MC-Rx

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Insights on the Drugs Pipeline

Exploring the changes in the drugs market.

February 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

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

"Hot Topic"

Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RA): An Increasing Trend in Potential Misuse

For the last couple of years, glucagon-like peptide-1 receptor agonists (GLP-1 RA), have been used to effectively treat type 2 Diabetes Mellitus due to their ability to aid in arteriosclerotic cardiovascular disease (ASCVD) by providing diabetes improvement and weight loss with low risk of hypoglycemia. Recently, the New England Journal of Medicine published articles on the use of GLP1-RAs: tirzepatide and semaglutide as effective medications for the management of obesity. It is important to note that currently only two GLP-1 RA agents have the indication for management of obesity: Wegovy (semaglutide) and Saxenda (liraglutide). The purpose of this article is to create awareness among healthcare professionals and patients regarding potential misuse of GLP-1 RAs for non-FDA approved indications.

In 2021, Wegovy (semaglutide), a product with the same active ingredient as Ozempic (semaglutide) was released for the treatment of obesity showing a reduction of 15% body weight in clinical trials. The clinical evidence resulted in a rising trend in GLP-1 RAs utilization with a potential for misuse. Our goal is to review some of the factors that led to the GLP-1 RAs increase in utilization and offer recommendations to providers and payers.

As research advances, GLP-1 RAs represent another treatment option for patients that struggle with obesity along with other comorbidities such as: hypertension and dyslipidemia. Upon the release of information regarding the benefits of GLP-1 RAs in weight loss, news spread on social media about the medication that labels it as a simple way to lose weight. However, in order to receive Wegovy, patients should meet specific criteria for weight loss. According to the drug package insert, to qualify for Wegovy treatment, adult patients must have 30 kg/m2 or greater (obesity) or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia). Wegovy is indicated for pediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater for age and sex (obesity). There are concerns that patients receiving prescriptions for Wegovy do not meet this criteria, which is leading to overutilization and a shortage of these medications (Wegovy and Ozempic) as reported by the ASHP and other health organizations. It is important to note that Wegovy and Ozempic are not interchangeable, have different indications, and are used at different dosage strengths as established by the FDA. Due to this shortage, patients may not have access to Ozempic for the treatment of diabetes.

During the Ozempic shortage, there are treatment alternatives that may be recommended for patients with type 2 diabetes mellitus. It is important for patients to consult with their doctor regarding other GLP-1 RA options such as Liraglutide (Victoza), Dulaglutide (Trulicity), Exenatide (Byetta), Exenatide (Bydureon BCISE), oral Semaglutide (Rybelsus), Tirzeparide (Mounjaro), Lixisenatide (Adlyxin), etc.

For persons diagnosed with obesity and unable to access Wegovy, there may be other treatment options or weight loss programs available. It is

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important to note that not all insurance benefits cover weight loss treatments. Beneficiaries diagnosed with obesity should confirm their insurance benefits first and consult with their doctor regarding treatment options. Other FDA approved medications for weight loss include: Liraglutide (Saxenda), Naltrexone ER/Bupropion ER (Contrave), Phentermine/ Topiramate ER (Qsymia) and Orlistat (Alli- OTC, Xenical). In addition, establishing a healthy diet and exercise recommended by health professionals may aid in weight loss and general health.

Medication GLP1-RAs	Indication	Drug Availability
Dulaglutide (Trulicity)	Indicated: • As an adjunct to diet and exercise to improve glycemic control in patients 10 years and older with **type 2 diabetes mellitus** • To reduce the risk of major adverse cardiovascular events in adults with **type 2 diabetes mellitus** and established cardiovascular disease	Currently in shortage Started on: 12/15/2022
Exenatide (Bydureon BCISE)	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with **type 2 diabetes mellitus**	Available
Exenatide (Byetta)	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with **type 2 diabetes mellitus**	Available
Liraglutide Recombinant (Saxenda)	Indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in: • Adult patients with an initial body mass index (BMI) of 30 kg/m2 or greater (obese), or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g. hypertension, **type 2 diabetes mellitus**, or dyslipidemia) • Pediatric patients aged 12 years and older with: body weight above 60 kg and an initial BMI corresponding to 30 kg/m2 for adults (obese) by international cut-offs	Available
Liraglutide Recombinant (Victoza)	Indicated: • As an adjunct to diet and exercise to improve glycemic control in patients 10 years and older with **type 2 diabetes mellitus** • To reduce the risk of major adverse cardiovascular events in adults with **type 2 diabetes mellitus** and established cardiovascular disease	Available
Lixisenatide (Adlyxin)	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with **type 2 diabetes mellitus**	Available

