MC-Rx
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Insights on the Drugs Pipeline

EXPLORING THE CHANGES IN THE DRUGS MARKET.

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Insights on the Drugs Pipeline Q1 2026

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01

Overview

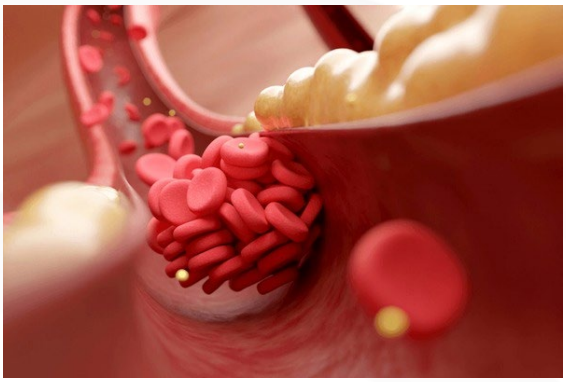
MC-Rx is dedicated to improved drug therapy vigilance, continuity of care, patient safety and effective formulary management. This edition is developed by our clinical team, which is comprised of registered clinical pharma- cists, to provide you with continuous evaluation and insights of the drugs market 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

02 Hot Topic

Major Updates in the 2026 ACC/AHA Guideline on the Management of Dyslipidemia



The 2026 ACC/AHA guideline of the management of dyslipidemia replaces the 2018 blood cholesterol guideline and reflects an important shift toward preventive and earlier treatment, more personalized risk assessment, broader use of lipid biomarkers, and clearer low-density lipoprotein cholesterol (LDL-C) target goals. The new guideline shifts away from the mainly statin treatment approach and toward a more comprehensive model, aiming to reduce lifetime exposure to atherogenic lipoproteins and better match therapy intensity to individual cardiovascular risk.

One of the most significant changes is the adoption of PREVENT equations in place of older Pooled Cohort Equations for primary prevention risk assessment in adults age 30 to 79 years old. The new guideline categorizes 10-year Atherosclerotic Cardiovascular Disease (ASCVD) risk as low (<3%), borderline (3% to <5%), intermediate (5% to <10%), and high (≥10%), and recommends using a "CRPR" model: calculate risk, personalize risk, and reclassify or reassess risk with coronary artery calcium (CAC) when appropriate. This is a major difference from the previous guideline since it introduces a more individualized approach for deciding when to initiate lipid-lowering therapy (LLT).

The 2026 guideline also supports earlier pharmacologic intervention, including even some patients with lower short-term risk. In adults age 30 to 59 years with low 10-year ear risk but LDL-C values of 160-189 mg/dL or a 30-year ASCVD risk ≥10%, starting moderate intensity statin therapy is now considered reasonable.

This change reflects a life course prevention model: rather than waiting short-term risk becomes elevated, the new guideline emphasizes reducing cumulative exposure to atherogenic lipoproteins over time. The expected outcome of such change is earlier atherosclerosis prevention and, ultimately, fewer cardiovascular events later in life.

Another major difference is the return of explicit LDL-C and non-HDL-C treatment goals. The previous guideline emphasized percentage LDL reduction and statin intensity. The 2026 guideline brings back specific numeric goals to guide treatment intensification. For example, in primary prevention, adults at borderline or intermediate risk who start statins may be treated to LDL-C <100 mg/dL and non-HDL-C <130 mg/dL values, while high risk primary prevention patients may be treated to LDL-C <70 mg/dL and non-HDL-C <100 mg/dL. In secondary prevention, patients at very high risk now have a recommended goal of LDL-C <55 mg/dL and non-HDL-C <85 mg/dL. Newly defined targets are expected to improve clinical decision making by reducing therapeutic inertia, as well as encouraging timely addition of non-statin therapies when statins alone seem to be insufficient.

02 Hot Topic (cont'd)

The role of non-statin therapy is also broaden in the updated guideline. Compared with the 2018 guideline, the 2026 version clearly incorporates PCSK9 monoclonal antibodies, bempedoic acid, and, in selected settings, inclisiran. This is especially relevant for patients with severe and/or familial hypercholesterolemia, as well as patients with established ASCVD who do not meet treatment goals on maximally tolerated statins. Including bempedoic acid as an evidence-based option reflects newer outcome data supporting cardiovascular benefit in statin-intolerant or high risk patients. From this approach, a broader access to individualized LDL-lowering strategies and better attainment of lipid targets in patients who remain undertreated is expected.

The stronger incorporation of Apolipoprotein B (ApoB) and lipoprotein(a) [Lp(a)] into routine care is particularly important. It is now recommended in the 2026 guideline that the Lp(a) should be measured at least once in all adults for ASCVD risk assessment. It also states that ApoB measurement is reasonable in patients on LTL, especially those with ASCVD, diabetes, elevated triglycerides, or cardiometabolic disease, to guide further treatment intensification. These changes recognize that the standard lipid panel may underestimate residual atherogenic risk in some patients. This approach is expected to improve hidden risk identification, better risk stratification, and more appropriate intensification of therapy.

While CAC was already useful in the 2018 guideline when the decision to start a statin was uncertain, the new guideline strongly recommends CAC for risk stratification in intermediate risk and select borderline risk adults and adds more detailed management pathways based on CAC burden. For example, if CAC is 0, therapy may be deferred in select patients with repeat CAC in 3 to 7 years; if CAC is >0, especially ≥100 Agatston units or ≥75th percentile, LLT is recommended. This change is expected to improve precision in treatment decisions by avoiding unnecessary therapy pharmacotherapy in truly low risk individuals while identifying subclinical atherosclerosis earlier in patients whose risk may be underestimated.

Other important updates include broader recognition of risk enhancers and special populations. The new guideline highlights reproductive risk markers such as early menopause and adverse pregnancy outcomes, recommends LTL in adults aged 40 to 75 years with diabetes, stage 3 or 4 Chronic Kidney Disease, or HIV regardless of LDL-C level, and discourages the use of dietary supplements for LDL-C or triglyceride lowering due to limited and inconsistent benefit. These changes are expected to promote more equitable, evidence-based prevention by identifying groups whose cardiovascular risk may have been underappreciated.

Overall, the 2026 ACC/AHA dyslipidemia guideline represents a more proactive prevention strategy than the 2018 guideline. Created changes are expected to produce earlier detection of risk, more personalized treatment, improved goal attainment, and ultimately lower rates of ASCVD events across both primary and secondary prevention strategies.

