MC-Rx

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Insights on the Drugs Pipeline

Exploring the changes in the drugs market.

September 2024

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.

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Drug pipeline

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Pharmacogenomics: Impact on Medication Costs and Challenges for Managed Care

Pharmacogenomics, the study of how genetic variation impacts the pharmacokinetic and pharmacodynamic properties of an administered drug, has the potential to revolutionize personalized medicine. By tailoring drug therapies based on individual genetic profiles, pharmacogenomics aims to optimize drug efficacy, reduce adverse drug reactions (ADRs), and improve overall patient outcomes. However, the integration of pharmacogenomic testing into clinical practice poses significant challenges, particularly within the framework of Pharmacy Benefit Management (PBM) and its influence on medication costs.

Pharmacogenomics involves testing patients for specific genetic markers that can predict their response to certain medications. For instance, the presence of genetic variants can indicate whether a patient is likely to experience severe side effects from a drug or whether a standard dose will be effective. By using pharmacogenomic data, healthcare providers can select the most appropriate medication and dosage for each individual, thereby enhancing treatment efficacy and safety. Examples of how pharmacogenomic testing could impact treatments are genetic variants in the SLCO1B1 gene which can influence how a patient metabolizes statins, such as simvastatin and atorvastatin. However, patients with certain SLCO1B1 genetic variants are at a higher risk of developing statin-induced myopathy. Incorporating pharmacogenomic testing for the SLCO1B1 gene allows healthcare providers to identify patients at risk for adverse reactions to statins. This enables clinicians to adjust the dosage, choose a different statin, or consider alternative therapies, thereby optimizing treatment efficacy and minimizing the risk of side effects. Another example is the use of clopidogrel, which requires activation by the enzyme CYP2C19. Patients with certain CYP2C19 genetic variants, particularly those who are poor metabolizers, may not effectively convert clopidogrel into its active form, resulting in reduced therapeutic efficacy and an increased risk of cardiovascular events. Pharmacogenomic testing for CYP2C19 can guide clinicians in selecting alternative antiplatelet therapies, such as prasugrel or ticagrelor, which do not require CYP2C19 activation.

Pharmacy Benefit Managers (PBMs) play a critical role in the healthcare system by managing prescription drug benefits on behalf of health insurers, Medicaid and Medicare Part D drug plans, large employers, and other payers. The integration of pharmacogenomic testing presents both opportunities and challenges. On one hand, pharmacogenomics has the potential to improve the precision of drug therapy, reduce waste associated with ineffective treatments, and decrease the incidence of ADRs, which can result in cost savings for both patients and payers. For example, identifying patients who are poor metabolizers of certain drugs can prevent the use of medications that would be ineffective or harmful, thereby avoiding unnecessary healthcare costs associated with ADRs and hospitalizations. On the other hand, the implementation of pharmacogenomic testing poses several challenges. One significant concern is the upfront cost of genetic testing, which can be substantial. Payers must weigh these costs against the potential long-term savings from more personalized therapy. Additionally, there is the issue of integrating genetic data into existing medical record systems, which requires investments in technology and expertise. Furthermore, healthcare provider and managed care organizations must navigate complex ethical

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and privacy concerns related to the use of genetic information, ensuring that patient data is protected while still allowing for the benefits of pharmacogenomics to be realized.

In MC-Rx, we have strategies and drug management tools that incorporate pharmacogenetic testing, in line with the FDA approved indication, particularly in the oncology class. For instance, pembrolizumab is a targeted immunotherapy that requires testing for PD-L1 expression in tumors. Similarly, olaparib used to treat several types of cancer, also requires specific genetic testing before use. These examples demonstrate how MC-Rx integrates genetic testing into its medication approval process, ensuring that treatments like pembrolizumab and olaparib are tailored to the individual genetic profiles of patients, thereby optimizing therapeutic outcomes and minimizing unnecessary treatments. However, incorporating genetic testing into maintenance therapies, such as cholesterol medications and other long-term treatments, remains a challenge. Determining how to effectively integrate genetic insights into these areas will be critical to decide whether and how such testing might be needed in the future.

The costs associated with implementing pharmacogenomic testing, including the price of the tests themselves and the need for specialized healthcare providers to interpret and act on the results, can be significant. To fully understand the economic impact of pharmacogenomics, it is necessary to evaluate if these costs may be offset by the cost-effective, tailored use of medications, preventing the trial-and-error approach often associated with prescribing. By identifying the most suitable drug from the outset, pharmacogenomics can reduce the need for multiple prescriptions and minimize the risk of expensive ADRs, leading to lower overall healthcare costs. However, pharmacogenomic-guided therapies may involve the use of newer, more expensive medications that are not yet widely available in generic form, potentially increasing drug costs for patients and payers.

Pharmacogenomics holds significant promise for transforming personalized medicine, offering the potential to improve drug efficacy, reduce adverse effects, and lower overall healthcare costs. However, the integration of pharmacogenomic testing into managed care is not without challenges. Healthcare providers and payers must evaluate the complexities of cost, technology, and ethics to effectively incorporate pharmacogenomics into their strategies. As the field continues to evolve, it will be important for managed care organizations to develop innovative approaches to manage the costs and benefits of pharmacogenomics, ensuring that patients have access to the most effective and personalized therapies available.