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What's New

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Medication GLP1-RAs	Indication	Drug Availability
Semaglutide (Ozempic)	Indicated as: • An adjunct to diet and exercise to improve glycemic control in adults with **type 2 diabetes mellitus** • To reduce the risk of major adverse cardiovascular events in adults with **type 2 diabetes mellitus** and established cardiovascular disease	Currently in shortage Started on: 08/23/2022
Semaglutide (Rybelsus)	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with **type 2 diabetes mellitus**	Available
Tirzepatide (Mounjaro)	Indicated as an adjunct to diet and exercise to improve glycemic control in adults with **type 2 diabetes mellitus**	Currently in shortage Started on: 12/15/2022
Semaglutide (Wegovy)	Indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in: • Adult patients with an initial body mass index (BMI) of 30 kg/m2 or greater (obesity) or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, **type 2 diabetes mellitus**, or dyslipidemia) • Pediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater for age and sex (obesity)	Currently in shortage Date first posted: 03/31/2022

References:

1. American Diabetes Association. (2023). *Standards of Care in Diabetes* (Vol. 46, Ser. Suppl 1).
2. *Drug shortage detail: Semaglutide injection*. ASHP (2023). from https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx?id=813&loginreturnUrl=SSOCheckOnly
3. Dungan, K., & Desantis, A. (2022). Glucagon-like peptide 1-based therapies for the treatment of type 2 diabetes mellitus. Retrieved from https://www.uptodate.com/contents/glucagon-like-peptide-1-based-therapies-for-the-treatment-of-type-2-diabetes-mellitus?search=GLP1%20shortage&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1#references.
4. *FDA Approved Drugs*. Food and Drug Administration (FDA). (2023) from https://www.access.fda.gov/
5. *FDA Drug Shortages*. Food and Drug Administration (FDA). (2023) from https://www.access.fda.gov/
6. Food and Drug Administration (FDA). (2017). OZEMPIC (semaglutide) injection, for subcutaneous use.
7. Food and Drug Administration (FDA). (2021). WEGOVY (semaglutide) injection, for subcutaneous use.
8. Jastreboff, A., Alves, B., Connery, L., Wharton, S., Ahmad, N., Aronne, L., Stefanski, A., Bunck, M., Liu, B., Zhang, S., & Kiyosue, A. (2022). Tirzepatide once weekly for the treatment of obesity. *New England Journal of Medicine*, *387*(15), 1433–1435. https://doi.org/10.1056/nejmc2211120

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9. Landwehr, J. (2022). *Ozempic shortage: How a viral trend could be putting people with diabetes at risk*. Health. Retrieved from https://www.health.com/ozempic-wegovy-shortage-weight-loss-diabetes-risk-6823914

10. Wilding, J., Batterham , R., Calanna, S., Davies, M., Van Gaal, L., Lingvay, I., McGowan, B., Rosenstock, J., Wadden, T., Wharton, S., & Yokote, K. (2021). Once-weekly semaglutide in adults with overweight or obesity. *New England Journal of Medicine, 385*(1). https://doi.org/10.1056/nejmc2106918

