MC-Rx

Powered by ProCare Rx

Insights on the Drugs Pipeline

Exploring the changes in the drugs market.

August 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 July 31st, 2023.

Biosimilars: An Opportunity to Reduce Costs and Increase Access for Patients

Biologics are medications made from proteins, living cells and tissue, or a combination of these, and are mostly used for the treatment of conditions such as cancer and immune-mediated inflammatory diseases.[1] Though highly effective, the average biologic costs around $10,000 to $30,000 per year, representing a big financial burden that limits patient access to these treatments.[2] The introduction of biosimilars into the market provides an opportunity to reduce healthcare costs and improve healthcare access and outcomes. As patents for original biologics begin to expire in the upcoming years, the launch of new biosimilars will exponentially increase, potentially shifting the current market for biologicals. The purpose of this article is to inform readers about new biosimilars entering the market, the potential cost reductions they bring, and how they compete with branded biologicals.

It is always a jolting event whenever a multibillion-dollar product loses its exclusivity. Such is the case of AbbVie's $20 billion biological drug, Humira™, which faces serious competition with the launch of multiple biosimilars in 2023. The first biosimilar to Humira, Amgen's Amjevita, launched in January 2023. This was followed by the launch of multiple others in July 2023 from companies such as Samsung Bioepis/ Organon, Boehringer Ingelheim, and Pfizer.[3] These products are expected to be offered at significant discounts as compared to Humira, possibly shifting the utilization of the branded products and how they are managed by payers through cost-saving strategies. As expected, Humira's huge market share is not the only one threatened by the advent of new biosimilars. The following table provides insight on some of the biologics for which biosimilars are expected to launch in the upcoming years.

Table 1. Timeline for the anticipated launch of new biosimilar products.[3]

Expected launch year	Reference product	Number of potential biosimilars
2023	Humira™	12
2023-2024	Remicade®	1
	NovoLog®	3
	Lantus®	3
	Herceptin®	3
2023-2025	Actemra® IV	3
2024-2025	Simponi®	2
	Soliris®	2
	Xolair®	4
2025	Stelara®	8
2025-2026	Prolia®/Xgeva®	10
2026-2027	Actemra® SC	3
2027+	Cimzia®	1
2029	Enbrel®	3

As these new biosimilars make their way into the market, payers may want to move utilization to these lower-cost products through prior authorization, step therapies, formulary tiering, and other strategies that help increase savings and optimize healthcare expenditure. To date, biosimilars have been used for around 364 million days of treatment and have generated more than $13 billion in savings since 2015 due to lower cost.[4] Therefore, their impact in healthcare cost reduction should not be underestimated. As their utilization increases in the upcoming years, they are projected to

Updated through July 31st, 2023.

generate worldwide savings of approximately $290 billion by 2027.[5] The average sales price (ASP) of biologics and biosimilars is also expected to drop throughout the years. For example, the ASP of Rituxan and its biosimilar Truxima, has reduced 19% and 35% respectively, since their launch dates. This reduction in price is expected as drug manufacturers try to stay competitive in the market. However, pricing is not the only factor that contributes to a product's competitiveness. Rebates and negotiation strategies between manufacturers and payers can also impact the placement of biologics and their biosimilars in drug formularies.

Nonetheless, the performance of a new drug product in the market is influenced by many other variables. For example, several biosimilars for Humira were launched this year, but they differ in some key characteristics. First, not all of them have FDA approval for interchangeability, meaning only a few can be switched from Humira in the pharmacy without previously consulting the prescriber.[6] Biosimilars may also differ in some of their ingredients, as some may contain chemicals like latex and citrate, which not all patients can or will agree to use. The design of the product also affects its acceptance by patients, as some could be more convenient to use than others. In the case of biosimilars for Humira, they come in auto-injectors that require either two or three steps for administration, which patients may take into consideration if their medical condition (e.g. arthritis) causes motor difficulties. Product details such as these determine how biosimilars and biologics compete in the market, and payers evaluate each of them when deciding which products will be preferred for coverage.

In conclusion, biosimilars increase patient access to life-saving treatments and can significantly reduce healthcare costs. As the exclusivity periods of original biological products end, more biosimilars will enter the market and cause a reduction in the average sales prices of these products. However, product differences between biosimilars and biologics will determine how they compete in the market, as payers may base their preferences on these variables. Even though biosimilars have already saved the healthcare system billions of dollars, their competition in the market needs to be furthered encouraged by regulations.[7] This ensures access to these effective medications can be greatly expanded to more patient populations, putting us one step closer to reaching health equity.