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Specialty Pipeline

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

Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Acoramidis (BridgeBio Pharma)	NDA Filed	11/29/2024	Transthyretin (TTR) stabilizer for the treatment of patients with symptomatic transthyretin amyloidosis (ATTR) cardiomyopathy; oral
afamitresgene autoleucel (afami-cel- Adaptimmune)	BLA Filed	8/4/2024	Autologous genetically modified gene therapy for the treatment of HLA-A*02 eligible and MAGE-A4 positive subjects with metastatic or inoperable (advanced) Synovial Sarcoma; IV infusion (one time).
arimoclomol (Zevra Therapeutics)	NDA Filed	9/21/2024	Molecular chaperone activator that stimulates the normal cellular protein repair pathway for the treatment of Niemann-Pick Disease Type C (NPC); oral
concizumab (Novo Nordisk)	Complete Response	2025	A humanized monoclonal antibody against tissue factor pathway inhibitor (TFPI) for the prevention and treatment of bleeding in patients with haemophilia A and B with inhibitors; subcutaneous therapy.
crinecerfont (Neurocrine -Biosciences)	NDA Filed	12/29/2024	Selective corticotropin-releasing factor type 1 receptor (CRF1) antagonist for the treatment of adult patients with classic congenital adrenal hyperplasia (CAH) due to 21-hydroxylase deficiency (21-OHD); oral solution.
datopotamab deruxtecan (Dato-DXd - AstraZeneca/ Daiichi Sankyo)	BLA Filed	12/20/2024	Anti-Trop2 antibody-drug conjugate for the treatment of patients with advanced or metastatic non-small cell lung cancer (NSCLC); IV infusion.
depemokimab (GSK)	Phase 3	2025	Long-acting IL-5 monoclonal antibody for the treatment of severe eosinophilic asthma; Subcutaneous (SC every 6 months).
eladocagene exuparvovec (Upstaza - PTC Therapeutics)	BLA Filed	11/13/2024	Recombinant, adeno-associated virus, containing the human cDNA encoding the AADC enzyme for the treatment of AADC deficiency; intracerebral infusion.
garadacimab – (CSL Behring)	BLA Filed	H2: 2024	Humanized monoclonal antibody targeting interleukin 13 (IL-13) for the treatment of atopic dermatitis; SC.

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Specialty Pipeline

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

Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
linvoseltamab (Regeneron Pharmaceuticals)	BLA Filed	08/22/2024	BCMAxCD3 bispecific antibody for the treatment of multiple myeloma; IV.
marstacimab (Pfizer)	BLA Filed	Q4: 2024	Anti-tissue factor pathway inhibitor (anti-TFPI) to prevent bleeds in patients with hemophilia A or hemophilia B without inhibitors to Factor VIII (FVIII) or Factor IX (FIX); SC (once weekly).
obecabtagene autoleucel (obe-cel - Autolus Therapeutics)	BLA Filed	11/16/2024	Anti-CD19 CAR-T cell therapy for the treatment of acute lymphoblastic leukemia (ALL); IV.
odronextamab (Regeneron)	Complete Response	2025	CD20xCD3 bispecific antibody for the treatment of relapsed or refractory (R/R) B-cell non-Hodgkin lymphoma (B-NHL); IV infusion.
olezarsen (Ionis Pharmaceuticals)	NDA Filed	12/19/2024	Antisense drug that targets the ApoC-III protein to reduce serum triglycerides for the treatment of familial chylomicronemia syndrome (FCS); SC (weekly).
revumenib (Syndax Pharmaceuticals)	NDA Filed	12/26/2024	Menin inhibitor for the treatment of adult and pediatric patients with relapsed or refractory (R/R) acute leukemia harboring a KMT2A rearrangement (KMT2Ar); oral.
seladelpar (Gilead)	NDA Filed	8/14/2024	Selective peroxisome proliferator-activated receptor delta (PPARδ) agonist under development for the treatment of primary biliary cholangitis; oral.
vanzacaftor/tezacaftor/deutivacaftor (vanza triple; VX-121/VX-661/VX-561 - Vertex)	NDA Filed	1/2/2025	Triple combination for the treatment of patients with cystic fibrosis (CF) heterozygous for F508del and a minimal function mutation (F/MF); oral.
vusolimogene oderparepvec (Replimune)	Phase 2	2025	Oncolytic immunotherapy for the treatment of anti-PD-1 refractory melanoma; intra-tumoral.
zanidatamab (BeiGene/ Jazz Pharmaceuticals)	BLA Filed	11/29/2024	HER2-targeted bispecific antibody in combination with chemotherapy as a therapeutic option for patients with previously treated HER2-amplified biliary tract cancers (BTC); IV infusion.