References:

2026 ACC/AHA/AACVPR/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Dyslipidemia: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines
https://doi.org/10.1161/CIR.0000000000001423

03 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?
Atacicept (Atacicept-EMD Serono (Merck KGaA), ZymoGenetics, Vera Therapeutics)	BLA Filed	7/7/2026	B-cell modulator targeting both B-cell activating factor and a proliferation-inducing ligand for the treatment of adults with IgA Nephropathy; subcutaneous injection
Belzutifan (Welireg-Merck & Co (MSD), Peloton Therapeutics)	NDA Filed	10/4/2026	Adjuvant treatment of adult patients with clear cell renal cell carcinoma (ccRCC) at increased risk of recurrence following nephrectomy; oral
Brepocitinib (Pfizer, Roivant, Priovant Therapeutics)	NDA Filed	2026	A dual Janus kinase (JAK) and Tyrosine kinase inhibitor formulation for the treatment of dermatomyositis; oral and topical formulations
Bulevirtide (Hepcludex-Gilead; MYR Pharmaceuticals)	BLA Filed	2026	Antiviral developed as a first-in-class, targeted treatment for chronic Hepatitis Delta Virus (HDV) infection in adult with compensated liver disease; subcutaneous injection
Cefepime; Zidebactam (Zaynich- Wockhardt)	NDA Filed	2026	Cephalosporin and Beta-Lactam inhibitor antimicrobial combination for the treatment of complicated urinary tract infections, including peylonephritis, with or without current bacteremia; intravenous
Centanafadine (Otsuka)	NDA Filed	7/24/2026	Triple monoamine reuptake inhibitor for the treatment of attention deficit hyperactivity disorder (ADHD) in children, adolescents, and adults; oral
Deramiocel (Deramiocel- Nippon Shinyaku, Capricor Therapeutics)	BLA Filed	6/2/2026	Antibody-drug conjugate of Anti-HER2 antibody and Topoisomerase I inhibitor for treatment of adult patients with unresectable or metastatic triple-negative breast cancer (TNBC) who are not candidates for PD-1/PD-L1 inhibitor therapy; intravenous

03 Specialty Pipeline (cont'd)

Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Deramiocel (Deramiocel- Nippon Shinyaku, Capricor Therapeutics)	BLA Filed	8/22/2026	Stromal cell therapy for the treatment of cardiomyopathy associated with Duchenne muscular dystrophy; intravenous
Efgartigimod Alfa (Vyvgart- Argenx)	BLA Filed	5/10/2016	FcRn antagonist for the treatment of adults with acetylcholine receptor antibody seronegative generalized myasthenia gravis (gMG); intravenous
Fam-Trastuzumab Deruxtecan (Enhertu- AstraZeneca, Daiichi Sankyo)	BLA Filed	5/18/2026	Antibody-drug conjugate of Anti-HER2 antibody and Topoisomerase I inhibitor for neoadjuvant treatment of high-risk HER2-positive (IHC3+ or ISH+) Stage II or Stage III breast cancer prior to surgery; intravenous
Garetosmab (Regeneron)	BLA Filed	8/1/2026	Activin A inhibitor for the treatment of Fibrodysplasia ossificans progressiva (FOP); intravenous
Gedatolisib (Gedatolisib- Pfizer, Celcuity)	NDA Filed	7/17/2026	Phosphoinositide 3-kinase (PI3K) inhibitor and mTOR kinase inhibitor for the treatment of adult patients with hormone receptor-positive (HR+), human epidermal growth factor receptor 2-negative (HER2-), PIK3CA wild-type, locally advanced or metastatic breast cancer; intravenous
Lecanemab (Leqembi- Eisai, Biogen, BioArctic Neuroscience)	BLA Filed	8/31/2026	Amyloid beta protein inhibitor for initial dose in treatment of early Alzheimer's disease, specifically for patients with mild cognitive impairment or mild dementia stage; subcutaneous injection
Marnetegragene Autotemcel (Kresladi- Rocket Pharma)	BLA Filed	3/28/2026	Gene therapy for the treatment of severe Leukocyte Adhesion Deficiency-I (LAD-I) immune disorder; intravenous
Molgramostim (Molbreevi- PARI, Savara, Fujifilm)	BLA Filed	8/22/2026	Colony stimulating factor for the treatment of autoimmune pulmonary alveolar proteinosis (aPAP); inhalation

03 Specialty Pipeline (cont'd)

Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Nivolumab (Opdivo- Bristol-Myers Squibb Ono Pharmaceutical)	BLA Filed	4/8/2026	Programmed cell death 1 (PD-1) inhibitor for the previously untreated Stage III or IV classical Hodgkin lymphoma in combination with AVD chemotherapy (doxorubicin, vinblastine, and dacarbazine) in adult and pediatric patients 12 years and older; intravenous
Olezarsen Sodium (Tryngolza- Ionis Pharmaceuticals, Akcea)	NDA Filed	6/30/2026	Apolipoprotein inhibitor for the treatment of severe hypertriglyceridemia; subcutaneous injection
Rusfertide (Takeda, Protagonist Therapeutics)	NDA Filed	2026	First-in-class hepcidin mimetic peptide for the treatment of adults with polycythemia vera; subcutaneous injection
Setmelanotide Acetate (Imcivree- Rhythm Pharmaceuticals)	BLA Filed	2026	Melanocorticoid receptor agonist for treatment of acquired hypothalamic obesity in patients 4 years and older; subcutaneous injection
Sonrotoclax (Sonrotoclax- BeiGene, BeOne Medicines)	NDA Filed	2026	BCL-2 inhibitor for the treatment of adult patients with relapsed or refractory mantle cell lymphoma who have previously received a Btuton tyrosine kinase (BTK) inhibitor; oral
Tebipenem Pivoxil Hydrobromide (GSK, Meiji Seika, Spero Therapeutics)	NDA Filed	6/18/2026	Carbapenem antimicrobial agent for the treatment of complicated urinary tract infections, including pyelonephritis; oral
Teplizumab (Tzield- Sanofi, Prevention Bio)	BLA Filed	4/29/2026	Anti-CD3 antibody for delaying the onset of stage III type 1 diabetes in patients 1 year and older; intravenous

03 Specialty Pipeline (cont'd)

Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Tividenofusp Alfa (Denali Therapeutics)	BLA Filed	4/5/2026	Enzyme replacement therapy (human iduronate-2-sulfatase) for the treatment of Hunter Syndrome (Mucopolysaccharidosis Type II or MPS II); intravenous
Vusolimogene Oderparepvec (Replimune)	BLA Filed	4/10/2026	Oncolytic immunotherapy for the treatment of advanced melanoma in patients who have progressed on an anti-PD-1 containing regimen

