MC-Rx

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Insights on the Drugs Pipeline

Exploring the changes in the drugs market.

April 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
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Compounded Semaglutide: Is It Worth The Risk?

Semaglutide is a drug developed by Novo Nordisk that has become a revolutionary treatment for weight management. This drug was first approved in 2017 by the brand name Ozempic® for the treatment of diabetes. Due to its effects in weight loss semaglutide was also approved in 2021 for weight management under the name Wegovy®. The sheer popularity of this drug has resulted in supply shortages, prompting some people to seek out compounded versions of the drug instead. Novo Nordisk had to open a new facility in Denmark to address those shortages. However, the goal of this article is to inform providers about the risks and concerns of compounded semaglutide.

In general, the federal regulations prohibit compounding pharmacies from producing identical copies of commercially available drugs unless the FDA places a commercial drug on its official shortage list. Currently, semaglutide is on the list, and some compounding pharmacies and health care professionals are capitalizing on this loophole and the demand of the drug. They are offering compounded semaglutide (sometimes even marketed as “generic” Ozempic) at lower prices and easier access.

Concerns regarding compounded Semaglutide

There are several risks associated with compounded semaglutide. The most concerning aspect is that the source of the semaglutide is unknown or whether what they sell is even semaglutide at all. Novo Nordisk is the only FDA-approved supplier of the drug and they do not sell it for compounding purposes. Furthermore, semaglutide is patent protected in the United States at least until 2026. As a result, it is unclear where pharmacies and health care professionals are obtaining the semaglutide, but it is certainly not from an FDA-approved manufacturer.

Where are compounding pharmacies obtaining the Semaglutide?

There are reports that some compounding pharmacies are obtaining a sodium salt of semaglutide from sources outside the United States. Semaglutide Sodium is a research product that can be purchased online. The Alliance for Pharmacy Compounding (APC) has issued a warning to its members that semaglutide sodium "should not be used in human drug compounding”. This salt is not used in FDA approved products and it has not been evaluated for safety and effectiveness in clinical trials. While different salts of active pharmaceutical ingredients are frequently considered pharmaceutical alternatives by the FDA, there are currently no therapeutic equivalents to semaglutide listed in the FDA's Orange Book.

Furthermore, some compounding pharmacies are also thought to be purchasing brand-name versions of the drug in their highest-dose formats. The medication is then diluted and mixed with other ingredients such as Vitamin B6, Vitamin B12, and L Carnitine. These combinations have not been evaluated in clinical trials for safety and effectiveness. This practice also carries risks such as loss of sterility and stability of the drug, which can compromise its safety and cause contamination.

Legal Issues regarding Compounded Semaglutide

Obtaining semaglutide from a non-FDA-approved source not only jeopardizes the patient's health, but it may also lead to litigation, as semaglutide is patent protected in the United States. Novo

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Nordisk has already issued cease-and-desist letters to some compounding pharmacies, claiming that selling compounded semaglutide infringes its intellectual property.

Recommendation to Health Care Specialists

Healthcare providers, particularly endocrinologists and obesity medicine specialists, must be cautious when considering prescribing compounded semaglutide because of the potential hazards associated with its preparation and ingredient sourcing. It is crucial to prioritize patient safety by avoiding medications that have not undergone rigorous testing for efficacy and safety.

The FDA provides guidance on human drug compounding, including guidelines for compounding pharmacies and healthcare providers on the appropriate use of compounded drugs and regulatory requirements to ensure their safety and effectiveness. The Alliance for Pharmacy Compounding also provides resources and information for compounding pharmacies, including warnings about the dangers of using semaglutide sodium. Providers can consult with Novo Nordisk, the FDA-approved supplier of semaglutide, for more information on the drug and its proper usage.