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Biosimilar Pipeline

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

Product Name/ Investigational Name	Manufacturer(s)	Reference Biological	Possible FDA Approval Date	Potential Launch Date
ustekinumab biosimilar	Fresenius Kabi/ Formycon	Stelara (ustekinumab)	9/2024	4/15/ 2025
ustekinumab biosimilar	Accord BioPharma/ Intas	Stelara (ustekinumab)	11/4/2024	5/15/2025
denosumab biosimilar	Celltrion	Prolia (denosumab)	11/2024	2025
insulin aspart biosimilar	Sandoz/Gan & Lee	Novolog (insulin aspart)	H2:2024	Pending FDA Approval
insulin lispro biosimilar (Prandilin)	Sandoz/Gan & Lee	Humalog (insulin lispro)	H2:2024	Pending FDA Approval
ustekinumab biosimilar	Biocon	Stelara (ustekinumab)	Q4:2024	2/1/2025
ustekinumab biosimilar	Celltrion	Stelara (ustekinumab)	H2:2024	3/7/2025
bevacizumab biosimilar (Equidacent)	Centus	Avastin (bevacizumab)	H2:2024	Pending FDA Approval
aflibercept biosimilar	Amgen	Eylea (aflibercept)	H2:2024	2024-2032
pegfilgrastim biosimilar (Lupifil-P)	Lupin	Neulasta (pegfilgrastim)	2024-2025	Pending FDA Approval
insulin glargine biosimilar (Basalin)	Sandoz/Gan & Lee	Lantus (insulin glargine)	H2:2024	Pending FDA Approval
bevacizumab biosimilar (Aybintio)	Samsung Bioepis/ Organon	Avastin (bevacizumab)	H2:2024	Pending FDA Approval
aflibercept biosimilar	Celltrion	Eylea (aflibercept)	H2:2024	2024-2032
insulin aspart biosimilar	Amphastar	Novolog (insulin aspart)	1/10/2025	Pending FDA Approval
omalizumab biosimilar (Omlyclo)	Celltrion	Xolair (omalizumab)	3/10/2025	Pending FDA Approval
denosumab biosimilar	Fresenius Kabi	Prolia (denosumab)	Q1:2025	Pending FDA Approval
trastuzumab biosimilar	Tanvex BioPharma	Herceptin (trastuzumab)	Q1:2025	Pending FDA Approval

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New Drug Entities

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

New Drug Entities	Details
Pivmecillinam (Pivya)	**Dosage form:** Tablet: 185 mg **Indication:** Penicillin class antibacterial for the treatment of female patients 18 years of age and older with uncomplicated urinary tract infections (uUTI) caused by susceptible isolates of Escherichia coli, Proteous mirabilis and Staphylococcus saprophyticus. **Comparables:** nitrofurantoin monohydrate/macrocrystals, trimethoprim-sulfamethoxazole, fosfomycin, and pivmecillinam. **Guidelines:** • American Urological Association. Recurrent Uncomplicated Urinary Tract Infections in Women: AUA/CUA/SUFU Guideline. (2019) • Infectious Diseases Society of America (IDSFA). International Clinical Practice Guidelines for the Treatment of Acute Uncomplicated Cystitis and Pyelonephritis in Women: A 2010 Update by the Infectious Diseases Society of America and the European Society for Microbiology and Infectious Diseases. (2011)
Trastuzumab-strf (Hercessi) biosimilar* to Herceptin (trastuzumab)	**Dosage form:** 150 mg lyophilized powder in single dose vial for reconstitution **Indication:** HER2/neu receptor antagonist for the treatment of HER2-overexpressing breast cancer and metastatic gastric or gastroesophageal junction adenocarcinoma. **Comparables:** Herceptin, trastuzumab biosimilars **Guidelines:** • American Society of Clinical Oncology. Systemic Therapy for Advanced Human Epidermal Growth Factor Receptor 2–Positive Breast Cancer: ASCO Guideline Update. (2022)
Fidanacogene elaparvovec-dzkt (Beqvez)	**Dosage form:** 1x1013 vg/mL suspension for IV infusion after dilution. **Indication:** Adeno-associated virus vector-based gene therapy for the treatment of adults with moderate to severe 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, and, • Do not have neutralizing antibodies to adeno-associated virus serotype Rh74var (AAVRh74var) capsid as detected by an FDA-approved test **Comparables:** CSL Behring's Hemgenix **Guidelines:** • National Bleeding Disorders Foundation. MASAC Document 284 - MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Selected Disorders of the Coagulation System. (2024)

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New Drug Entities

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

New Drug Entities	Details
Donanemab-azbt (Kisunla)	**Dosage form:** Injection:350 mg/20 mL injection **Indication:** Amyloid beta-directed antibody indicated for the treatment of Alzheimer's disease. Treatment with KISUNLA should be initiated in patients with mild cognitive impairment or mild dementia stage of disease, the population in which treatment was initiated in the clinical trials. **Comparables:** Leqembi (lecanemab-irmb) **Guidelines:** • American Academy of Neurology. Practice Guideline on Mild Cognitive Impairment, Update. (2018, reaffirmed 2021)
Filgrastim-txid (Nypozi) biosimilar* to NEUPOGEN® (filgrastim)	**Dosage form:** Injection: 300 mcg/0.5 mL or 480 mcg/0.8 mL in single-dose prefilled syringe **Indication:** Leukocyte growth factor for the treatment of decreasing the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever; reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of patients with acute myeloid leukemia (AML); reducing the duration of neutropenia and neutropenia-related clinical sequelae, e.g., febrile neutropenia, in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by bone marrow transplantation (BMT); mobilizing autologous hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; reducing the incidence and duration of sequelae of severe neutropenia (e.g., fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia; increasing survival in patients acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome) **Comparables:** filgrastim and biosimilars **Guidelines:** • American Society of Clinical Oncology (ASCO) and Infectious Disease Society of America (IDSA). Clinical practice guideline on outpatient management of fever and neutropenia in adults treated for malignancy, update. (2018)