References

1. Food and Drug Administration (FDA). Biosimilar Basics for Patients. FDA [Internet]. FDA; 2023 Mar 21; Available from: https://www.fda.gov/drugs/biosimilars/biosimilar-basics-patients
2. Chen BK, Yang YT, Bennett CL. Why Biologics and Biosimilars Remain So Expensive: Despite Two Wins for Biosimilars, the Supreme Court's Recent Rulings do not Solve Fundamental Barriers to Competition. Drugs. 2018 Nov;78(17):1777–1781. PMID: 30446980
3. IPD Analytics. Biosimilar Pipeline Report: 2H 2023 [Internet]. IPD Analytics. 2023. Available from: https://www.ipdanalytics.com/featured-sample-reports
4. Sandoz. The Bigger Picture: How Biosimilars Are Delivering Value Beyond Cost Savings [Internet]. Sandoz.. Available from: https://www.sandoz.com/news/bigger-picture-how-biosimilars-are-delivering-value-beyond-cost-savings
5. Jeremias S. Global Use of Medicines Report Predicts Biosimilars Will Save $290 Billion by 2027 [Internet]. Center for Biosimilars. 2023. Available from: https://www.centerforbiosimilars.com/view/global-use-of-medicines-report-predicts-biosimilars-will-save-290-billion-by-2027
6. Tariman JD. Biosimilars: Exploring the History, Science, and Progress. Clin J Oncol Nurs. 2018 Oct 1;22(5):5–12. PMID: 30239529
7. Salib V. Top Challenges Facing Biosimilar Adoption and Manufacturing [Internet]. PharmaNewsIntelligence. 2023. Available from: https://pharmanewsintel.com/news/top-challenges-facing-biosimilar-adoption-manufacturing

Updated through July 31st, 2023.

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
Avacincaptad pegol (ACP - Iveric Bio)	BLA Filed	08/19/2023	Inhibitor of complement component 5 (C5) for treating geographic atrophy secondary to age-related macular degeneration (AMD); intravitreal injection
Bimekizumab (Bimzelx - UCB)	BLA Filed	3Q: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	3Q:2023	Recombinant human acid α-glucosidase (rhGAA) enzyme replacement therapy/chaperone therapy for the treatment of late-onset Pompe disease; IV infusion
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
Elranatamab (Pfizer)	BLA Filed	08/22/2023	B-cell maturation antigen (BCMA) CD3-targeted bispecific antibody (BsAb) for the treatment of patients with relapsed or refractory multiple myeloma (RRMM); SC
Eplontersen (Ionis Pharmaceuticals/ AstraZeneca)	BLA Filed	12/22/2023	Antisense medicine designed to inhibit production of transthyretin (TTR) for the treatment of hereditary transthyretin-mediated amyloid polyneuropathy (hATTR-PN); SC 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

Updated through July 31st, 2023.

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?
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)
Lebrikizumab (Eli Lilly)	BLA Filed	Sept. 2023	Humanized monoclonal antibody targeting interleukin 13 (IL-13) for the treatment of atopic dermatitis; SC
Otibeglogene 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 vasoocclusive events; IV infusion
Mirikizumab (Eli Lilly)	Complete Response	2024	Monoclonal antibody targeting IL-23p19 for the treatment of moderate-to-severe ulcerative colitis; administered via IV infusion and SC injection
Nedosiran (Novo Nordisk)	NDA Filed	Sept. 2023	RNA interference therapeutic designed to inhibit hepatic lactate dehydrogenase (LDH; encoded by LDHA), the enzyme responsible for oxalate overproduction for the treatment of primary hyperoxaluria type 1; SC injection
Resmetirom (Madrigal Pharmaceuticals)	Phase 3	2024	Thyroid hormone receptor (THR) ß -selective agonist for the treatment of nonalcoholic steatohepatitis (NASH) with liver fibrosis; oral
Ritlecitinib (Litfulo - Pfizer)	Approved	06/23/2023	JAK3/TEC inhibitor for the treatment of adults and adolescents aged 12 years and older with alopecia areata; oral
Rozanolixizumab (Rystiggo - UCB)	Approved	06/27/2023	Neonatal Fc Receptor (FcRn) inhibitor for the treatment of generalized myasthenia gravis (gMG); SC

Updated through July 31st, 2023.