Conclusion

Compounded semaglutide poses significant risks to patients, as there are considerable questions about its preparation and source of the active ingredient. Compounding pharmacies and healthcare professionals who offer this medication may be jeopardizing their patients' health and violating Novo Nordisk's intellectual property rights. Therefore, MC-Rx recommends that healthcare specialists exercise caution when prescribing compounded semaglutide, as its efficacy, safety, and quality cannot be guaranteed. Ultimately, the risks of compounded semaglutide outweigh the potential benefits. Keeping up with drug safety and efficacy information can assist providers in making responsible decisions about their patients' health and well-being.

References:

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Specialty Pipeline

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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	8/19/2023	Inhibitor of complement component 5 (C5) for treating geographic atrophy secondary to age-related macular degeneration (AMD); intravitreal injection
Bimekizumab (Bimzelx - UCB)	BLA Filed	5/22/2023	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	1H2023	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	5/29/2023	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	Sept. 2023	Humanized monoclonal antibody targeting interleukin 13 (IL- 13) for the treatment of atopic dermatitis; SC injection
Leniolisib (Pharming)	NDA Filed	3/29/2023	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.

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Drug Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Lovotibeglogene autotemcel (Lovo-cel - Bluebird bio)	Phase 3	2023	Lenti-D gene therapy for the treatment of sickle cell disease; IV infusion
Mirikizumab (Eli Lilly)	BLA Filed	4/28/2023	Monoclonal antibody targeting IL-23p19 for the treatment of moderate-to-severe ulcerative colitis; IV infusion and SC injection.
Obeticholic acid (Intercept Pharmaceuticals	NDA Filed	6/23/2023	Farnesoid X receptor (FXR) agonist for the treatment of liver fibrosis due to nonalcoholic steatohepatitis (NASH); oral
Pegunigalsidase alfa (Protalix Biotherapeutics)	BLA Filed	5/9/2023	Plant cell-expressed, recombinant alpha-galactosidase-A enzyme for the treatment of Fabry disease; IV infusion (monthly)
Ritlecitinib (Pfizer)	NDA Filed	2Q 2023	JAK3/TEC inhibitor for the treatment of adults and adolescents aged 12 years and older with alopecia areata; oral
SER-109 (Seres Therapeutics)	BLA Filed	4/26/2023	Oral microbiome therapy where manufacturing process inactivates vegetative bacteria and other potential pathogens, which have been linked with fecal microbiota transplant (FMT)-associated disease transmission; oral
Talquetamab (Janssen/ Genmab)	BLA Filed	8/9/2023	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 injection
Trofinetide (Acadia Pharmaceuticals)	NDA Filed	3/12/2023	A novel synthetic analog of the amino-terminal tripeptide of IGF-1 to reduce neuroinflammation and supporting synaptic function in patients with Rett syndrome; oral solution
Valoctocogene roxaparvovec (Roctavian – BioMarin Pharmaceuticals)	BLA Filed	3/31/2023	Adenoviral vector-mediated transfer of the Human Factor VIII gene to treat severe hemophilia A; IV infusion.

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Biosimilar Pipeline

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Biosimilar	Manufacturer(s)	Reference Biologic	Possible FDA Approval Date	Potential Launch Date
Abevmy	Biocon; Viatris; Mylan	Avastin (bevacizumab)	2024	TBD (Pending FDA Approval)
ABP 654	Amgen	Stelara (ustekinumab)	2H/2023	TBD (Pending FDA Approval)
Abrilada	Pfizer	Humira (adalimumab)	2023 (interchangeability)	Settlement: 07/01/2023
AVT-04	Teva; Alvotech	Stelara (ustekinumab)	11/2023	TBD (Pending FDA Approval)
Aybintio	Organon; Samsung Bioepis	Avastin (bevacizumab)	2023	TBD (Pending FDA Approval)
BAT1706	Bio-Thera Solutions; Sandoz	Avastin (bevacizumab)	2023	TBD (Pending FDA Approval)
BAT1806	Biogen; Bio-Thera Solutions	Actemra (tocilizumab)	10/09/2023	TBD (Pending FDA Approval and resolution of ongoing litigation)
EG12014	EirGenix; Sandoz	Herceptin (trastuzumab)	2023	TBD (Pending FDA Approval)
Equidacent	Centus Biotherapeutics	Avastin (bevacizumab)	2023	TBD (Pending FDA Approval)
GP2411	Sandoz; Hexal	Prolia (denosumab)	12/06/2023	TBD (Feb, 2025?)
Hukyndra	Teva; Alvotech	Humira (adalimumab)	04/13/2023	Settlement: 07/01/2023
Hyrimoz	Sandoz	Humira (adalimumab)	05/05/2023	Settlement: 07/01/2023
Lupifil-P	Lupin	Neulasta (pegfilgrastim)	2023	TBD (Pending FDA Approval)
MSB11456	Fresenius Kabi	Actemra (tocilizumab)	2Q/2023	TBD (Settlement agreement. Terms not disclosed)