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New Drug Entities

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

New Drug Entities	Details
Ustekinumab-ttwe (Pyzchiva) biosimilar to STELARA (ustekinumab)	**Dosage form:** Injection: 45 mg/0.5 mL or 90 mg/mL solution in a single-dose prefilled SC syringe; or mg/26 mL (5 mg/mL) solution in a single-dose vial for IV infusion. **Indication:** For the treatment of adults and pediatric patients 6 years of age and older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy; for the treatment of adults and pediatric patients 6 years of age and older with active psoriatic arthritis; the treatment of adult patients with moderately to severely active Crohn's disease; for the treatment of adult patients with moderately to severely active ulcerative colitis. **Comparables:** Ustekinumab and biosimilars **Guidelines:** • 2020 AGA American Gastroenterological Association Clinical Practice Guidelines on the Management of Moderate-to-Severe Ulcerative Colitis. • 2018 ACG American College of Gastroenterology Clinical Guideline: Management of Crohn's Disease in Adults. • 2021 AGA Clinical Practice Guidelines on the Medical Management of Moderate to Severe Luminal and Perianal Fistulizing Crohn’s Disease • 2021 Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with topical therapy and alternative medicine modalities for psoriasis severity measures • 2021 Joint AAD-NPF Guidelines of care for the management of psoriasis with systemic non-biological therapies • 2021 Joint AAD-NPF Guidelines of care for the management and treatment of psoriasis with biologics

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New Drug Formulations

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

New Drug Formulations	Details
Immune globulin intravenous, human-dira (Yimmugo)	New Dosage form: Intravenous injection: 100 mg/mL IgG sugar-free, ready-to-use solution Indication: For the treatment of primary humoral immunodeficiency in patients 2 years of age or older. Comparables: None Guidelines: • Immune Deficiency Foundation. Diagnostic & Clinical Care Guidelines for Primary Immunodeficiency Diseases. (2015)
Aflibercept-jbvf (Yesafili) biosimilar to EYLEA (aflibercept) Aflibercept-yszy (Opuviz) biosimilar to EYLEA (aflibercept) Aflibercept-mrbb (Ahzantive) biosimilar to EYLEA® (aflibercept)	New Dosage form: Injection: 2 mg solution in single-dose vial for intravitreal use Indication: Vascular endothelial growth factor (VEGF) inhibitor for the treatment of patients with: • Neovascular (Wet) Age-Related Macular Degeneration (AMD) • Macular Edema Following Retinal Vein Occlusion (RVO) • Diabetic Macular Edema (DME) • Diabetic Retinopathy (DR) Comparables: Eylea (aflibercept) Guidelines: • American Academy of Ophthalmology. Age-Related Macular Degeneration Preferred Practice Pattern®. (2020)
Clonidine hydrochloride (Onyda XR)	New Dosage form: Extended-release oral suspension: 0.1 mg/mL Indication: Centrally acting alpha2-adrenergic agonist for the treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) as monotherapy or as adjunctive therapy to central nervous system (CNS) stimulant medications in pediatric patients 6 years of age and older Comparables: Kapvay® (clonidine) extended-release tablets Guidelines: • American Academy of Pediatrics. Clinical Practice Guideline for the Diagnosis, Evaluation, and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. (2019)
Eculizumab-aeeb (Bkemv) biosimilar to SOLIRIS® (eculizumab)	New Dosage form: Indication: Complement inhibitor indicated for the treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis and the treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy. Comparables: Soliris® (eculizumab) Guidelines: • 2021 Consensus statement for diagnosis and treatment of paroxysmal nocturnal haemoglobinuria.
Thiotepa (Tepylute)	New Dosage form: Injection: 15 mg/1.5mL (10 mg/mL) in single-dose vial Indication: Alkylating drug indicated for treatment of adenocarcinoma of the breast or ovary. Comparables: Generic thiotepa Guidelines: • National Comprehensive Cancer Network (NCCN). Brest Cancer Version 4. (2024)
Tadalafil (Chewtadzy)	New Dosage form: Chewable tablets: 5 mg, 10 mg, 20 mg Indication: Phosphodiesterase 5 (PDE5) inhibitor for the treatment of erectile dysfunction (ED), the signs and symptoms of benign prostatic hyperplasia (BPH) and ED, and the signs and symptoms of BPH (ED/BPH). Comparables: tadalafil Guidelines: • American Urological Association (AUA): Guidelines for the management of benign prostatic hyperplasia/lower urinary tract symptoms. (2021)