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?
Talquetamab (Janssen/ Genmab)	BLA Filed	08/09/2023	First in class; bispecific antibody that targets both GPRC5D, a novel multiple myeloma target, and CD3 on T-cells for the treatment of adult patients with relapsed or refractory multiple myeloma, who have previously received at least 3 prior lines of therapy; SC
Valoctocogene roxaparvovec (Roctavian – BioMarin Pharmaceuticals)	Approved	06/29/2023	Adenoviral vector-mediated transfer of the Human Factor VIII gene to treat severe hemophilia A; IV infusion
Zilucoplan (UCB)	NDA Filed	09/14/2023	A synthetic macrocyclic peptide inhibitor of complement component 5 (C5) for the treatment of generalized myasthenia gravis (gMG) who are anti-acetylcholine receptor (AchR) antibody+ (AChR-Ab+); SC

Updated through July 31st, 2023.

Biosimilar Pipeline

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

Generic Name Biosimilar Investigational Name	Manufacturer(s)	Reference Biological	Possible FDA approval date	Potential launch date
Adalimumab biosimilar (Simlandi) AVT-02	Teva/Alvotech	Humira (adalimumab)	2023	Settlement: 07/01/2023
Adalimumab-afzb (Abrilada) PF-06410293	Pfizer	Humira (adalimumab)	2023	Settlement: 07/01/2023
Aflibercept biosimilar CT-P42, ABP 938, SOK583A1	Celltrion	Eylea (aflibercept)	4/29/2024	TBD (2024?)
Aflibercept biosimilar M710; MYL-1701P	Momenta/Biocon	Eylea (aflibercept)	July 2023	TBD (2024?)
Bevacizumab biosimilar (Abevmy) Bmab-100; MYL-14020	Biocon	Avastin (bevacizumab)	2024	TBD (Pending FDA Approval)
Bevacizumab biosimilar (Aybintio) SB8	Samsung Bioepis/ Organon	Avastin (bevacizumab)	2023	TBD (Pending FDA Approval)
Bevacizumab biosimilar (Equidacent) FKB238	Centus	Avastin (bevacizumab)	2023-2024	TBD (Pending FDA Approval)
Bevacizumab biosimilar BAT-1706	Biothera/Sandoz	Avastin (bevacizumab)	2023	TBD (Pending FDA Approval)
Denosumab biosimilar GP2411	Sandoz	Prolia (denosumab)	12/6/2023	TBD (Feb 2025?)
Eculizumab biosimilar ABP-959	Amgen/Daiichi Sankyo	Solirirs (eculizumab)	2/28/2024	Settlement agreement: March 1, 2025
Filgrastim biosimilar TX-01	Tanvex BioPharma	Neupogen (filgrastim)	2023	TBD (Pending FDA Approval)

Updated through July 31st, 2023.

Biosimilar Pipeline

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

Generic Name Biosimilar Investigational Name	Manufacturer(s)	Reference Biological	Possible FDA approval date	Potential launch date
Infliximab biosimilar CT-P13 SC	Celltrion	Remicade (infliximab)	10/22/2023	TBD (Pending FDA Approval)
Natalizumab biosimilar PB006	Sandoz	Tysabri (natalizuman)	Mid 2023	TBD (Pending FDA Approval)
Pegfilgrastim biosimilar (Lupifil-P)	Lupin	Neulasta (pegfilgrastim)	2023	TBD (Pending FDA Approval)
Pegfilgrastim-cbqv (Udenyca OBI) CHS-1701	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?)
Tocilizumab biosimilar BIIB800; BAT1806	Biothera/Biogen	Actemra (tocilizumab)	10/9/2023	TBD (Pending FDA Approval and resolution of ongoing litigation)
Tocilizumab biosimilar MSB11456	Fresenius /Merck KGaA	Actemra (tocilizumab)	Mid 2023	TBD (Settlement agreement. Terms not disclosed)
Trastuzumab biosimilar HLX02	Henlius/Accorda	Herceptin (trastuzumab)	12/14/2023	TBD (Pending FDA Approval)
Trastuzumab biosimilar TX-05	Tanvex BioPharma	Herceptin (trastuzumab)	2024	TBD (Pending FDA Approval)
Ustekinumab biosimilar ABP 654	Amgen	Stelara (ustekinumab)	2H 2023	Settlement: Jan. 1, 2025
Ustekinumab biosimilar AVT-04	Alvotech/Teva	Stelara (ustekinumab)	10/11/2023	Settlement: Feb. 21, 2025

Updated through July 31st, 2023.