04 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
Bevacizumab	Henlius, AstraZeneca, Fujifilm Kyowa Kirin, Centus Biotherapeutics	Avastin	Q4: 2026
Aflibercept	Sam Chun Dang Pharm, Fresenius Kabi	Eylea	10/2026
Trastuzumab	Tanvex	Herceptin	06/2026
Insulin Lispro	Prandilin-Sandoz, Gan & Lee	Humalog	Pending Approval Date
Insulin Glargine	Basalin- Sandoz, Gan & Lee	Lantus	Pending Approval Date
Ranibizumab	Lupin	Lucentis	06/2026
Pegfilgrastim	Lapelga- Apotex, Accord, Intas	Neulasta	Pending Approval Date
Insulin Aspart	Amphastar, Rapilin-Sandoz, Gan & Lee	Novolog	Pending Approval Date

04 Biosimilar Pipeline (cont'd)

Product Name / Investigational Name	Manufacturer(s)	Reference Biological	Possible FDA approval date
Abatacept	Dr. Reddy's Laboratories	Orencia	12/2026
Pertuzumab	Biocon	Perjeta	Q4: 2026
Denosumab	Osqay-Alken Labs, Ascend, Enzene	Prolia	Q2: 2026
Golimumab	Accord, Intas, Bio-Thera Solutions	Simponi	5/16/2026
Denosumab	Alken Labs, Ascend, Enzene	Xgeva	Q2: 2026
Omalizumab	Amneal, Kashiv Biosciences	Xolair	Q4: 2026

05 New Drug Entities

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

New Drug Entities	Details
Etuvetidigene autotemcel (Waskyra)	Dosage Form: Infusion bag- 2–11.4 x 10^6 cells /mL (1.9–11.4 x 10^6 CD34+ cells/mL) Indication: Autologous hematopoietic stem cell-based gene therapy for the treatment of pediatric patients 6 months and older and adults with Wiskott-Aldrich Syndrome (WAS) who have a mutation in the WAS gene for whom hematopoietic stem cell transplantation (HSCT) is appropriate and no suitable human leukocyte antigen (HLA)-matched related stem cell donor is available. Comparables: None. Guidelines: Wiskott - Aldrich syndrome. Merck Manual 2024. James Fernandez. https://www.merckmanuals.com/professional/immunology-allergic-disorders/immunodeficiency-disorders/wiskott-aldrich-syndrome
Onasemnogene abeparvovec-brve (Itvisma)	Dosage Form: Intrathecal injection- 1.2×10^{14} vector genomes (vg) Indication: Adeno-associated virus (AAV) vector-based gene therapy indicated for the treatment of spinal muscular atrophy (SMA) in adult and pediatric patients 2 years of age and older with a confirmed mutation in the SMN1 gene. Comparables: Spinraza (nusinersen), Zolgensma (onasemnogene abeparvovec-xioi), Evrysdi (risdiplam) Guidelines: Spinal Muscular Atrophy Update in Best Practices: Recommendations for Diagnosis Considerations, DOI: https://doi.org/10.1212/cpj.0000000000200310
Zoliflodacin (Nuzolvence)	Dosage Form: Packet for oral suspension- 3g per packet Indication: Spiropyrimidinetrione bacterial type II topoisomerase inhibitor for the treatment of uncomplicated urogenital gonorrhea due to Neisseria gonorrhoeae in adults and pediatric patients 12 years of age and older. Comparables: Gepotidacin Guidelines: Sexually Transmitted Infections Treatment Guidelines, 2021 (CDC), https://www.cdc.gov/std/treatment-guidelines/gonorrhea-adults.htm

06 New Drug Formulations

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

New Drug Formulations	Details
Bimatoprost (Zolymbus)	New Dosage Form: Ophthalmic gel- 0.01% Indication: Prostaglandin analog indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. Comparables: Bimatoprost (Lumigan), Latanoprost (Xalatan), Travoprost (Travatan Z) Guidelines: Glaucoma: Diagnosis and Management; Am Fam Physician. 2023;107(3):253-262
Clotrimazole (Clotic)	New Dosage Form: Otic solution- 1% Indication: Azole antifungal indicated for the treatment of fungal otitis externa (otomycosis) due to Aspergillus species and Candida species in patients 18 years of age and older. Comparables: Clotrimazole Topical Solution (1%), Ketoconazole Topical Solution (2%) Guidelines: Fungal Ear Infection (Octomycosis): Symptoms & Treatment, Cleveland Clinic, https://my.clevelandclinic.org/health/diseases/25009-fungal-ear-infection
Lidocaine (Bondlido)	New Dosage Form: Rectangular topical system- 10% Indication: Amide local anesthetic, and is indicated in adults for relief of pain associated with post-herpetic neuralgia (PHN). Comparables: Lidocaine Patch 5% (Lidoderm), Lidocaine Topical Patch 1.8% (Ztlido) Guidelines: Herpes Zoster and Postherpetic Neuralgia: Prevention and Management; Am Fam Physician. 2017;96(10):656-663, https://www.aafp.org/pubs/afp/issues/2017/1115/p656.html

07 New Indications

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

New Indications	Details
Adalimumab-aaty (Yuflyma), Adalimumab-adaz (Hyrimoz), Adalimumab-adbm (Cyltezo), Adalimumab-atto (Amjevita), Adalimumab-ryvk (Simlandi), Adalimumab-aacf (Idacio)	For the expansion of the indication: of treatment uvietis (UV) in pediatric patients 2 years of age and older and hidradenitis suppurativa (HS) in adolescent patients 12 years of age and older.
Atezolizumab (Tecentriq)	For addition of the indication: in combination with lurbinectedin, for the maintenance treatment of adult patients with ES-SCLC whose disease has not progressed after first-line induction therapy with TECENTRIQ
Bempedoic acid (Nexletol)	For addition of the indication: reducing risk of major adverse cardiovascular events (cardiovascular death, myocardial infarction, stroke, or coronary revascularization) in adults at increased risk for these events who are unable to take recommended statin therapy (including those not taking a statin).
Bempedoic acid and ezetimibe (Nexlizet)	For addition of the indication: reducing risk of major adverse cardiovascular events (cardiovascular death, myocardial infarction, stroke, or coronary revascularization) in adults at increased risk for these events who are unable to take recommended statin therapy (including those not taking a statin).
Cariprazine (Vraylar)	For the expansion of the treatment population: inclusion of pediatric patients 13 to 17 years of age for the treatment of schizophrenia, inclusion of pediatric patients 10 to 17 years of age for the acute treatment of manic or mixed episodes associated with bipolar I disorder, and addition of the results from studies with autism spectrum disorder (ASD) patients to the prescribing information.
Cemiplimab-rwlc (Libtayo)	For addition of the indication: for the adjuvant treatment of patients with cutaneous squamous cell carcinoma (CSCC) at high risk of recurrence after surgery and radiation.