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New Indications

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New Indications	Details
Iloperidone (Fanapt)	For the treatment of acute manic or mixed episodes associated with bipolar I disorder in adults.
Dolutegravir and lamivudine (Dovato)	New Patient Population: a two-drug combination of dolutegravir (integrase strand transfer inhibitor [INSTI]) and lamivudine (nucleoside analogue reverse transcriptase inhibitor [NRTI]) for the treatment of HIV1 infection in adults and adolescents 12 years of age and older and weighing at least 25 kg with no antiretroviral treatment history, or to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable antiretroviral regimen with no history of treatment failure and no known substitutions associated with resistance to the individual components of DOVATO.
Fam-trastuzumab deruxtecan-nxki (Enhertu)	For the treatment of adult patients with unresectable or metastatic HER2-positive (IHC 3+) solid tumors who have received prior systemic treatment and have no satisfactory alternative treatment options. (These indications are approved under accelerated approval)
Vedolizumab (Entyvio)	For the treatment of adults with moderately to severely active Crohn's disease.
Alectinib (Alecensa)	For the treatment of adult patients following tumor resection of anaplastic lymphoma kinase (ALK)-positive non-small cell lung cancer (NSCLC) (tumors ≥ 4 cm or node positive) as an adjuvant, as detected by an FDA-approved test.
Lutetium Lu 177 dotatate (Lutathera)	New Patient Population: For the treatment of pediatric patients 12 years and older with somatostatin receptor (SSTR)-positive gastroenteropancreatic neuroendocrine tumors (GEP-NETs), including foregut, midgut, and hindgut neuroendocrine tumors. Lutetium Lu 177 dotatate received approval for this indication for adults in 2018.
Idecabtagene vicleucel (Abecma)	For the treatment of adult patients with relapsed or refractory multiple myeloma after two or more prior lines of therapy including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody.
Ciltacabtagene autoleucel (Carvykti)	To extend the indication based on the results of the CARTITUDE-4 clinical trial (NCT04181827) for treatment in lenalidomide-refractory participants, following 1 to 3 prior lines of therapy for multiple myeloma. This supplemental application also provides for a modification to the approved Risk Evaluation and Mitigation Strategy (REMS).
Lipid injectable emulsion (Clinolipid)	New Patient Population is indicated in adults and pediatric patients, including term and preterm neonates, as a source of calories and essential fatty acids for parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated.

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New Indications

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New Indications	Details
Apremilast (Otezla)	For treatment of pediatric patients 6 to 17 years of age and weighing at least 20 kg with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy.
Tisotumab vedotin-tftv (Tivdak)	For recurrent or metastatic cervical cancer with disease progression on or after chemotherapy. Tisotumab vedotin-tftv previously received accelerated approval for this indication.
Lisocabtagene maraleucel (Breyanzi)	Accelerated approval: For the treatment of adults with relapsed or refractory follicular lymphoma (FL) who have received two or more prior lines of systemic therapy.
Belimumab (Benlysta)	Expands the use of Benlysta for SC administration via the autoinjector for the treatment of pediatric patients 5 years and older with active systemic lupus erythematosus (SLE) who are receiving standard therapy.
Lisocabtagene maraleucel (Breyanzi)	For the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) who have received at least two prior lines of systemic therapy, including a Bruton tyrosine kinase inhibitor (BTKi).
Lacosamide (Motpoly XR)	New Dosing Regimen: for the treatment of primary generalized tonic-clonic seizures in adults and in pediatric patients weighing at least 50 kg.
Sarilumab (Kevzara)	Use in active polyarticular juvenile idiopathic arthritis (pJIA) in patients 63 kg or greater.
Dapagliflozin (Farxiga)	New Patient Population: for the expansion of the approved indication as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus to include pediatric patients aged 10 years and older.
Dapagliflozin and metformin hydrochloride extended-release (Xigduo XR)	New Patient Population: for the expansion of the approved indication as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus to include pediatric patients aged 10 years and older.
Selpercatinib (Retevmo)	For conversion of Retevmo from accelerated approval to full approval. For the treatment of adult and pediatric patients 2 years of age and older with advanced or metastatic thyroid cancer with a RET gene fusion, as detected by an FDA approved test, who require systemic therapy and who are radioactive iodine-refractory (if radioactive iodine is appropriate).
Repotrectinib (Augtyro)	For the treatment of adult and pediatric patients 12 years of age and older with solid tumors that: have a neurotrophic tyrosine receptor kinase (NTRK) gene fusion, are locally advanced or metastatic or where surgical resection is likely to result in severe morbidity and have progressed following treatment or have no satisfactory alternative therapy.