Specialty Pipeline

Pipeline Drug	Current Status	Anticipated Approval	What is this drug being developed for?
Altuviiio (Efanesoctocog Alfa)	(Pending) BLA	02/28/2023	Hemophilia: Hemophilia A
ARGX-113 SC (IgG Fc fragment)	(Pending) BLA	03/20/2023	Nervous System Diseases (not otherwise classified): • Myasthenia gravis • Chronic inflammatory demyelinating polyneuropathy (CIDP) Skin And Subcutaneous Diseases (not otherwise classified): • Pemphigus • Pemphigus vulgaris • Bullous pemphigoid Thrombocytopenia: • Immune thrombocytopenia Musculoskeletal System and Connective Tissue Diseases (not otherwise classified): • Idiopathic inflammatory myositis
AVT02 (Adalimumab)	(Pending) Biosimilar	04/13/2023	Plaque Psoriasis: Plaque psoriasis
Brukinsa (Zanubrutinib)	(Pending) sNDA	01/20/2023	Leukemia: Chronic lymphocytic leukemia Viral Infections (not otherwise classified): Coronavirus disease 2019 (COVID-19) Non-Hodgkin's Lymphoma: Follicular lymphoma
Daprodustat (Daprodustat)	(Pending) NDA	02/01/2023	Anemia: Anemia due to kidney disease

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Specialty Pipeline

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Pipeline Drug	Current Status	Anticipated Approval	What is this drug being developed for?
Evkeeza (Evinacumab-dgnb)	(Pending) sBLA	03/30/2023	Dyslipidemia: Homozygous familial hypercholesterolemia (HoFH)
GEN3013 (Epcoritamab)	(Pending) BLA	05/21/2023	Non-Hodgkin's Lymphoma: Several Leukemia: Chronic lymphocytic leukemia
Hyrimoz (Adalimumab)	(Pending) Biosimilar	03/2023	Ankylosing Spondylitis: Ankylosing spondylitis Inflammatory Bowel Disease (IBD): Crohn's disease and Ulcerative Colitis Plaque Psoriasis: Plaque psoriasis Psoriatic Arthritis: Psoriatic arthritis Rheumatoid Arthritis (RA): Juvenile idiopathic arthritis and Rheumatoid arthritis
Jakafi (Ruxolitinib Phosphate)	(Pending) NDA	03/23/2023	Graft Versus Host Disease (GVHD): Graft versus host disease Myelodysplastic Syndromes: Myelofibrosis Myelodysplastic Syndromes: Polycythemia Vera
LOXO-305 (Pirtobrutinib)	(Pending) NDA	1Q 2023	Non-Hodgkin's Lymphoma: Several Leukemia: Chronic lymphocytic leukemia Multiple Myeloma: Multiple myeloma
LY3074828 (Mirikizumab)	(Pending) BLA	1Q 2023	Inflammatory Bowel Disease (IBD): Ulcerative colitis and Crohn’s Disease Plaque Psoriasis: Plaque psoriasis
Lynparza (Olaparib)	(Pending) sNDA	1Q 2023	Prostate Cancer: Prostate cancer Lung Cancer: Non-small cell lung cancer (NSCLC) and Small cell lung cancer Colorectal Cancer: Colorectal cancer Gastric Cancer: Gastric cancer
NNZ-2566 (Trofinetide)	(Pending) NDA	03/12/2023	Mental, Behavioral And Neurodevelopmental Disorders (not otherwise classified): Rett syndrome Congenital And Chromosomal Abnormalities (not otherwise classified): Fragile X syndrome

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Specialty Pipeline

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

Pipeline Drug	Current Status	Anticipated Approval	What is this drug being developed for?
Omav (Omaveloxolone)	(Pending) NDA	02/28/2023	Nervous System Diseases (not otherwise classified): Friedreich's ataxia Melanoma: Melanoma Metabolic, Endocrine And Nutritional Diseases (not otherwise classified): Mitochondrial myopathy
Quizartinib (Quizartinib)	(Pending) NDA	04/24/2023	Leukemia: Acute myeloid leukemia
SER-109 (TBD)	(Pending) BLA	04/26/2023	Abdominal Infections: Prevention of Clostridioides difficile infection (CDI)
Tukysa (Tucatinib)	Pending	01/19/2023	Colorectal Cancer: Colorectal cancer Gastric Cancer: Gastric cancer Gastroesophageal Cancer: Gastroesophageal junction cancer
TransCon PTH (Palopegteriparatide)	(Pending) NDA	04/30/2023	Metabolic, Endocrine And Nutritional Diseases (not otherwise classified): Hypoparathyroidism
Trikafta (Elexacaftor; Ivacaftor; Tezacaftor)	(Pending) NDA	04/28/2023	Cystic Fibrosis: Cystic fibrosis patients with CFTR gene mutations
TX01 (Filgrastim)	(Pending) Biosimilar	02/2023	Neutropenia: Severe chronic neutropenia

