/11/2023	Sandimunne Oral Solution (cyclosporine oral solution, USP) 100 mg/mL	Crystal formation which could potentially result in incorrect dosing	Novartis
8/31/2023	Digoxin Tablets USP, 0.125mg and 0.25mg	Label Mix-Up	Marlex Pharmaceuticals, Inc.

Safety Notifications

There are no new safety notifications.

Shortages (New)

Generic name (Brand Name)	Presentation	Posting Date	Related Information
Vinblastine Sulfate Injection	Vinblastine Sulfate, Injection, 1 mg/1 mL (NDC 63323-278-10)	9/14/2023	Backordered

References:

FDA Approved Drugs. Food and Drug Administration (FDA). Retrieved from https://www.access.fda.gov/

FDA: Drug Shortages. https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages

FDA: First Generic Drug Approvals. https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals

FDA: Recalls, Market Withdrawals, & Safety Alerts. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts

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