New Drug Entities

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

New Drug Entities	Details
Delandistrogene moxeparvovec-rokl (Elevidys)	**Dosage form:** suspension for intravenous infusion with a nominal concentration of 1.33×10^{13} vg/mL. **Indication:** For the Treatment of ambulatory pediatric patients aged 4 through 5 years with Duchenne muscular dystrophy (DMD) with a confirmed mutation in the DMD gene. **Comparables:** none **Guidelines:** • Duchenne Muscular Dystrophy. National Organization of Rare Disorders. (2023). https://rarediseases.org/rare-diseases/duchenne-muscular-dystrophy/
Donislecel-jujn (Lantidra)	**Dosage form:** cellular suspension. Dosage strength depends on the total number of islets packaged for infusion, which is reported on the container label and associated documents. **Indication:** Is an allogeneic pancreatic islet cellular therapy indicated for the treatment of adults with Type 1 diabetes who are unable to approach target HbA1c because of current repeated episodes of severe hypoglycemia despite intensive diabetes management and education. Use in conjunction with concomitant immunosuppression. **Comparables:** none **Guidelines:** • Standards of Care – 2023. American Diabetes Association. https://diabetesjournals.org/care/issue/46/Supplement_1
Somatrogon-ghla (Ngenla)	**Dosage form:** Injection 24 mg, 60 mg **Indication:** To treat growth failure due to inadequate secretion of endogenous growth hormone. **Comparables:** Skytrofa (lonapegsomatropin-tcgd), Sogroya (somapacitan-beco) **Guidelines:** • American College of Medical Genetics (ACMG): Practice resource for genetic evaluation of short stature, focused revision (2021) • Growth Hormone Research Society (GRS): Diagnosis, genetics, and therapy of short stature in children - A international perspective (2019) • American Association of Clinical Endocrinologists (AACE) and American Col-lege of Endocrinology (ACE): Guidelines for management of growth hormone deficiency in adults and patients transitioning from pediatric to adult care (2019) • Endocrine Society (ES): Clinical practice guideline on hypothalamic-pituitary and growth disorders in survivors of childhood cancer (2018) • Guidelines for Growth Hormone and Insulin-Like Growth Factor-I Treatment in Children and Adolescents: Growth Hormone Deficiency, Idiopathic Short Stature, and Primary Insulin-Like Growth Factor-I Deficiency 2016

Updated through July 31st, 2023.

New Drug Entities

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

New Drug Entities	Details
Sulbactam for injection; durlobactam for injection (Xacduro)	**Dosage form:** XACDURO is a co-packaged kit containing the following two components as sterile powders for reconstitution: • 1 clear single-dose vial of sulbactam for injection 1 g and • 2 amber single-dose vials of durlobactam for injection 0.5 g **Indication:** is a co-packaged product containing sulbactam, a beta-lactam antibacterial and beta lactamase inhibitor, and durlobactam, a beta lactamase inhibitor, indicated in patients 18 years of age and older for the treatment of hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP), caused by susceptible isolates of Acinetobacter baumannii-calcoaceticus complex. **Comparables:** ampicillin-sulbactam (Unasyn), cefiderocol, and colistin **Guidelines:** • Management of Adults With Hospital-acquired and Ventilator-associated Pneumonia: 2016 Clinical Practice Guidelines by the Infectious Diseases Society of America and the American Thoracic Society Published CID • Clinical Infectious Diseases, Volume 63, Issue 5, 1 September 2016, Pages e61–e111, https://doi.org/10.1093/cid/ciw353
Valoctocogene roxaparvovec-rvox (Roctavian)	**Dosage form:** Suspension for intravenous infusion. Has a nominal concentration of 2 × 10^{13} vg valoctocogene roxaparvovec-rvox per mL, each vial contains an extractable volume of not less than 8 mL (16 × 10^{13} vg) **Indication:** Is an adeno-associated virus vector-based gene therapy indicated for the treatment of adults with severe hemophilia A (congenital factor VIII deficiency with factor VIII activity < 1 IU/dL) without pre-existing antibodies to adeno-associated virus serotype 5 detected by an FDA-approved test **Comparables:** none. First Gene Therapy for the Treatment of Adults with Severe Hemophilia A **Guidelines:** • Guidelines for the management of hemophilia are published by the World Federation of Hemophilia (WFH) and the National Hemophilia Foundation: • World Federation of Hemophilia (WFH) 2020 guideline – https://www1.wfh.org/publications/files/pdf-1863.pdf • Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF) recommendations on various subjects

Updated through July 31st, 2023.