07 New Indications (cont'd)

New Indications	Details
Daratumumab and hyaluronidasefvihj (Darzalex Faspro)	For addition of the indication: for the treatment of adult patients with high-risk smoldering multiple myeloma as monotherapy.
Durvalumab (Imfinzi)	For addition of the indication: as neoadjuvant and adjuvant treatment, in combination with fluorouracil, leucovorin, oxaliplatin and docetaxel (FLOT), followed by single-agent for the treatment of adult patients with resectable gastric or gastroesophageal junction adenocarcinoma (GC/GEJC).
Enfortumab vedotin (Padcev)	For addition of the indication: as neoadjuvant treatment, in combination with pembrolizumab, and then continued after cystectomy as adjuvant treatment for the treatment of adult patients with muscle invasive bladder cancer who are ineligible for cisplatin-containing chemotherapy.
Epcoritamab-bysp (Epkinly)	For addition of the indication: in combination with lenalidomide and rituximab for the treatment of adult patients with relapsed or refractory follicular lymphoma (FL), as well as monotherapy for the treatment of adult patients with relapsed or refractory FL after two or more lines of systemic therapy.
Fam trastuzumab deruxtecan-nxki (Enhertu)	For addition of the indication: in combination with pertuzumab for the first-line treatment of adult patients with unresectable or metastatic HER2-positive (IHC 3+ or ISH+) breast cancer as determined by an FDA-approved test.
Ferric maltol (Accrufer)	For the expansion of the treatment population: iron replacement product indicated for the treatment of iron deficiency in adult and pediatric patients 10 years of age and older.
Gepotidacin (Blujepa)	For addition of the indication: adult and pediatric patients 12 years of age and older weighing at least 45 kilograms (kg) who have limited or no alternative options for the treatment of uncomplicated urogenital gonorrhea caused by susceptible strains of Neisseria gonorrhoeae.
Golimumab (Simponi)	For the expansion of the treatment population now including pediatric patients weighing at least 15kg for the indication: for treatment of severely active ulcerative colitis (UC0.
Linaclotide (Linzess)	For the expansion of the treatment population: for treatment of irritable bowel syndrome with constipation (IBS-C) in adults and pediatric patients 7 years of age and older, as well as for functional constipation (FC) in pediatric patients 6 years of age and older.

07 New Indications (cont'd)

New Indications	Details
Lumateperone (Caplyta)	For addition of the indication: adjunctive therapy to antidepressants for treatment of major depressive disorder (MDD).
Lurbinectedin (Zepzelca)	For addition of the indication: in combination with atezolizumab or atezolizumab and hyaluronidase-tqjs, for the maintenance treatment of adult patients with extensive-stage small cell lung cancer in whose disease has not progressed after first-line induction therapy with atezolizumab or atezolizumab and hyaluronidase-tqjs, carboplatin, and etoposide.
Niraparib/abiraterone acetate fixed-dose combination (Akeega)	For addition of the indication: with prednisone for adults with deleterious or suspected deleterious BRCA2-mutated metastatic castration-sensitive prostate cancer.
Nivolumab and hyaluronidase-nvhy (Opdivo Qvantig)	For the expansion of the treatment population: for current indication of treatment melanoma and unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer indications in product labeling to allow for use in pediatric patients 12 years of age and older. For addition of the indication: as monotherapy for the treatment of adult patients with unresectable or metastatic microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) colorectal cancer (CRC) following treatment with intravenous nivolumab and ipilimumab combination therapy.
Pembrolizumab (Keytruda)	For addition of the indication: in combination with enfortumab vedotin, as neoadjuvant treatment, and then continued after cystectomy as adjuvant treatment for the treatment of adult patients with muscle invasive bladder cancer who are ineligible for cisplatin containing chemotherapy.
Pirtobrutinib (Jaypirca)	For addition of the indication: for the treatment of adult patients with relapsed or refractory CLL/SLL who have previously been treated with a covalent BTK inhibitor
Rucaparib (Rubraca)	For the expansion of the treatment population: the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy.
Tezepelumab-ekko (Tezspire)	For addition of the indication: for the add on maintenance treatment of adult and pediatric patients aged 12 years and older with inadequately controlled chronic rhinosinusitis with nasal polyps (CRSwNP).

07 New Indications (cont'd)

New Indications	Details
Tirzepatide (Mounjaro)	For the expansion of the treatment population: as an adjunct to diet and exercise to improve glycemic control in adults and pediatric patients 10 years of age.
Tofacitinib (Xeljanz)	For addition of the indication: for the treatment of active Psoriatic Arthritis (PsA) in patients 2 years of age and older who have had an inadequate response or intolerance to one or more tumor necrosis factor (TNF) blockers.

08 In-Market Brand

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

In-Market Brands	Details
Aficamten (Myqorzo)	Dosage Form: Film coated tablets- 5mg, 10mg, 15mg, 20mg Indication: Cardiac myosin inhibitor indicated for the treatment of adults with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) to improve functional capacity and symptoms. Comparables: Mavacamten (Camzyos) Guidelines: 2024 AHA|ACC|AMSSM|HRS|PACES|SCMR Guideline for the Management of Hypertrophic Cardiomyopathy: A Report of the American Heart Association/American College of Cardiology Joint Committee on Clinical Practice Guidelines, DOI: https://doi.org/10.1161/CIR.0000000000001250
Amivantamab and hyaluronidase-lpuj (Rybrevant Faspro)	New Dosage Form: Injection- 160mg and 2,000 units per mL in each vial Indication: For adults with locally advanced or metastatic non–small cell lung cancer (NSCLC) harboring specific EGFR mutations. It is used in combination regimens as first-line therapy or after progression (depending on mutation type), and also as monotherapy for EGFR exon 20 insertion–mutated disease that has progressed following platinum-based chemotherapy. Comparables: Amivantamab-vmjw (Rybrevant), Nivolumab (Opdivo), Nivolumab + hyaluronidase (Opdivo Qvantig) Guidelines: NCCN Clinical Practice Guidelines in Oncology (Non–Small Cell Lung Cancer) Version 5 2026.
Belantamab mafodotin-blmf (Blenrep)	New Dosage Form: Injection vial- 100mg Indication: B-cell maturation antigen (BCMA)-directed antibody and microtubule inhibitor conjugate indicated for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least 4 prior therapies including an anti-CD38 monoclonal antibody, a proteasome inhibitor, and an immunomodulatory agent. Comparables: Teclistamab (Tecvayli), Elranatamab (Elrexfio) Guidelines: Treatment of Multiple Myeloma: ASCO–Ontario Health (Cancer Care Ontario) Living Guideline, Journal of Clinical Oncology, DOI: https://doi.org/10.1200/JCO-25-02587