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Biosimilar Pipeline

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Biosimilar	Manufacturer(s)	Reference Biological	Possible FDA approval date	Potential Launch Date
ABP 654	Janssen	Stelara IV and SC	Pending (2H 2023)	Regulatory approval: 2H 2023
AVT02	TEVA	Humira (100 mg/mL)	Pending (04/13/23)	Settlement: 07/01/23
AVT04	Teva	Stelara SC	Pending (11/2023)	Regulatory approval: 2H 2023
BAT1806	Roche; Chugai; Genentech	Actemra IV	Pending (10/2023)	Regulatory approval: 4Q 2023
Hyrimoz HCF	Sandoz	Humira (100mg/mL)	Pending (03/2023)	TBD: 07/2023
Lupifil-P	Amgen	Neulasta	Pending	Regulatory approval: 2023
MSB11456	Roche, Chugai, Genentech	Actemra IV	Pending (2Q 2023)	Regulatory approval: 2023
PB006	Biogen; Royalty Pharma	Tysabri IV	Pending (05/2023)	Regulatory approval: 2023 - 2024
Ryzneuta	Amgen	Biobetter of Neulasta	Pending	Settlement:2023
TX01	Amgen	Neupogen	Pending (02/2023)	Regulatory approval: 02/2023
Udenyca OBI	Coherus BioSciences	Neulasta Onpro	Pending 2023	Regulatory approval: 2023
Yuflyma	Celltrion	Humira (100 mg/mL)	Pending	Settlement: 07/01/23

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FDA Approval

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FDA Approvals	Details
Adalimumab-aacf (Idacio)	**Dosage form:** Injection: Single-dose prefilled pen (IDACIO Pen) 40 mg/0.8 mL; Single-dose prefilled glass syringe 40 mg/0.8 mL **Indication:** Rheumatoid Arthritis (RA): reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderate- to-severe active RA. • Juvenile Idiopathic Arthritis (JIA): reducing signs and symptoms of moderate-to-severe active polyarticular JIA in patients 2 years of age and older. • Psoriatic Arthritis (PsA): reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active PsA. • Ankylosing Spondylitis (AS): reducing signs and symptoms in adult patients with active AS. • Crohn's Disease (CD): treatment of moderate-to-severe active Crohn's disease in adults and pediatric patients 6 years of age and older. • Ulcerative Colitis (UC): treatment of moderate-to-severe active ulcerative colitis in adult patients. • Plaque Psoriasis (Ps): treatment of adult patients with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate. **Comparables:** Adalimumab biosimilars **Guidelines:** • ACR: Guideline for the treatment of rheumatoid arthritis (2021) • AGA: Clinical practice guidelines on the management of moderate to severe ulcerative colitis (2020) • AGA: Clinical practice guidelines on the medical management of moderate to severe luminal and perianal fistulizing Crohn's disease (2021) • American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF): Joint guidelines of care for the management and treatment of psoriasis in pediatric patients (2020) • AAD and NPF: Joint guidelines of care for the management and treatment of psoriasis with biologics (2019)