New Drug Formulations

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

New Drug Formulations	Details
Buprenorphine extended-release (Brixadi)	**New dosage form:** weekly and monthly injection provided in a pre-filled single dose syringe with a 23 gauge ½ inch needle- (weekly) is available in 8 mg/0.16 mL, 16 mg/0.32 mL, 24mg/0.48 mL, and 32 mg/0.64 mL; (monthly) is available in 64 mg/0.18 mL, 96 mg/0.27 mL, and 128 mg/0.36 mL **Indication:** Is indicated for the treatment of moderate to severe opioid use disorder in patients who have initiated treatment with a single dose of a transmucosal buprenorphine product or who are already being treated with buprenorphine. **Comparables:** Suboxone (buprenorphine and naltrexone), Sublocade (buprenorphine extended-release) **Guidelines:** • 2020 National Practice Guideline for the Treatment of Opioid Use Disorder - Focused Update https://www.cdc.gov/opioids/healthcare-professionals/prescribing/opioid-use-disorder.html
Coagulation Factor IX (Recombinant), Albumin Fusion Protein (Idelvion)	**New dosage form:** single-dose vials containing nominally 250, 500, 1000, 2000, or 3500 IU **Indication:** IDELVION®, Coagulation Factor IX (Recombinant), Albumin Fusion Protein (rIX-FP), a recombinant DNA-derived coagulation Factor IX concentrate, is indicated in children and adults with Hemophilia B (congenital Factor IX deficiency) for: • On-demand treatment and control of bleeding episodes • Perioperative management of bleeding • Routine prophylaxis to reduce the frequency of bleeding episodes **Comparables:** Recombinant human factor IX (e.g., BeneFIX, Ixinity, Rixubis) **Guidelines:** • Guidelines for the management of hemophilia are published by the World Federation of Hemophilia (WFH) and the National Hemophilia Foundation: • World Federation of Hemophilia (WFH) 2020 guideline – https://www1.wfh.org/publications/files/pdf-1863.pdf • Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF) recommendations on various subjects

Updated through July 31st, 2023.

New Drug Formulations

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

New Drug Formulations	Details
Colchicine (Lodoco)	**New dosage form:** Tablet; Oral 0.5 mg. **Indication:** New Formulation or New Manufacturer: is an alkaloid indicated: • to reduce the risk of myocardial infarction (MI), stroke, coronary revascularization, and cardiovascular death in adult patients with established atherosclerotic disease or with multiple risk factors for cardiovascular disease **Comparables:** other colchicine generic formulations **Guidelines:** • American Diabetes Association (ADA): Standards of care in diabetes (2023) Cardiovascular disease and risk management • National Institute for Health and Care Excellence (NICE): Clinical guideline on cardiovascular disease – Risk assessment and reduction, including lipid modification (2014, updated 2023) • 2019 ACC/AHA Guideline on the Primary Prevention of Cardiovascular Disease
Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo)	**New dosage form:** Sub Q Injection: 1,008 mg efgartigimod alfa and 11,200 units hyaluronidase per 5.6 mL (180 mg/2,000 units per mL) in a single-dose vial. **Indication:** Is a combination of efgartigimod alfa, a neonatal Fc receptor blocker, and hyaluronidase, an endoglycosidase, indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody positive **Comparables:** Vyvgart (efgartigimod alfa-fcab) IV infusion **Guidelines:** • International Consensus Guidance for Management of Myasthenia Gravis. (2020). https://n.neurology.org/content/neurology/96/3/114.full.pdf
Lidocaine (Lidosol)	**New Dosage form:** 5% ointment-dressing kit **Indication:** Is indicated for production of anesthesia of accessible mucous membranes of the oropharynx. It is also useful as an anesthetic lubricant for intubation and for the temporary relief of pain associated with minor burns, including sunburn, abrasions of the skin, and insect bites **Comparables:** generic lidocaine formulations

Updated through July 31st, 2023.