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Biosimilar	Manufacturer(s)	Reference Biologic	Possible FDA Approval Date	Potential Launch Date
MYL-1701P	Janssen; Biocon; Viatris; Momenta; Mylan	Eylea (aflibercept)	1Q/2023	TBD (2024?)
PB006	Polpharma; Sandoz	Tysabri (natalizumab)	05/2023	TBD (Pending FDA Approval)
TX01	Tanvex	Neupogen (filgrastim)	2024	TBD (Pending FDA Approval)
TX05	Tanvex	Herceptin (trastuzumab)	1Q/2023	TBD (Pending FDA Approval)
Udenyca OBI	Coherus BioSciences	Neulasta (pegfilgrastim)	10/2023	TBD; New On-body device
Yuflyma	Celltrion	Humira (adalimumab)	1Q/2023	Settlement: 07/01/2023
Zercepac	Henlius; Accord	Herceptin (trastuzumab)	12/14/2023	TBD (Pending FDA Approval)

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FDA Approvals

In-Market Brands	Details
Antihemophilic factor (recombinant), Fc-VWF-XTEN fusion protein-ehtl] (Altuviiio)	**Dosage form:** For injection: nominally 250, 500, 750, 1000, 2000, 3000, or 4000 IU, lyophilized powder in single-dose vials for reconstitution. **Indication:** ALTUVIIIO is a recombinant DNA-derived, Factor VIII concentrate indicated for use in adults and children with hemophilia A (congenital factor VIII deficiency) for: ● Routine prophylaxis to reduce the frequency of bleeding episodes ● On-demand treatment & control of bleeding episodes ● Perioperative management of bleeding **Comparables:** Extended half-life factor VIII products (Eloctate, Adynovate, Jivi, Esperoct), Hemlibra **Guidelines:** ● National Haemophilia Foundation. MASAC Recommendation Concerning Prophylaxis for Hemophilia A and B with and without Inhibitors. https://www.hemophilia.org/healthcare-professionals/guidelines-on-care/masac-documents/masac-document-267-masac-recommendation-concerning-prophylaxis-for-hemophilia-a-and-b-with-and-without-inhibitors