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FDA Approvals

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

FDA Approvals	Details
Etranacogene dezaparvovec (Hemgenix)	**Dosage form:** HEMGENIX is a suspension for intravenous infusion provided in kits containing 10 to 48 single-use vials;.each kit containing a dosage unit based on the patient's body weight; HEMGENIX has a nominal concentration of 1 x 1013 gc/mL and each vial contains an extractable volume of not less than 10 mL **Indication:** Indicated for adults with the condition who currently use factor IX prophylaxis therapy for blood clotting, those who have or have had life-threatening hemorrhage, or those who have repeated serious spontaneous bleeding episodes. Letter FDA: Etranacogene dezaparvovec-drlb is indicated for treatment of adults with Hemophilia B (congenital Factor IX deficiency) who: currently use Factor IX prophylaxis therapy, or have current or historical life-threatening hemorrhage, or have repeated, serious spontaneous bleeding episodes **Comparables:** None. First Gene Therapy For Patients With Hemophilia **Guidelines:** • NHF: MASAC recommendations concerning products licensed for the treatment of hemophilia and other bleeding disorders (2020) • World Federation of Hemophilia (WFH): Guidelines for the management of hemophilia, 3rd edition (2020)

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New Drug Formulations

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

NDF	Details
Latanoprost (Iyuzeh)	**Dosage form:** Ophthalmic solution containing latanoprost 0.005% (50 mcg/mL). **Indication:** Is a prostaglandin F2α analogue indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension **Comparables:** Omlonti, Bimatoprost, Latanoprost, Latanoprostene bunod, Tafluprost, Travoprost **Guidelines:** • https://www.aafp.org/pubs/afp/issues/2016/0415/p668.html • https://www.nice.org.uk/guidance/ng81
Sodium phenylbutyrate (Olpruva)	**Dosage form:** For oral suspension: 2 g, 3 g, 4 g, 5 g, 6 g, and 6.67 g of sodium phenylbutyrate as pellets in packets for reconstitution. **Indication:** As adjunctive therapy to standard of care, which includes dietary management, for the chronic management of adult and pediatric patients weighing 20 kg or greater and with a body surface area (BSA) of 1.2 m2 or greater, with urea cycle disorders (UCDs) involving deficiencies of carbamylphosphate synthetase (CPS), ornithine transcarbamylase (OTC), or argininosuccinic acid synthetase (AS). **Comparables:** Buphenyl; Pheburane **Guidelines:** https://rarediseases.org/gard-rare-disease/urea-cycle-disorders/

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New Drug Entities

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NME	Details
Adagrasib (Krazati)	**Dosage form:** Tablets: 200 mg **Indication:** Is an inhibitor of the RAS GTPase family, indicated for the treatment of adult patients with KRAS G12C-mutated locally advanced, or metastatic non-small cell lung cancer (NSCLC) as determined by an FDA approved test, who have received at least one prior systemic therapy **Comparables:** Sotorasib **Guidelines:** • https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf
Fecal microbiota, live-jslm (Rebyota)	**Dosage form:** Suspension. Administer a single dose of 150 mL rectally **Indication:** Is indicated for the prevention of recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older, following antibiotic treatment for recurrent CDI **Guidelines:** • American Academy of Pediatrics (AAP): Red Book – Clostridioides difficile (formerly Clostridium difficile) (2021) • American College of Gastroenterology (ACG): Clinical guidelines for prevention, diagnosis, and treatment of Clostridioides difficile infections (2021) • American Society of Colon and Rectal Surgeons (ASCRS): Clinical practice guidelines for the management of Clostridioides difficile infection (2021) • Infectious Diseases Society of American (IDSA) and Society for Healthcare Epidemiology of America (SHEA): Clinical practice guideline on management of Clostridioides difficile infection in adults, focused update (2021)
Lecanemab-irmb (Legembi)	**Dosage Forms:** Single-dose 500 mg/5 mL and 200 mg/2 mL vials of solution for dilution and IV infusion **Indication:** For the treatment of Alzheimer's disease. Treatment with LEQEMBI should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in clinical trials. There are no safety or effectiveness data on initiating treatment at earlier or later stages of the disease than were studied. This indication is approved under accelerated approval based on reduction in amyloid beta plaques observed in patients treated with LEQEMBI. Continued approval for this indication may be contingent upon verification of clinical benefit in a confirmatory trial. **Comparables:** Aduhelm® (aducanumab-avwa - Biogen/Eisai)