New Drug Formulations

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

New Drug Formulations	Details
Nalmefene (Opvee)	**New dosage form:** Nasal spray: 2.7 mg of nalmefene in 0.1 mL. **Indication:** an opioid antagonist indicated for the emergency treatment of known or suspected overdose induced by natural or synthetic opioids in adults and pediatric patients aged 12 years and older, as manifested by respiratory and/or central nervous system depression. Is intended for immediate administration as emergency therapy in settings where opioids may be present **Comparables:** Narcan (naloxone hydrochloride) **Guidelines:** • CDC Clinical Practice Guideline for Prescribing Opioids for Pain - United States, 2022. Centers for Disease Control and prevention. https://www.cdc.gov/mmwr/volumes/71/rr/rr7103a1.htm
Polyethylene glycol 3350, sodium sulfate, potassium chloride, magnesium sulfate, and sodium chloride (Suflave)	**New dosage form:** Oral Solution: Two bottles and two flavor enhancing packets. Each bottle contains 178.7 g polyethylene glycol 3350, 7.3 g sodium sulfate, 1.12 g potassium chloride, 0.9 g magnesium sulfate, and 0.5 g sodium chloride. The bottle also contains lemon-lime flavoring. **Indication:** New Combination: Is an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adults **Comparables:** CoLyte, GaviLyte, GoLytely, Moviprep, NuLytely, Plenvu, TriLyte, Suprep, Sutab **Guidelines:** • American Society of Colon and Rectal Surgeons (ASCRS): Clinical practice guidelines for the use of bowel preparation in elective colon and rectal surgery (2019)
Vevye (cyclosporine ophthalmic solution)	**New Dosage form:** Ophthalmic solution containing cyclosporine 0.1%. **Indication:** Is a calcineurin inhibitor immunosuppressant indicated for the treatment of the signs and symptoms of dry eye disease **Comparables:** Cequa; Restasis; Verkazia; Xiidra, Tyrvaya **Guidelines:** • Dry Eye Syndrome Preferred Practice Pattern. American Academy of Ophthalmology. (2019). DOI: 10.1016/j.ophtha.2018.10.023

Updated through July 31st, 2023.

New Indications

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

New Indications	Details
Abacavir, dolutegravir, and lamivudine (Triumeq PD)	For the expansion of the indication of the treatment of HIV-1 infection in adults and in pediatric patients aged at least 3 months and weighing at least 6 kg.
Adalimumab-adbm (Cyltezo)	For the addition of the indication for the treatment of non-infectious intermediate, posterior, and panuveitis in adult patients.
Adalimumab-atto (Amjevita)	For the addition of the indication for the treatment of non-infectious intermediate, posterior, and panuveitis in adult patients.
Adalimumab-bwwd (Hadlima)	For the addition of the indication for the treatment of moderate to severe hidradenitis suppurativa in adult patients. For the addition of the indication for the treatment of non-infectious intermediate, posterior, and panuveitis in adult patients.
Avapritinib (Ayvakit)	For the addition of the indication for the treatment of adult patients with indolent systemic mastocytosis (ISM).
Bezlotoxumab (Zinplava)	For the expansion of the indication to reduce recurrence of Clostridioides difficile infection (CDI) in adults and pediatric patients 1 year of age and older who are receiving antibacterial drug treatment for CDI and are at a high risk for CDI recurrence.
Coagulation Factor X [human] (Coagadex)	For the expansion of the indication of perioperative management of bleeding in patients with mild and moderate hereditary Factor X deficiency, to include severe Factor X deficiency.
Letermovir (Prevymis)	For the addition of the indication for prophylaxis of cytomegalovirus (CMV) disease in adult kidney transplant recipients at high risk (Donor CMV seropositive/Recipient CMV seronegative [D+/R-])
Leuprolide acetate (Eligard)	For the expansion of the indication for the treatment of advanced prostate cancer.
Levonorgestrel-releasing intrauterine system (Liletta)	For the addition of the indication for the treatment of heavy menstrual bleeding for up to 5 years in patients who choose intrauterine contraception as their method of contraception.
Odevixibat (Bylvay)	For the addition of the indication for the treatment of cholestatic pruritus in patients 12 months of age and older with Alagille syndrome (ALGS)
Olaparib (Lynparza)	For the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC), in combination with abiraterone and prednisone or prednisolone.
Talazoparib (Talzenna)	For the addition of the indication for treatment of adult patients with HRR gene-mutated metastatic castration-resistant prostate cancer (mCRPC), in combination with enzalutamide.