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New Indications

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New Indications	Details
Tapentadol (Nucynta)	To obtain pediatric information on Nucynta (tapentadol) from birth (i.e., neonates) to less than 17 years of age for the management of moderate to severe acute pain. Related labeling changes were previously incorporated in the approval letter for sNDA-024 dated July 3, 2023.
Blinatumomab (Blincyto)	For the treatment of CD19-positive Philadelphia chromosome-negative B-cell precursor acute lymphoblastic leukemia (ALL) in the consolidation phase of multiphase chemotherapy in adult and pediatric patients one month and older.
Durvalumab (Imfinzi)	For the use of Imfinzi in combination with carboplatin and paclitaxel followed by Imfinzi as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial cancer that is mismatch repair deficient (dMMR).
Pembrolizumab (Keytruda)	In combination with carboplatin and paclitaxel, followed by KEYTRUDA as a single agent, for the treatment of adult patients with primary advanced or recurrent endometrial carcinoma.
Skyrizi (risankizumab-rzaa) injection.	For the addition of an indication for the treatment of moderately to severely active ulcerative colitis in adults.
Bedaquiline (Sirturo)	For conversion of Sirturo from accelerated approval to full approval. Combination therapy for the treatment of adult and pediatric patients (5 years and older and weighing at least 15 kg) with pulmonary tuberculosis (TB) due to Mycobacterium tuberculosis resistant to at least rifampin and isoniazid.
Pitolisant (Wakix)	New Patient Population: for the treatment of excessive daytime sleepiness in patients 6 years of age and older with narcolepsy.
Adagrasib (Krazati)	Colorectal cancer (CRC) In combination with cetuximab, for the treatment of adult patients with KRAS G12C-mutated locally advanced or metastatic CRC, as determined by an FDA-approved test, who have received prior treatment with fluoropyrimidine-, xaliplatin-, and irinotecan-based chemotherapy. And add as a single agent for Non-small cell lung cancer (NSCLC).
Epcoritamab-bysp (Epkinly)	Provides for a new indication: for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL) after two or more lines of systemic therapy.
Velphoro (sucroferric oxyhydroxide)	New Patient Population: For the control of serum phosphorus levels in adult and pediatric patients 9 years of age and older with chronic kidney disease on dialysis.

Last Updated August 15, 2024.

New Indications

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

New Indications	Details
IncobotulinumtoxinA (Xeomin)	This Prior Approval supplemental biologics license application provides for the temporary improvement of the appearance of upper facial lines in adults: • moderate to severe glabellar lines associated with corrugator and/or procerus muscle activity • moderate to severe horizontal forehead lines associated with frontalis muscle activity • moderate to severe lateral canthal lines associated with orbicularis oculi muscle activity.
Delandistrogene moxeparvovec-rokl (Elevidys)	To expand the approved indication to individuals at least 4 years of age for the treatment of Duchenne muscular dystrophy (DMD) in patients who are ambulatory and have a confirmed mutation in the DMD gene.

Last Updated August 15, 2024.

In-Market Brand

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In-Market-Brands	Details
Alpelisib (Vijoice)	**New Dosage form:** Oral Granules: 50 mg **Indication:** Kinase inhibitor indicated for the treatment of adult and pediatric patients 2 years of age and older with severe manifestations of PIK3CA related Overgrowth Spectrum (PROS) who require systemic therapy. **Comparables:** Piqray **Guidelines:** • A standard of care for individuals with PIK3CA-related disorders: An international expert consensus statement. (2022)
Crovalimab-akkz (Piasky)	**Dosage form:** Injection: 340 mg/2mL (170 mg/mL) **Indication:** Complement C5 inhibitor for the treatment of adult and pediatric patients 13 years and older with paroxysmal nocturnal hemoglobinuria (PNH) and body weight of at least 40 kg. **Comparables:** Soliris (eculizumab), Ultomiris (ravulizumab-cwvz), Empaveli (pegcetacoplam), Fabhalta (iptacopan) **Guidelines:** • Paroxysmal Nocturia Hemoglobinuria (PNH). (2022)
Deutetrabenazine extended-release (Austedo XR)	**New Dosage form:** Tablet: 30 mg, 36 mg, 42 mg, 48 mg **Indication:** Vesicular monoamine transporter 2 (VMAT2) inhibitors for the treatment of Chorea associated with Huntington's disease and Tardive dyskinesia in adults. **Comparables:** Valbenazine tosylate (Ingrezza) **Guidelines:** • Frontiers in Neurology. International Guidelines for the Treatment of Huntington's Disease. (2019) • American Academy of Neurology. Evidence-based guideline: Treatment of tardive syndromes. (2013)
Diazepam (Libervant)	**New Dosage form:** Buccal film: 5 mg, 7.5 mg, 10 mg, 12.5 mg, 15 mg **Indication:** Benzodiazepine indicated for the acute treatment of intermittent, stereotypic episodes of frequent seizure activity (i.e., seizure clusters, acute repetitive seizures) that are distinct from a patient's usual seizure pattern in patients with epilepsy 2 to 5 years of age. **Comparables:** diazepam, Diastat, Valium, Valtoco **Guidelines:** • American Epilepsy Society. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new-onset epilepsy. (2018) • American Epilepsy Society. Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs II: Treatment of new-onset epilepsy. (2018)

Last Updated August 15, 2024.