08 In-Market Brand (cont'd)

In-Market Brands	Details
Berotralstat (Orladeyo)	New Dosage Form: Oral pellets- 72mg, 96mg, 108mg, 132mg Indication: Plasma kallikrein inhibitor indicated for prophylaxis to prevent attacks of hereditary angioedema (HAE) in pediatric patients 2 years to less than 12 years of age. Comparables: Berotralstat (Orladeyo) capsules, Lanadelumab (Takhzyro) Guidelines: Treatment of Hereditary Angioedema, AAAAI, March 2026; https://www.aaaai.org/tools-for-the-public/drug-guide/immunomodulator-medications
Bumetanide (Enbumyst)	New Dosage Form: Nasal spray- 0.5mg/0.1mL Indication: For the treatment of edema associated with congestive heart failure, hepatic and renal disease, including nephrotic syndrome in adults. Comparables: Bumetanide (Bumex), Furosemide (Lasix) Guidelines: 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines; DOI: https://doi.org/10.1161/CIR.0000000000001063
Clonidine hydrochloride (Javadin)	New Dosage Form: Oral solution- 0.02mg/mL Indication: Central alpha-2 adrenergic agonist, indicated for the treatment of hypertension in adult patients to lower blood pressure. Comparables: Clonidine (Catapres) tablets Guidelines: 2025 AHA/ACC/AANP/AAPA/ABC/ACCP/ACPM/AGS/AMA/ASPC/NMA/PCNA/SGIM Guideline for the Prevention, Detection, Evaluation, and Management of High Blood Pressure in Adults; DOI: https://doi.org/10.1161/HYP.0000000000000249
Depemokimab-ulaa (Exdensur)	Dosage Form: Injection vial/prefilled syringe- 100mg/mL Indication: Interleukin 5 (IL-5) antagonist for add-on maintenance treatment of severe asthma characterized by an eosinophilic phenotype in adult and pediatric patients aged 12 years and older Comparables: Nucala (mepolizumab) Guidelines: 2025 Gina strategy report - global initiative for asthma. GINA. https://ginasthma.org/2025-gina-strategy-report/

08 In-Market Brand (cont'd)

In-Market Brands	Details
Doxecitine and doxribtimine (Kygevvi)	Dosage Form: Powder for oral solution- 2g/2g Indication: Pyrimidine nucleoside combination for the treatment of thymidine kinase 2 deficiency (TK2d) in adults and pediatric patients with a symptom onset on or before 12 years old. Comparables: None Guidelines: The National Organization for Rare Disorders (NORD). Available at https://rarediseases.org/rare-diseases/thymidine-kinase-2-deficiency/.
Elinzanetant (Lynkuet)	Dosage Form: Capsules- 60mg Indication: Neurokinin 1 (NK1) and neurokinin 3 (NK3) receptor antagonist for the treatment of moderate to severe vasomotor symptoms due to menopause. Comparables: Fezolinetant (Veozah) Guidelines: The 2023 nonhormone therapy position statement of The North American Menopause Society: The Journal of The Menopause Society (2023); DOI: 10.1097/GME.0000000000002200
Etripamil (Cardamyst)	Dosage Form: Nasal spray- 70mg per device Indication: Calcium channel blocker indicated for the conversion of acute symptomatic episodes of paroxysmal supraventricular tachycardia (PSVT) to sinus rhythm in adults. Comparables: Verapamil HCl Injection Guidelines: Contemporary Management of Paroxysmal Supraventricular Tachycardia (AHA|ASA Journals), https://doi.org/10.1161/01.CIR.0000059743.36226.E8
Fosfomycin (Contepo)	New Dosage Form: Indication: Epoxide antibacterial indicated for the treatment of patients 18 years of age and older with complicated urinary tract infections (cUTI) including acute pyelonephritis caused by susceptible isolates of Escherichia coli and Klebsiella pneumoniae. Comparables: Fosfomycin trometamol (Monurol) Guidelines: IDSA 2025 Guideline Update on Complicated Urinary Tract Infections, https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/

08 In-Market Brand (cont'd)

In-Market Brands	Details
Furosemide (Lasix ONYU)	New Dosage Form: Injection- 80mg/2.67mL Indication: Loop diuretic indicated for the treatment of edema in adult patients with chronic heart failure. Comparables: Furosemide (Lasix) tablets, Furosemide (Furoscix), Bumetanide (Bumex) Guidelines: 2022 AHA/ACC/HFSA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines; DOI: https://doi.org/10.1161/CIR.0000000000001063
Imlunestrant (Inluriyo)	Dosage Form: Tablets- 200mg Indication: Estrogen receptor antagonist indicated for treatment of adults with ER-positive, HER2-negative, ESR1-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy. Comparables: Orserdu (Elacestrant), Guidelines: National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology – Breast Cancer (Version 5.2025). Available at https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf
Immune globulin human-kthm (Qivigy)	Dosage Form: Intravenous vial- 5g/50mL, 10g/100mL Indication: Human immune globulin for treatment of adults with primary humoral immunodeficiency Comparables: Hizentra (Immune Globulin Subcutaneous), Gammagard Liquid ERC (Immune globulin intravenous) Guidelines: Primary immunodeficiency (PI). Mayo Clinic. https://www.mayoclinic.org/diseases-conditions/primary-immunodeficiency/diagnosis-treatment/drc-20376910.
Lamotrigine (Subvenite)	New Dosage Form: Oral suspension- 10mg/mL Indication: Anticonvulsant indicated for adjunctive or conversion to monotherapy treatment of partial and generalized seizures in patients aged 2 years and older, as well as for maintenance treatment of bipolar disorder to help delay the recurrence of depressive, manic, or mixed mood episodes. Comparables: Lamotrigine (Lamictal) Guidelines: Practice guideline update summary: Efficacy and tolerability of the new antiepileptic drugs I: Treatment of new-onset epilepsy, AES; DOI: https://doi.org/10.5698/1535-7597.18.4.260 The CANMAT and ISBD Guidelines for the Treatment of Bipolar Disorder: Summary and a 2023 Update of Evidence; DOI: https://doi.org/10.1176/appi.focus.20230009