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Atorvastatin calcium (Atorvaliq)	**Dosage form:** Oral suspension: 20 mg/5mL. **Indication:** ATORVALIQ is an HMG-CoA reductase inhibitor (statin) indicated: ● To reduce the risk of: o Myocardial infarction (MI), stroke, revascularization procedures, and angina in adults with multiple risk factors for coronary heart disease (CHD) but without clinically evident CHD. o MI and stroke in adults with type 2 diabetes mellitus with multiple risk factors for CHD but without clinically evident CHD. o Non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for congestive heart failure (CHF), and angina in adults with clinically evident CHD. ● As an adjunct to diet to reduce low-density lipoprotein (LDL-C) in: o Adults with primary hyperlipidemia. o Adults and pediatric patients aged 10 years and older with heterozygous familial hypercholesterolemia (HeFH). ● As an adjunct to other LDL-C lowering therapies to reduce LDL-C in adults and pediatric patients aged 10 years and older with homozygous familial hypercholesterolemia. ● As an adjunct to diet for the treatment of adults with: o Primary dysbetalipoproteinemia. o Hypertriglyceridemia **Comparables:** Atorvastatin tablet, other statins **Guidelines:** ● 2018 AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines https://www.ahajournals.org/doi/10.1161/CIR.0000000000000625
Clindamycin phosphate (Xaciato)	**Dosage form:** Vaginal gel: 2% clindamycin present as clindamycin phosphate in an 8 g tube. One single-dose, user-filled disposable applicator delivers 5 g of gel containing 100 mg of clindamycin. **Indication:** XACIATO is a lincosamide antibacterial indicated for the treatment of bacterial vaginosis in female patients 12 years of age and older. **Comparables:** Metronidazole intravaginal gel 0.75%, Clindamycin phosphate Vaginal cream 2%, Clindamycin phosphate Vaginal cream 2% (Clindesse), metronidazole intravaginal gel 1.3% (Nuvessa), Metronidazole gel 0.75% (Vandazole) **Guidelines:** ● Sexually Transmitted Infections Treatment Guidelines, 2021. Centers for Disease Control and Prevention. https://www.cdc.gov/std/treatment-guidelines/bv.htm

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Elacestrant (Orserdu)	**Dosage form:** Tablets: 345 mg and 86 mg. **Indication:** ORSERDU is an estrogen receptor antagonist indicated for the treatment of postmenopausal women or adult men, with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy **Comparables:** • Fulvestrant-based treatment (fulvestrant plus palbociclib, fulvestrant plus abemaciclib, fulvestrant plus ribociclib, fulvestrant, with or without everolimus) • Everolimus plus Aromatase Inhibitors (anastrozole, letrozole, exemestane), everolimus plus tamoxifen **Guidelines:** • NCCN Guidelines: Breast Cancer. Version 4.2023. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf
Fingolimod (Tascenso ODT)	**Dosage form:** Orally disintegrating tablets: 0.25 mg and 0.5 mg **Indication:** TASCENSO ODT is a sphingosine 1-phosphate receptor modulator indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in patients 10 years of age and older. **Comparables:** Fingolimod (Gilenya) **Guidelines:** • Costello, K., & Kalb, R. (2019). The use of disease-modifying therapies in multiple sclerosis: principles and current evidence. Multiple Sclerosis Coalition. Retrieved from https://mymsaa.org/PDFs/dmt_consensus_ms_coalition07111-9.pdf • 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 recommenda-tions summary: Disease-modifying therapies for adults with multiple sclerosis. Neurology, 90(17), 777–788. https://doi.org/10.1212/wnl.0000000000005347
Pegcetacoplan injection (Syfovre)	**Dosage Form:** For intravitreal injection: 150 mg/mL in a single-dose vial **Indication:** SYFOVRE is a complement inhibitor indicated for the treatment of geographic atrophy (GA) secondary to age-related macular degeneration (AMD) **Comparables:** None. **Guidelines:** • American Academy of Ophthalmology. Age-Related Macular Degeneration Preferred Practice Pattern. (2019). http://dx.doi.org/10.1016/j.ophtha.2019.09.024