In-Market Brand

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In-Market-Brands	Details
Elafibranor (Iqirvo)	**Dosage form:** Tablet: 80 mg **Indication:** Peroxisome proliferator-activated receptor (PPAR) agonist indicated for the treatment of primary biliary cholangitis (PBC) in combination with ursodeoxycholic acid (UDCA) in adults who have an inadequate response to UDCA, or as monotherapy in patients unable to tolerate UDCA. **Comparables:** Ocaliva (obeticholic acid **Guidelines:** • American Association for the Study of Liver Diseases. Primary biliary cholangitis: 2021 practice guidance update from the American Association for the Study of Liver Diseases.
Imetelstat (Rytelo)	**Dosage form:** 47 mg or 188 mg powder for reconstitution and IV infusion **Indication:** For the treatment of adult patients with low-to-intermediate-1 risk myelodysplastic syndromes (LR-MDS) with transfusion-dependent anemia requiring four or more red blood cell units over eight weeks who have not responded to, have lost response to, or are ineligible for erythropoiesis-stimulating agents (ESAs). **Comparables:** Reblozyl (luspatercept) **Guidelines:** • Cancer Management and Research. Clinical Management of Anemia in Patients with Myelodysplastic Syndromes: An Update on Emerging Therapeutic Options. (2021) • National Comprehensive Cancer Network (NCCN). Myelodysplastic syndrome Version 2. (2024)
Mavorixafor (Xolremdi)	**Dosage form:** Capsules: 100 mg **Indication:** CXC chemokine receptor-4 antagonist for the treatment of WHIM syndrome (warts, hypogammaglobulinemia, infections and myelokathexis) in patients 12 years of age and older to increase the number of circulating mature neutrophils and lymphocytes. **Comparables:** None. **Guidelines:** • National Organization for Rare Disorders (NORD). WHIM Syndrome. (2024) • National Library of Medicine. WHIM Syndrome: from Pathogenesis towards Personalized Medicine and Cure. (2019)

Last Updated August 15, 2024.

In-Market Brand

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

In-Market-Brands	Details
Mycophenolate mofetil (Myhibbin)	**New Dosage form:** Ready-to-use oral suspension: 200 mg/mL **Indication:** Antimetabolite immunosuppressant for the prophylaxis of organ rejection in adult and pediatric recipients 3 months of age and older of allogeneic kidney, heart or liver transplants, in combination with other immunosuppressants. **Comparables:** Mycophenolate, CellCept, Myfortic **Guidelines:** • American College of Clinical Pharmacy. Consensus recommendations for use of maintenance immunosuppression in solid organ transplantation: Endorsed by the American College of Clinical Pharmacy, American Society of Transplantation, and the International Society for Heart and Lung Transplantation. (2022) • Long-term management of the successful adult liver transplant: 2012 practice guideline by the American Association for the Study of Liver Diseases and the American Society of Transplantation.
Tarlatamab-dlle (Imdelltra)	**Dosage form:** Injection: 1 mg or 10 mg of lyophilized powder in single-dose vial for reconstitution and further dilution. **Indication:** Bispecific delta-like ligand 3 (DLL3)-directed CD3 T cell engager indicated for the treatment of adult patients with extensive-stage small cell lung cancer (ES-SCLC) with disease progression on or after platinum-based chemotherapy. **Comparables:** Tototecan and Zepzelca (lurbinectedin) **Guidelines:** • National Comprehensive Cancer Network (NCCN). Small Cell Lung Cancer Version 2. (2024)
Selpercatinib (Retevmo)	**New Dosage form:** Tablets: 40 mg, 80 mg, 120 mg, 160 mg **Indication:** For the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) with a rearranged during transfection (RET) gene fusion, as detected by an FDA-approved test in adult patients; treatment on adult and pediatric patients 2 years of age and older with advanced or metastatic medullary thyroid cancer (MTC) with a RET mutation, as detected by an FDA-approved test; treatment of adult and pediatric patients 2 years of age and older with advanced or metastatic thyroid cancer with a RET gene fusion, as detected by an FDA-approved test; and treatment of adult and pediatric patients 2 years of age and older with locally advanced or metastatic solid tumors with a RET gene fusion, as detected by an FDA-approved test, that have progressed on or following prior systemic treatment or who have no satisfactory alternative treatment options. **Comparables:** None **Guidelines:** • National Comprehensive Cancer Network (NCCN). Non-Small Cell Lung Cancer. (2024)

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In-Market Brand

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In-Market-Brands	Details
Sofpironium (Sofdra)	**Dosage form:** Topical gel: 12.45% **Indication:** Anticholinergic for the treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older. **Comparables:** None **Guidelines:** • National Institute for Health and Care Excellence (NICE): Interventional procedures guidance on transcutaneous microwave ablation for severe primary axillary hyperhidrosis. (2017) • NICE: Interventional procedures guidance on endoscopic thoracic sympathectomy for primary hyperhidrosis of the upper limb. (2014)
Valbenazine tosylate (Ingrezza Sprinkle)	**New Dosage form:** Sprinkle Capsule: 40 mg, 60 mg, 80 mg **Indication:** Vesicular monoamine transporter 2 (VMAT2) inhibitors indicated for the treatment of adults with: tardive dyskinesia, chorea associated with Huntington's disease **Comparables:** Xenazine (tetrabenazine), Austedo, Austedo XR (deutetrabenazine) **Guidelines:** • Frontiers in Neurology. International Guidelines for the Treatment of Huntington's Disease. (2019) • American Academy of Neurology. Evidence-based guideline: Treatment of tardive syndromes. (2013)
Vigabatrin (Vigafyde)	**New Dosage form:** Oral Solution: 100 mg/mL ready-to-use oral solution/concentrated formulation **Indication:** Monotherapy for the treatment of infantile spasms in pediatric patients 1 month to 2 years of age for whom the potential benefits outweigh the potential risk of vision loss. **Comparables:** generic vigabatrin, Sabril, Vigadrone, Vigpoder **Guidelines:** • American Academy of Neurology. Evidence-based guideline update: Medical treatment of infantile spasms. (2012)