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New Drug Entities

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NME	Details
Lenacapavir (Sunlenca)	**Dosage form:** Tablets: 300 mg; Injection: 463.5 mg/1.5 mL (309 mg/mL) in single-dose vials. **Indication:** A human immunodeficiency virus type 1 (HIV-1) capsid inhibitor, in combination with other antiretroviral(s), is indicated for the treatment of HIV-1 infection in heavily treatment-experienced adults with multidrug resistant HIV-1 infection failing their current antiretroviral regimen due to resistance, intolerance, or safety considerations * Lenacapavir is a first-in-class inhibitor of HIV-1 capsid function. **Guidelines:** • Department of Health and Human Services (DHHS) Panel on Antiretroviral Guidelines for Adults and Adolescents: Guidelines for the use of antiretroviral agents in adults and adolescents with HIV (2022) • International Antiviral Society-USA Panel (IAS-USA): Recommendations on antiretroviral drugs for treatment and prevention of HIV infection in adults (2022) • IAS-USA: Recommendations on drug resistance mutations in HIV-1, update (2022) • Capsid Inhibition with Lenacapavir in Multidrug-Resistant HIV-1 Infection, May 12, 2022, N Engl J Med 2022; 386:1793-1803, DOI: 10.1056/NEJMoa2115542
Mosunetuzumab-axgb (Lunsumio)	**Dosage form:** Injection: 1 mg/mL solution in a single-dose vial; 30 mg/30 mL (1 mg/mL) solution 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 follicular lymphoma after two or more lines of systemic therapy. **Comparables:** rituximab, obinutuzumab **Guidelines:** https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf
Nadofaragene firadenovec-vncg (Adstiladrin)	**Dosage form:** Suspension for intravesical instillation, supplied as single-use vials. **Indication:** Is a non-replicating adenoviral vector-based gene therapy indicated for the treatment of adult patients with high-risk Bacillus Calmette Guérin (BCG)-unresponsive non-muscle invasive bladder cancer (NMIBC) with carcinoma in situ (CIS) with or without papillary tumors. **Guidelines:** https://www.nccn.org/professionals/physician_gls/pdf/bladder.pdf
Olutasidenib (Rezlidhia)	**Dosage form:** Capsules: 150 mg. **Indication:** Is an isocitrate dehydrogenase-1 (IDH1) inhibitor indicated for the treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible IDH1 mutation as detected by an FDA-approved test **Comparables:** Ivosidenib **Guidelines:** https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf

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New Indications

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NI	Details
Ibrexafungerp (Brexafemme)	**Dosage form:** Tablets: 150 mg of ibrexafungerp. **New Indication:** For reduction in the incidence of recurrent vulvovaginal candidiasis (RVVC) in adult and post-menarcheal pediatric females **Comparables:** Diflucan (fluconazole) oral tablet **Guidelines:** • Centers for Disease Control and Prevention (CDC): Sexually Transmitted Infections Treatment Guidelines (2021) • American College of Obstetricians and Gynecologists (ACOG): Practice bulletin on vaginitis in non-pregnant patients (2020) • Infectious Diseases Society of America (IDSA): Clinical practice guidelines for the management of candidiasis, update (2016)
Cariprazine (Vraylar)	**Dosage form:** Capsules: 1.5 mg, 3 mg, 4.5 mg, and 6 mg. **New Indication:** For a new indication of adjunctive therapy to antidepressants for the treatment of major depressive disorder in adults. **Comparables:** aripiprazole, brexpiprazole, olanzapine, quetiapine, risperidone, ziprasidone **Guidelines:** https://www.apa.org/depression-guideline

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New Generics

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Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indications
Penciclovir Cream, 1%	Teva Pharmaceuticals USA, Inc.	Denavir (Penciclovir) Cream	11/9/2022	Indicated for the treatment of recurrent herpes labialis (cold sores) in adults and pediatric patients 12 years of age and older

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Recall Notifications

Date	Brand Name	Product Description	Recall Reason Description	Company Name
12/21/2022	Lupin	Quinapril 20 and 40 mg tablets	Presence of nitrosamine impurity, N-Nitroso-Quinapril	Lupin Pharmaceuticals Inc.
01/09/2023	Spectrum	Epinephrine bulk API	Product discoloration	Spectrum Laboratory Products Inc.