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Pegfilgrastim-fpgk (Stimufend)	**Dosage form:** Injection: 6 mg/0.6 mL solution in a single-dose pre-filled syringe for manual use only. **Indication:** Stimufend is a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia. **Comparables:** Pegfilfrastim (Neulasta) and biosimilars **Guidelines:** • Taplitz, R. A., Kennedy, E. B., & Flowers, C. R. (2018). Outpatient management of fever and neutropenia in adults treated for malignancy: American Society of Clinical Oncology and Infectious Diseases Society of America Clinical Practice Guideline update summary. Journal of Oncology Practice, 14(4), 250-255. https://doi.org/10.1200/jop.18.00016
Phenobarbital (Sezaby)	**Dosage form:** For injection: 100 mg of phenobarbital sodium lyophilized powder in a single-dose vial for reconstitution **Indication:** SEZABY is a barbiturate indicated for the treatment of neonatal seizures in term and preterm infants. **Comparables:** Phenobarbital Injection **Guidelines:** • Pediatric Newborn Medicine Clinical Practice Guidelines- Neonatal Seizures. Department of Pediatric Newborn Medicine, Brigham and Women's Hospital. https://www.brighamandwomens.org/assets/BWH/pediatric-newborn-medicine/pdfs/seizures-cpg.pdf • Treatment of Seizures in the Neonate: Guidelines and Consensus-based Recommendations – Special Report from the ILAE Task Force on Neonatal Seizures https://www.ilae.org/files/dmfile/ilae-neonatal-guidelines.pdf
Pirtobrutinib (Jaypirca)	**Dosage form:** Tablets: 50 mg, 100 mg. **Indication:** JAYPIRCA is a kinase inhibitor indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a BTK inhibitor. **Comparables**: BTK inhibitors: Ibrutinib (Imbruvica), Acalabrutinib (Calquence), Zanubrutinib (Brukinsa) **Guidelines:** • NCCN Guidelines: B-cell Lymphomas. Version 2.2023. https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf

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Sparsentan (Filspari)	**Dosage form:** Tablets: 200 mg and 400 mg **Indication:** FILSPARI is an endothelin and angiotensin II receptor antagonist indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g. **Comparables:** Budesonide (Tarpeyo) **Guidelines:** • KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. https://kdigo.org/wp-content/uploads/2017/02/KDIGO-Glomerular-Diseases-Guideline-2021-English.pdf
Terlipressin (Terlivaz)	**Dosage form:** For injection: 0.85 mg (1 vial) as a lyophilized powder in a single-dose vial for reconstitution **Indication:** TERLIVAZ is a vasopressin receptor agonist indicated to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function. **Comparables:** Vasopressin **Guidelines:** • Biggins, S. W., Angeli, P., Garcia-Tsao, G., Ginès, P., Ling, S. C., Nadim, M. K., Wong, F., & Kim, W. R. (2021). Diagnosis, evaluation, and management of ascites, spontaneous bacterial peritonitis and Hepatorenal Syndrome: 2021 practice guidance by the American Association for the study of liver diseases. Hepatology, 74(2), 1014-1048. https://doi.org/10.1002/hep.31884
Testosterone undecanoate (Kyzatrex)	**Dosage form:** Capsules: 100 mg, 150 mg, 200 mg **Indication:** KYZATREX is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone **Comparables:** Testosterone undecanoate (Tlando), Testosterone undecanoate (Jatenzo)
Tezepelumab-ekko (Tezspire)	**Dosage forms:** • 210mg/1.91mL (110mg/mL) solution in a single-dose glass vial (injection). • 210mg/1.91mL (110mg/mL) solution in a single-dose pre-filled syringe (injection). **Indications:** TEZSPIRE is a thymic stromal lymphopoietin (TSLP) blocker, human monoclonal antibody (IgG2λ), indicated for the add-on maintenance treatment of adult and pediatric patients aged 12 years and older with severe asthma. • **Limitation of Use:** not for relief of acute bronchospasm or status asthmaticus **Comparables:** Dupixent, Fasenra, Nucala, Cinqair **Guidelines:** • GINA Difficult to Treat & Severe Asthma in Adolescent and Adult Patients. V3.0 April 2021. https://ginasthma.org/severeasthma/