08 In-Market Brand (cont'd)

In-Market Brands	Details
Lerodalcibep-liga (Lerochol)	Dosage Form: Injection pre-filled syringe- 300mg/1.2mL (250mg/mL) Indication: Proprotein convertase subtilisin kexin type 9 (PCSK9) inhibitor indicated as an adjunct to diet and exercise: to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH). Comparables: Alirocumab (Praluent), Evolocumab (Repatha), Inclisiran (Leqvio) Guidelines: 2026 ACC/AHA/AACVPR/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Dyslipidemia: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines, DOI: https://doi.org/10.1161/CIR.0000000000001423
Leuprolide mesylate (Camcevi ETM)	New Dosage Form: Injectable emulsion- 42mg Indication: Gonadotropin-releasing hormone (GnRH) agonist indicated for the treatment of adult patients with advanced prostate cancer. Comparables: Leuprolide (Eligard), Leuprolide (Lupron Depot) Guidelines: Updates to advanced prostate cancer: AUA/SUO guideline (2023). Lowrance W, Dreicer R, Jarrard DF, J Urol. 2023;209(6):1082-1090.
Midazolam Autoinjector	New Dosage Form: Single-dose pre-filled autoinjector- 10mg/0.7mL Indication: Benzodiazepine indicated for the treatment of status epilepticus in adults. Comparables: Diazepam injection Guidelines: Guidance for: The acute management of status epilepticus in adult patients, J Intensive Care Soc. 2025 May 8;26(2):249–262. doi: 10.1177/17511437251321338
Mitapivat (Aqvesme)	New Dosage Form: Tablets- 100mg Indication: Pyruvate kinase activator indicated for the treatment of anemia in adults with alpha- or beta-thalassemia. Comparables: Luspatercept-ammt (Reblozyl), Betibeglogene autotemcel (Zynteglo) Guidelines: The thalassemias and related disorders, Proc (Bayl Univ Med Cent). 2007 Jan;20(1):27–31. doi: 10.1080/08998280.2007.11928230

08 In-Market Brand (cont'd)

In-Market Brands	Details
Nerandomilast (Jascayd)	Dosage Form: Tablets- 9mg, 18mg Indication: Phosphodiesterase 4 (PDE4) inhibitor for the treatment of idiopathic pulmonary fibrosis in adult patients and the treatment of progressive pulmonary fibrosis in adult patients. Comparables: Nintedanib (Ofev), Pirfenidone (Esbriet) Guidelines: Idiopathic Pulmonary Fibrosis and Progressive Pulmonary Fibrosis in Adults: An Official ATS/ERS/JRS/ALAT Clinical Practice Guideline May 1, 2022.
Paltusotine (Palsonify)	Dosage Form: Tablets- 20mg, 30mg Indication: Somatostatin receptor agonist indicated for the treatment of adults with acromegaly who had an inadequate response to surgery or those on who surgery is not an option. Comparables: Sandostatin LAR (octreotide acetate), Somatuline DEPOT (lanreotide) Guidelines: Acromegaly: An Endocrine Society Clinical Practice Guideline: The Journal of Clinical Endocrinology & Metabolism (2014); DOI: https://doi.org/10.1210/jc.2014-2700, Multidisciplinary management of acromegaly: A consensus: Rev Endocr Metab Disord (2020); DOI: https://doi.org/10.1007/s11154-020-09588-z
Pembrolizumab and berahyaluronidase alfa-pmph (Keytruda QLEX)	New Dosage Form: Subcutaneous injection vial- 395mg and 4,800U in 2.4mL, 790mg and 9,600U in 4.8mL Indication: Programmed death-1 (PD-1) receptor blocking monoclonal antibody for the treatment of multiple cancers, including melanoma, non–small cell lung cancer, head and neck squamous cell carcinoma, renal cell carcinoma, and others. It is indicated either as monotherapy or in combination with chemotherapy or targeted agents in patients whose tumors meet specific criteria (e.g., PD-L1 expression or other biomarkers). Comparables: Keytruda (Pembrolizumab) intravenous injection Guidelines: NCCN Clinical Practice Guidelines in Oncology (NSCLC) Version 5 2026, NCCN Clinical Practice Guidelines in Oncology (Melanoma) Version 1 2026, NCCN Clinical Practice Guidelines in Oncology (Head & Neck Cancers) Version 1 2026, NCCN Clinical Practice Guidelines in Oncology (Renal Cell Carcinoma) Version 1 2026.
Plozasiran (Redemplo)	Dosage Form: Injection pre-filled syringe- 25mg/0.5mL Indication: Apolipoprotein C-III (apoC-III)-directed small interfering ribonucleic acid (siRNA) indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS). Comparables: Volanesorsen (Waylivra), Olezarsen (Tryngolza) Guidelines: Familial chylomicronemia syndrome: An expert clinical review from the National Lipid Association, https://www.lipidjournal.com/article/S1933-2874(25)00066-2/fulltext

08 In-Market Brand (cont'd)

In-Market Brands	Details
Remibrutinib (Rhapsido)	Dosage Form: Tablets- 25mg Indication: Kinase inhibitor for the treatment of chronic spontaneous urticaria (CSU) for patients remaining symptomatic despite H1 antihistamine treatment. Comparables: Xolair (Omalizumab), Dupixent (Dupilumab) Guidelines: 1. The diagnosis and management of acute and chronic urticaria: 2014 update. The Journal of allergy and clinical immunology, 133(5), 1270–1277. DOI: https://doi.org/10.1016/j.jaci.2014.02.036.
Semaglutide (Wegovy)	New Dosage Form: Tablets- 1.5mg, 4mg, 9mg, 25mg Indication: indicated in combination with a reduced calorie diet and increased physical activity to reduce the risk of major adverse CV events (CV death, non-fatal myocardial infarction, or non-fatal stroke) in adults with established CV disease and either obesity or overweight, as well as to reduce excess body weight and maintain weight reduction long term in adults with obesity, or in adults with overweight in the presence of at least one weight-related comorbid condition. Comparables: Semaglutide injection (Wegovy) Guidelines: Obesity and Weight Management for the Prevention and Treatment of Diabetes: Standards of Care in Diabetes–2026, ADA, DOI: https://doi.org/10.2337/dc26-S008
Sevabertinib (Hyrnuo)	Dosage Form: Tablets- 10mg Indication: Kinase inhibitor for the treatment of adult patients with locally advanced or metastatic non-squamous non-small cell lung cancer (NSCLC) whose tumors have HER2 (ERBB2) tyrosine kinase domain (TKD) activating mutations and who have received a prior systemic therapy Comparables: Trastuzumab deruxtecan (Enhertu), Zongertinib (Hernexeos) Guidelines: Non-Small Cell Lung Cancer Treatment (PDQ®)–Health Professional Version (NIH), https://www.cancer.gov/types/lung/hp/non-small-cell-lung-treatment-pdq
Sibeprenlimab-szsi (Voyxact)	Dosage Form: Prefilled injection syringe- 400mg/2mL (200mg/mL) Indication: Proliferation Inducing Ligand (APRIL) blocker, indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression. Comparables: Tarpeyo (Budenoside) Guidelines: KDIGO 2025 Clinical Practice Guideline for Management of Immunoglobulin ANephropathy (IgAN). https://kdigo.org/wp-content/uploads/2024/08/KDIGO-2025-IgAN-IgAV-Guideline.pdf