Safety Notifications

Date	Safety Communication
11/22/2022	FDA investigating risk of severe hypocalcemia in patients on dialysis receiving osteoporosis medicine Prolia (denosumab)

Shortages (New)

Generic Name	Presentation	Posting Date	Related Information
Abacavir Sulfate (Ziagen) Tablets	300 mg tablet	01/03/2023	The anticipated date that GSK will cease distribution of the product is approximately January 1, 2024; Ziagen Oral Solution (49702-222-48) will still be available
Abacavir Sulfate; Lamivudine (Epzicom) Tablets	600 mg; 300 mg tablets	01/03/2023	The anticipated date that GSK will cease distribution of the product is approximately January 1, 2024
Abacavir Sulfate; Lamivudine; Zidovudine (Trizivir) Tablets	300 mg; 150 mg; 300 mg tablets	01/03/2023	The anticipated date that GSK will cease distribution of the product is approximately November 27, 2023

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Shortages (New)

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Generic Name	Presentation	Posting Date	Related Information
Dolutegravir Sodium (Tivicay) Tablets	10 mg tablet 25 mg tablet	01/03/2023	The anticipated date that GSK will cease distribution of the product is approximately January 1, 2024; Tivicay 50 mg tablets (49702-228-13) will still be available as well as Tivicay PD 5 mg (49702-255-37)
Fosamprenavir Calcium (Lexiva) Oral Solution	50 mg/mL Oral Solution and 700 mg tablet	01/03/2023	The anticipated date that GSK will cease distribution of the product is approximately January 1, 2024
Glyburide (GLYNASE) Tablets	1.5 tablet; 6 mg tablet; 6 mg tablet; 3 mg tablet	01/03/2023	Discontinuation of the manufacture of the drug; supply is expected to be exhausted in early February 2023 Discontinuation of the manufacture of the drug; Supply is expected to be exhausted in early November 2023
Maraviroc (Selzentry) Tablets	25 mg tablet; 75 mg tablet	01/03/2023	The anticipated date that GSK will cease distribution of the product is approximately January 1, 2024; Selzentry 150mg (49702-223-18), Selzentry 300 mg (49702-224-18) and Selzentry Oral Solution (49702-260-55) will still be available.
Moxetumomab pasudotox-tdfk (Lumoxiti) Injection	1 mg vial	01/10/2023	The planned permanent discontinuation of moxetumomab pasudotox-tdfk) for injection from the U.S. market is August 31, 2023.
Somatropin Injection	Humatrope 12 mg KIT; Humatrope 24 mg KIT; Norditropin® FlexPro® 5 mg/1.5 mL; Norditropin® FlexPro® 10 mg/1.5 mL; Norditropin® FlexPro® 15 mg/1.5 mL	01/06/2023	Manufacturing delay
Sucralfate Tablets	1 g tablets	01/04/2023 - 01/09/2023	Multiple reasons for shortage

Updated through January 27, 2023.

Shortages (New)

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

Generic Name	Presentation	Posting Date	Related Information
Testosterone Transdermal System (Film, Extended Release)	2 mg/day (9.7 mg testosterone); 4 mg/day (19.5 mg testosterone)	01/10/2023	The discontinuation is limited to only the NDCs listed. Other NDCs of the same or similar products will continue to be available.

References:

1. FDA Approved Drugs. Food and Drug Administration (FDA). Retrieved from https://www.access.fda.gov/
2. Pending approvals for the specialty medications and projected biosimilars on the United States market monitor. IPD Analytics (2023). Retrieved from https://secure.ipdanalytics.com/User/Login.

Updated through January 27, 2023.

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