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Ublituximab-xiiy (Briumvi)	Dosage form: 150 mg/ 6 mL (25 mg/mL) single dose vial **Indication:** BRIUMVI is a CD20-directed cytolytic antibody indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults. **Comparables:** Ocrelizumab (Ocrevus), Ofatumumab (Kesimpta) **Guidelines:** • Costello, K., & Kalb, R. (2019). The use of disease-modifying therapies in multiple sclerosis: principles and current evidence. Multiple Sclerosis Coalition. Retrieved from https://mymsaa.org/PDFs/dmt_consensus_ms_coalition07111-9.pdf • 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 recommenda-tions summary: Disease-modifying therapies for adults with multiple sclerosis. Neurology, 90(17), 777-788. https://doi.org/10.1212/wnl.0000000000005347
Velmanase alfa-tycv (Lamzede)	**Dosage form:** For injection: 10 mg of velmanase alfa-tycv as a lyophilized powder in a single-dose vial for reconstitution **Indication:** LAMZEDE is recombinant human lysosomal alpha-mannosidase indicated for the treatment of non-central nervous system manifestations of alpha-mannosidosis in adult and pediatric patients. **Comparables:** Lamzede is the first and only FDA approved treatment for Alpha-mannosidosis (AM) **Guidelines:** • National Organization of Rare Disorders (NORD): Alpha-Mannosidosis. https://rarediseases.org/rare-diseases/alpha-mannosidosis/

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New Drug Entities

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New Drug Entities	Details
Daprodustat (Jesduvroq)	**Dosage forms:** Tablets: 1 mg, 2 mg, 4 mg, 6 mg, and 8 mg. **Indications:** JESDUVROQ is a hypoxia-inducible factor prolyl hydroxylase (HIF PH) inhibitor indicated for the treatment of anemia due to chronic kidney disease in adults who have been receiving dialysis for at least four months. • **Limitation of Use:** Not shown to improve quality of life, fatigue, or patient well-being. • Not indicated for use: As a substitute for transfusion in patients requiring immediate correction of anemia or in patients not on dialysis. **Comparables:** Epoetin alfa, Darbepoetin alfa, Methoxy polyethylene glycol-epoetin beta **Guidelines:** • Clinical Practice Guideline Anaemia of Chronic Kidney Disease 2022. https://ukkidney.org/sites/renal.org/files/Updated-130220-Anaemia-of-Chronic-Kidney-Disease-1-1.pdf
Omaveloxolone (Skyclarys)	**Dosage forms:** Capsules: 50 mg **Indications:** SKYCLARYS is indicated for the treatment of Friedreich's ataxia in adults and adolescents aged 16 years and older. **Comparables:** None. **Guidelines:** • Corben, L.A., Collins, V., Milne, S. et al. Clinical management guidelines for Friedreich ataxia: best practice in rare diseases. Orphanet J Rare Dis 17, 415 (2022). https://doi.org/10.1186/s13023-022-02568-3
Trofinetide (Daybue)	**Dosage Form:** Oral solution: 200 mg/mL **Indication:** DAYBUE is indicated for the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older. **Comparables:** None. **Guidelines:** • National Organization of Rare Disorders (NORD): Rett Syndrome. https://rarediseases.org/rare-diseases/rett-syndrome/
Zavegepant (Zavzpret)	**Dosage forms:** Nasal spray: 10 mg **Indication:** ZAVZPRET is a calcitonin gene-related peptide receptor antagonist indicated for the acute treatment of migraine with or without aura in adults. **Comparables:** Zomig, Imitrex, Onsentra Xsail, Ubrelvy, Nurtec ODT **Guidelines:** • Acute Migraine Headache: Treatment Strategies: https://www.aafp.org/pubs/afp/issues/2018/0215/p243.html • The American Headache Society Consensus Statement: Update on integrating new migraine treatments into clinical practice 2021: https://doi.org/10.1111/head.14153

Updated through March 28th, 2023.

New Drug Formulations

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

New Drug Formulations	Details
Albuterol sulfate and budesonide (Airsupra) Inhaled Aerosol	**Dosage form:** Inhalation aerosol: Pressurized metered dose inhaler that delivers a combination of albuterol 90 mcg and budesonide 80 mcg per actuation. **Indications:** AIRSUPRA is a combination of albuterol, a beta2-adrenergic agonist and budesonide, a corticosteroid, indicated for the as-needed treatment or prevention of bronchoconstriction and to reduce the risk of exacerbations in patients with asthma 18 years of age and older. **Comparables:** Budesonide/Formoterol fumarate (Symbicort), Albuterol (ProAir Digihale/ ProAir RespiClick/Proventil HFA/ Ventolin HFA) **Guidelines:** ● 2022 GINA Report, Global Strategy for Asthma Management and Prevention. https://ginasthma.org/wp-content/uploads/2022/07/GINA-Main-Report-2022-FINAL-22-07-01-WMS.pdf

Updated through March 28th, 2023.