08 In-Market Brand (cont'd)

In-Market Brands	Details
Sildenafil (Vybrique)	New Dosage Form: Oral film- 25mg, 50mg, 75mg, 100mg Indication: Phosphodiesterase-5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction (ED). Comparables: Sildenafil (Viagra) Guidelines: Erectile Dysfunction: AUA Guideline (2018), Burnett AL, Nehra A, Breau RH; 200: 633.
Tradipitant (Nereus)	Dosage Form: Capsules- 85mg Indication: Substance P/neurokinin-1 (NK-1) receptor antagonist indicated for the prevention of vomiting induced by motion in adults. Comparables: Similar Drugs: Transderm Scop (Scopolamine transdermal system), Meclizine (Antivert) Guidelines: Motion Sickness Treatment. CDC Yellow Book. https://www.cdc.gov/yellow-book/hcp/travel-air-sea/motion-sickness.html
Trofinetide (Daybue Stix)	New Dosage Form: Oral solution powder- 5,000mg, 6,000mg, 8,000mg Indication: For the treatment of Rett syndrome in adults and pediatric patients 2 years of age and older. Comparables: Trofinetide (Daybue) oral solution Guidelines: Rett Syndrome Treatment & Management; Bernstein, B. E., (Medscape); https://emedicine.medscape.com/article/916377-treatment?form=fpf
Ziftomenib (Komzifti)	Dosage Form: Capsules- 200mg Indication: Menin inhibitor for treatment of adult patients with relapsed or refractory acute myeloid leukemia (AML) with a susceptible nucleophosmin 1 (NPM1) mutation. Comparables: Revumenib (Revuforj) Guidelines: American Society of Hematology 2025 guidelines for treating newly diagnosed acute myeloid leukemia in older adults, https://doi.org/10.1182/bloodadvances.2025017934

08 In-Market Brand (cont'd)

In-Market Brands	Details
Inavolisib (ITOVEBI)	**Dosage form:** Tablets: 3 mg and 9 mg. **Indication:** Is a kinase inhibitor indicated in combination with palbociclib and fulvestrant for the treatment of adults with endocrine-resistant, PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, as detected by an FDA-approved test, following recurrence on or after completing adjuvant endocrine therapy. **Comparables:** none **Guidelines:** Invasive breast cancer. National Comprehensive Cancer Network (NCCN)(Version 6.2024)
Levacetylleucine (Aqneursa)	**Dosage form:** For oral suspension: 1 gram L-Acetylleucine in a unit-dose packet. **Indication:** Is indicated for the treatment of neurological manifestations of Niemann-Pick disease type C (NPC) in adults and pediatric patients weighting > 15 kg. **Comparables:** Miplyffa **Guidelines:** Geberhiwot T, Moro A, Dardis A, et al. Consensus clinical management guidelines for Niemann-Pick disease type C. Orphanet Journal of Rare Diseases. 2018;13(1). doi:10.1186/s13023- 018-0785-7
Xanomeline and trospium chloride (Cobenfy)	**Dosage form:** Capsules (xanomeline/trospium chloride): 50 mg/20 mg, 100 mg/20 mg, 125 mg/30 mg. **Indication:** Is a combination of xanomeline, a muscarinic agonist, and trospium chloride, a muscarinic antagonist, indicated for the treatment of schizophrenia in adults. **Comparables:** none **Guidelines:** APA Releases New Practice Guideline on Treatment of Patients with Schizophrenia. https://www.psychiatry.org/news-room/news-releases/apa-releases-new-practice-guideline-on-treatment-o
Vyloy (zolbetuximab- czlf)	**Dosage form:** For injection: 100 mg lyophilized powder in a single-dose vial. **Indication: I**s a claudin 18.2-directed cytolytic antibody and is indicated in combination with fluoropyrimidine- and platinum-containing chemotherapy for the first-line treatment of adults with locally advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)- negative gastric or gastroesophageal junction adenocarcinoma whose tumors are claudin (CLDN) 18.2 positive as determined by an FDA-approved test. **Comparables:** None. **Guidelines:** Esophageal and Esophagogastric JunctionCancers. National Comprehensive Cancer Network (NCCN) (Version 4.2024)

09 New Generics

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

Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indications
Amphetamine (ODT)	Actavis	Adzenys XR-ODT	12/8/2025	For the treatment of Attention Deficit Hyperactive Disorder (ADHD) in patients 6 years and older
Everolimus (oral suspension tablets)	Biocon	Afinitor Disperz	1/15/2026	For the treatment of several advanced cancers, including hormone receptor–positive, HER2-negative breast cancer (in combination with exemestane after prior therapy failure), pancreatic neuroendocrine tumors, and renal cell carcinoma after certain treatments have failed. It is also indicated for patients with tuberous sclerosis complex (TSC), including those with renal angiomyolipoma or subependymal giant cell astrocytoma (SEGA) that cannot be surgically removed
Ticagrelor (tablets)	Sunshine Lake Pharma	Brilinta	2/9/2026	For risk reduction of cardiovascular death, myocardial infarction, and stroke in patients with history of acute coronary syndrome or heart attack
Brivaracetam (injection, oral solution, tablet)	Hainan Poly Pharm, Alkem Labs, Indoco Remedies, Lupin, MSN Laboratories, Zhejiang Poly Pharm, Apotex, Aurobindo	Briviact	2/23/2026	For the treatment of partial-onset seizures in patients 1 month of age and older
Roflumilast (tablets)	Senores	Daliresp	1/20/2026	For risk reduction of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and history of exacerbations
Dalbavancin Hydrochloride (injection)	Kindos Pharmaceuticals	Dalvance	12/1/2025	For the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible strains of Gram-positive microorganisms, including MRSA

09 New Generics (cont'd)

Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indications
Dexlanzoprazole (capsules)	Alembic	Dexilant	1/14/2026	For treatment and maintenance of erosive esophagitis and to relieve heartburn associated with both erosive and non-erosive gastroesophageal reflux disease
Fidaxomicin (tablets)	Apotex, Torrent	Dificid	1/29/2026	For the treatment of C. difficile-associated diarrhea in adult and pediatric patients 6 months and older
Deflazacort (oral suspension, tablet)	Sun Pharmaceutical, Zydus, Amneal	Emflaza	12/12/2025	For the treatment of Duchenne muscular dystrophy (DMD) in patients 5 years and older
Deferiprone (tablets)	Senores	Ferriprox	12/11/2025	For treatment of transfusional iron overload in adult and pediatric patients (8 years ≥) with hematologic disorders such as thalassemia, sickle cell disease and other anemias
Teriparatide (injection)	Amphastar	Forteo	12/16/2025	For the treatment of osteoporosis in postmenopausal women, men with primary or hypogonadal osteoporosis, and both men and women with glucocorticoid induced osteoporosis
Perampanel (oral suspension)	MSN Laboratories	Fycompa	12/15/2025	For treatment of partial-onset seizures with or without secondarily generalized seizure as adjunctive therapy in patients with epilepsy aged 12 years and older