Updated through July 31st, 2023.

In Market Brand

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

In-Market-Brands	Details
Glofitamab-gxbm (Columvi)	**Dosage form:** Injection, for intravenous use 2.5 mg/2.5 mL (1 mg/mL) in a single-dose vial, 10 mg/10 mL (1 mg/mL) in a single-dose vial **Indication:** Is a bispecific CD20-directed CD3 T-cell engager indicated for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma, not otherwise specified (DLBCL, NOS) or large B-cell lymphoma (LBCL) arising from follicular lymphoma, after two or more lines of systemic therapy **Comparables:** Epkinly (epcoritamab-bysp) **Guidelines:** • B-cell Lymphomas. National Comprehensive Cancer Network. (2023). https://www.nccn.org/professionals/physician_gls/pdf/b-cell.pdf
Ritlecitinib (Litfulo)	**Dosage form:** Capsule. **Indication:** For the treatment of severe alopecia areata (AA) in adults and adolescents 12 years and older. **Comparables:** Olumiant (baricitinib) **Guidelines:** • European Dermatology Forum Guideline for the Treatment of Androgenetic Alopecia in Women and in Men. (2020). https://www.guidelines.edf.one//uploads/attachments/cl262ylye009ulajnpuci9r2i-androgenetic-alopecia-2017-gl.pdf
Rozanolixizumab-noli (Rystiggo)	**Dosage form:** Injection: 280 mg/2 mL (140 mg/mL) in a single-dose vial **Indication:** is a neonatal Fc receptor blocker indicated for the treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) or anti muscle-specific tyrosine kinase (MuSK) antibody positive **Comparables:** Soliris (eculizumab), Ultomiris (ravulizumab-cwvz), Vyvgart (efgartigimod alfa-fcab) and Vyvgart Hytrulo (efgartigimod alfa/hyaluronidase-qvfc) Rystiggo is the first drug for gMG that is also approved to treat patients who are MuSK antibody positive **Guidelines:** • International Consensus Guidance for Management of Myasthenia Gravis. (2020). https://n.neurology.org/content/neurology/96/3/114.full.pdf

Updated through July 31st, 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
Alcaftadine Ophthalmic Solution, 0.25% (OTC)	Eugia Pharma Specialities Limited	Lastacaft	6/23/2023	Temporarily relieves itchy eyes due to pollen, ragweed, grass, animal hair and dander
Amlodipine Benzoate Oral Suspension, 1 mg/mL (150 mL)	Amneal Pharmaceuticals LLC	Katerzia	6/13/2023	For the treatment of hypertension and coronary artery disease
Amphetamine Extended-Release Orally Disintegrating Tablets, 3.1 mg, 6.3 mg, 9.4 mg, 12.5 mg, 15.7 mg and 18.8 mg	Actavis Laboratories FL, Inc.	Adzenys XR-ODT	6/22/2023	For the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years and older
Baclofen Oral Suspension, 25 mg/5 mL (5 mg/mL)	Slayback Pharma LLC	Fleqsuvy	6/8/2023	Treatment of spasticity resulting from multiple sclerosis, particularly for the relief of flexor spasms and concomitant pain, clonus, and muscular rigidity and some value in patients with spinal cord injuries and other spinal cord diseases
Budesonide Rectal Foam, 2 mg/dose	Padagis Israel Pharmaceuticals Ltd.	Uceris	4/12/2023	For the induction of remission in patients with active mild to moderate distal ulcerative colitis extending up to 40 cm from the anal verge
Diazepam Rectal Gel Rectal Delivery System, 10 mg and 20 mg	Novel Laboratories, Inc.	Diastat AcuDial	5/30/2023	For the management of selected, refractory, patients with epilepsy, on stable regimens of AEDs, who require intermittent use of diazepam to control bouts of increased seizure activity