New Drug Indications

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

New Indications	Details
Lanadelumab-flyo (Takhzyro)	**Dosage form:** Injection: • 150 mg/1 mL (150 mg/mL) solution in a single-dose prefilled syringe • 300 mg/2 mL (150 mg/mL) solution in a single-dose prefilled syringe • 300 mg/2 mL (150 mg/mL) solution in a single-dose vial. **New Indication:** TAKHZYRO is a plasma kallikrein inhibitor (monoclonal antibody) indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in adult and pediatric patients 2 years and older. **Comparables:** Cinryze, Haegarda, Orladeyo **Guidelines:** • US HAEA Medical Advisory Board 2020 Guidelines for the Management of Hereditary Angioedema. https://www.haea.org/assets/img/TreatmentGuidelines040321.pdf
Maralixibat (Livmarli)	**Dosage form:** Oral solution: 9.5 mg of maralixibat per mL **New Indication:** LIVMARLI is an ileal bile acid transporter (IBAT) inhibitor indicated for the treatment of cholestatic pruritus in patients with Alagille syndrome (ALGS) 3 months of age and older. **Comparables:** None. **Guidelines:** • National Organization of Rare Disorders (NORD): Alagille Syndrome. https://rarediseases.org/rare-diseases/alagille-syndrome/
Sarilumab (Kevzara)	**Dosage form:** Injection: • 150 mg/1.14 mL or 200 mg/1.14 mL solution in a single-dose pre-filled syringe • 150 mg/1.14 mL or 200 mg/1.14 mL solution in a single-dose prefilled pen **New Indication:** • KEVZARA® is an interleukin-6 (IL-6) receptor antagonist indicated for treatment of adult patients with polymyalgia rheumatica (PMR) who have had an inadequate response to corticosteroids or who cannot tolerate corticosteroid taper. **Comparables:** Oral Prednisone **Guidelines:** • 2015 Recommendations for the Management of Polymyalgia Rheumatica https://www.rheumatology.org/Portals/0/Files/2015%20PMR%20guidelines.pdf

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

ANDA Number	Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indication+
215908	Nitisinone Capsules, 2 mg, 5 mg, 10 mg, and 20 mg	Torrent Pharma Inc.	Orfadin (Nitisinone) Capsules	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 phenylalanine

Off Market

Recall Notifications

Date	Brand Name	Reason for Recall	Company Name
2/2/2023	Artificial Tears Lubricant Eye Drops	Potential microbial contamination	Global Pharma Healthcare
2/24/2023	Artificial Eye Ointment	Due to possible microbial contamination	Global Pharma Healthcare
3/2/2023	Brimonidine Tartrate Ophthalmic Solution, 0.15%	Potential lack of sterility.	Apotex Corp.
3/22/2023	Dabigatran Etexilate Capsules, USP	Detection of N-Nitrosodimethylamine (NDMA) Impurity	Ascend Laboratories LLC.

Safety Notifications

There are no new safety notifications

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Shortages (New)

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

Posting Date	Generic Name	Strength	Related information
3/10/2023	Clonazepam Tablets	0.5 mg, 1 mg, 2 mg	
3/17/2023	Methamphetamine Hydrochloride Tablets	5 mg	Manufacturing delay
3/13/2023	Methotrexate Injection	25 mg/mL	Increased demand for the drug
1/19/2023	Quinapril and Hydrochlorothiazide Tablets	10-12.5 mg, 20-12.5 mg	Discontinued
1/19/2023	Quinapril Hydrochloride Tablets	5 mg, 10 mg, 20 mg, 40 mg	Long-term backorder for all NDCs

References

- 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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