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New Generics

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

Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indications
Phentermine and Topiramate Extended-release Capsules	Actavis Laboratories FL, Inc.	Qsymia (Phentermine and Topiramate) Extended-release Capsule	6/25/2024	For the treatment of chronic weight management in certain adult and pediatric patients as an adjunct to a reduced-calorie diet and increased physical activity.
Avanafil Tablets	Hetero Labs Limited Unit V	Stendra (Avanafil) Tablets	6/14/2024	For the treatment of erectile dysfunction.
Palbociclib Tablets	Synthon Pharmaceuticals, Inc	Ibrance (Palbociclib) Tablets	6/2/2024	For the treatment of adult patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic breast cancer in combination with an aromatase inhibitor as initial endocrine-based therapy or fulvestrant in patients with disease progression following endocrine therapy.
Timolol Maleate Ophthalmic Gel Forming Solution	Amneal EU, Limited	Timolol Maleate Ophthalmic Gel Forming Solution	5/23/2024	For the treatment of elevated intraocular pressure in patients with ocular hypertension or open-angle glaucoma.
Lanreotide Injection	InvaGen Pharmaceuticals, Inc.	Somatuline Depot (Lanreotide) Injection	5/21/2024	For the long-term treatment of acromegalic patients who have had an inadequate response to or cannot be treated with surgery and/or radiotherapy; for the treatment of adult patients with unresectable, well- or moderately differentiated, locally advanced or metastatic gastroenteropancreatic neuroendocrine tumors to improve progression-free survival; for the treatment of adults with carcinoid syndrome.

Last Updated August 15, 2024.

Recall Notifications

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

Date	Drug Name	Reason for Recall	Company Name
07/17/2024	Clonazepam Orally Disintegrating Tablets, USP (C-IV) 0.25 mg tablets	Mislabeled with the incorrect strength on the carton	Endo USA, Inc
06/26/2024	Potassium Chloride Extended Release 750 mg Capsules, 100 count and 500 count	Failed dissolution	American Health Packaging
06/25/2024	Potassium Chloride Extended Release 75 0mg Capsules, 100 count and 500 count	Failed dissolution	Glenmark Pharmaceuticals, Inc.

Last Updated August 15, 2024.

Safety Notifications

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

As of August 28, 2024, the FDA has not issued any new safety notifications.

Last Updated August 15, 2024.

Shortages (New)

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

Generic Name (Brand Name)	Presentation	Posting Date	Related Information
Bromocriptine Mesylate Tablet	Tablet: 2.5 mg	8/8/2024	None available
Memantine Hydrochloride (Namenda XR)	Capsule, Extended Release: 7 mg, 14 mg, 21 mg, 28 mg	8/7/2024	Distributed by Allergan, Inc.
Glipizide XL (Glucotrol XL)	Tablet, Extended Release: 5 mg	8/5/2024	Supply expected to exhaust mid-September 2024; discontinuation of the manufacture of the drug
Bisoprolol Fumarate; Hydrochlorothiazide (Ziac)	Tablet: 2.5 mg, 5 mg, 10 mg; 6.25 mg	7/26/2024	None available
Posaconazole (Noxafil)	Tablet, Delayed Release: 100 mg	7/22/2024	None available
Betaxolol Hydrochloride (Beptopic)	Ophthalmic Suspension: 2.8 mg/1 mL	7/2/2024	Novartis has made a business decision to permanently discontinue betaxolol hydrochloride ophthalmic suspension, 0.25% as base. Discontinuation of the product is not due to manufacturing, product quality, safety, or efficacy concerns.
Triazolam (Halcion)	Tablet: .25 mg	6/27/2024	None available
Fluconazole (Diflucan)	Tablet: 100 mg	6/14/2024	Discontinuation of the manufacture of the drug.
Estradiol Valerate (Delestrogen)	Delestrogen, Injection: 40 mg/1 mL	6/4/2024	None available
Azithromycin (Zithromax)	For Suspension: 1 g, 200 mg/5 mL, 900 mg/22.5 mL, 1200 mg/30 mL	5/17/2024	Discontinuation of the manufacture of the drug.

Last Updated August 15, 2024.

Shortages (New)

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

References:

- FDA Approved Drugs. Food and Drug Administration (FDA). Retrieved from https://www.access.fda.gov/
- FDA: Drug Shortages. https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages
- FDA: First Generic Drug Approvals. https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals
- FDA: Recalls, Market Withdrawals, & Safety Alerts. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts

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