Updated through July 31st, 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
Estradiol Transdermal System USP, 0.014 mg/day	Zydus Noveltech, Inc	Menostar	4/17/2023	For the prevention of postmenopausal osteoporosis
Loteprednol Etabonate Ophthalmic Suspension, 0.2%	Akorn Operating Company LLC	Alrex	4/12/2023	For the temporary relief of the signs and symptoms of seasonal allergic conjunctivitis
Methsuximide Capsules USP, 300 mg	Novitium Pharma LLC	Celontin	5/1/2023	For the control of absence (petit mal) seizures that are refractory to other drugs
Obeticholic Acid Tablet, 5 mg and 10 mg	MSN Laboratories Private Limited, Lupin Limited, Apotex Inc	Ocaliva	5/30/2023	For the treatment of adult patients with primary biliary cholangitis.
Safinamide Tablets, 50 mg and 100 mg	Aurobindo Pharma Limited	Xadago	6/14/2023	Adjunctive treatment to levodopa/carbidopa in patients with Parkinson's disease (PD) experiencing "off" episodes
Sugammadex Injection, 200 mg/2 mL (100 mg/mL), 500 mg/5 mL (100 mg/mL) Single-Dose Vial	Aspiro Pharma Limited	Bridion	6/9/2023	Reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adults undergoing surgery
Tenofovir Alafenamide Tablets, 25 mg	Lupin Limited	Vemlidy	3/30/2023	For the treatment of chronic hepatitis B virus (HBV) infection in adults with compensated liver disease

Updated through July 31st, 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
Thalidomide Capsules USP, 50 mg, 100 mg, 150 mg, 200 mg	Natco Pharma Limited	Thalomid	4/27/2023	For the treatment of patients with newly diagnosed multiple myeloma; for the acute treatment of the cutaneous manifestations of moderate to severe erythema nodosum leprosum (ENL); as maintenance therapy for prevention and suppression of the cutaneous manifestations of ENL recurrence
Tiotropium Bromide Inhalation Powder, 18 mcg/ capsule	Lupin Inc	Spiriva HandiHaler	6/20/2023	For the long-term, once-daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema
Trifluridine and Tipiracil Tablets, 15 mg/6.14 mg and 20 mg/8.19 mg	Natco Pharma Limited	Lonsurf	6/13/2023	For the treatment of adult patients with metastatic colorectal cancer 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

Updated through July 31st, 2023.

Recall Notifications

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

Date	Drug Name	Reason for Recall	Company name
06/14/2023	Dronabinol Capsules 2.5mg and Ziprasidone Hydrochloride Capsules 20mg	Packaging may contain incorrect product due to labeling mix-up	Major Pharmaceuticals Pharmaceutical and Rugby Laboratories
07/07/2023	Albuterol Sulfate Inhalation Aerosol, 90 mcg (200 Metered Inhalation)	Failure to deliver the recommended dose	Cipla
07/31/2023	Tydemy oral contraceptive	Out of Specification Results	Lupin Pharmaceuticals, Inc.

Updated through July 31st, 2023.

Shortages (New)

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

Generic name (Brand Name)	Presentation	Posting Date	Related Information
Liraglutide injection (Saxenda)	3 mL (6 mg/mL) pen	07/18/2023	Limited availability
Lisdexamfetamine dimesylate capsules (Vyvanse)	10 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg, 70 mg capsules	07/14/2023	Temporary delay at contract manufacturing sites
Methotrexate Tablets (Trexall)	2.5 mg, 5 mg, 7.5 mg, 10 mg, 15 mg	07/21/2023	Demand increase
Methylphenidate Hydrochloride Extended Release Tablets (Concerta)	5 mg, 10 mg, 20 mg, 18 mg, 27 mg, 36 mg, 54 mg	07/26/2023	Regulatory delay, increased demand, and manufacturing constraints

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

Updated through July 31st, 2023.

MC-Rx
Powered by ProCare Rx

DRUG INFORMATION CENTER:

1-877-741-7470
druginfo@mc-rx.com

U.S. Corporate Park
1267 Professional Pkwy
Gainesville, GA 30507
(800) 377-1037

Road #1 Km. 33.3 Lot #4
Angora Industrial Park
Bo. Bairoa Caguas, P.R. 00725
(787) 286-6032

urac
ACCREDITED
Pharmacy Benefit Management
Expires 01/01/2025

AUGUST 2023

mc-rx.com