09 New Generics (cont'd)

Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indications
Eribulin Mesylate (injection)	Dr. Reddy's Laboratories	Halaven	1/14/2026	For the treatment of metastatic breast cancer in patients who had previously received at least two chemotherapeutic regimens
Sapropterin Dihydrochloride (powder)	TP ANDA Holding	Kuvan	12/10/2025	For the reduction of blood phenylalanine (Phe) levels in patients with tetrahydrobiopterin-(BH4-) responsive phenylketonuria ages 1 month and older
Tapentadol Hydrochloride (tablets)	Roxane (AG), West-Ward (AG)	Nucynta, Nucynta ER	2/25/2026	For the treatment of moderate to severe acute pain in patients 18 years or older
Pomalidomide (capsules)	Apotex, Breckenridge, Eugia Pharma, Hetero, Teva	Pomalyst	2/28/2026	For the treatment of multiple myeloma who have received at least two prior therapies (including lenalomide and bortezomib) and have demonstrated disease progression on or within 60 days of completion of therapy
Eltrombopag Olamine (tablets)	Amneal, MSN Laboratories, Somerset Therapeutics, Zydus	Promacta	1/15/2026	For treatment of thrombocytopenia in patients with chronic immune thrombocytopenia purpura with demonstrated insufficient response to corticosteroids, immunoglobulins, or splenectomy
Sirolimus (oral solution)	Rising Pharmaceuticals	Rapamune	12/18/2025	For the prevention of organ rejection in patients receiving a renal transplant ages 13 and older

09 New Generics (cont'd)

Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indications
Lenalidomide (capsules)	Accord, Amneal, Deva Holdings, Novugen, Qilu Pharmaceutical	Revlimid	1/27/2026	For the treatment of adult patients with multiple myeloma, in combination with dexamethasone or as maintenance following autologous stem cell transplantation, as well as those with transfusion-dependent anemia due to certain myelodysplastic syndromes. It is also indicated for patients with relapsed or refractory mantle cell lymphoma and for previously treated follicular or marginal zone lymphoma in combination with a rituximab product
Liraglutide Recombinant (injection)	Orbicular	Saxenda	2/11/2026	For chronic weight management in adults and adolescents 12 years and older with obesity o overweight, alongside lifestyle modifications
Dasatinib (tablet)	Lupin	Sprycel	12/12/2025	For the treatment of adults and children (age ≥1) with Philadelphia chromosome-positive chronic myeloid leukemia (various phases) or acute lymphoblastic leukemia, including newly diagnosed cases and those resistant or intolerant to prior therapies, sometimes in combination with chemotherapy adults and children (age ≥1) with Philadelphia chromosome-positive chronic myeloid leukemia (various phases) or acute lymphoblastic leukemia, including newly diagnosed cases and those resistant or intolerant to prior therapies, sometimes in combination with chemotherapy
Nilotinib Hydrochloride (tablets)	Torrent	Tasigna	1/5/2026	For the treatment of adult patients with Philadelphia chromosome–positive chronic myeloid leukemia (Ph+ CML) in chronic phase, including newly diagnosed patients, and for those with chronic or accelerated phase disease who are resistant to or intolerant of prior therapy such as imatinib

09 New Generics (cont'd)

Generic Name	ANDA Applicant	Brand Name	ANDA Approval Date	ANDA Indications
Ceftaroline Fosamil (Injection)	Apotex	Teflaro	2/11/2026	For the treatment of acute bacterial skin and skin structure infections (ABSSSI) and community-acquired bacterial pneumonia (CABP)
Sodium Oxybate (oral solution)	Ascent	Xyrem	1/9/2026	For the treatment of cataplexy or excessive daytime sleepiness in patients with narcolepsy 7 years and older

10 Recall Notifications

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

Date	Drug Name	Reason for Recall	Company Name
11/24/2025	FreeStyle Libre® 3 and FreeStyle Libre 3 Plus Sensord	Internal testing determined that some sensors may provide incorrect low glucose readings.	Abbot
3/12/2026	Omnipod 5 Pods	Company stated Pods from certain lots may have a small tear in the internal tubing that delivers insulin, increasing risk of insulin leakage inside the Pod and interfering with proper insulin infusion to the patient.	Insulet

11 Safety Notifications

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

FDA reviewed the available data regarding a potential risk of suicidal ideation and behavior with glucagon-like peptide-1 receptor agonists used for weight reduction, specifically Saxenda, Wegovy, and Zepbound. After a comprehensive review, including 91 placebo controlled clinical trials involving 107,910 patients as well as a large retrospective cohort study of more than 2.2 million patients, the FDA found no increase risk of suicidal ideation, behavior, or other related psychiatric adverse events with these medications. Based on the totality of evidence, it was concluded that no data supported any causal relationship between the claim and use of medication. The FDA proceeded to request removal of this warning from the labeling of affected GLP-1 receptor agonists.

FDA announced a labeling correction for all TRUE METRIX blood glucose monitoring systems after determining that the current instructions did not adequately emphasize that users should seek immediate medical attention if an E-5 error code was received and if they are experiencing symptoms of hyperglycemia. The E-5 error code may indicate either an extremely high blood glucose value, greater than 600 mg/dL, or a test strip error. Failure to promptly seek care could delay treatment and lead to serious injury or death. Since the product's launch in 2014, there have been 114 reported serious injuries and 1 death associated with the E-5 error code. The products may continue to be used and no removals or returns need to be carried out, but the labeling and instructions for use are being updated to better guide patients and caregivers.

The FDA updated the labeling for capecitabine and fluorouracil to strengthen warnings about the risks associated with dihydropyrimidine dehydrogenase deficiency. Because the DPYD gene encodes the enzyme responsible for breaking down more than 80% of fluorouracil, patients with complete or partial DPD deficiency are at risk of severe, early onset, and potentially fatal toxicities such as mucositis, diarrhea, neutropenia, and neurotoxicity. The revised labeling now includes a Boxed Warning recommending DPYD genetic testing before starting treatment unless immediate therapy is necessary, advises avoiding use in patients with certain variants associated with complete DPD deficiency, and states that dosing in partial deficiency should be individualized.

FDA is requiring a new warning for all drug products containing carbidopa/levodopa to inform prescribers and patients that these medications may cause vitamin B6 deficiency and vitamin B6 deficiency-associated seizures. The FDA identified 14 cases of seizures linked to vitamin B6 deficiency in patients receiving these therapies, including 2 fatalities, and found that many cases did not respond to traditional anti-seizure medications but resolved after vitamin B6 administration. The agency concluded there is reasonable evidence of casual association and now recommends evaluating baseline vitamin B6 levels before treatment, periodic monitoring during therapy, and considering vitamin B6 supplementation as needed, particularly at higher doses.

12 Shortages (New)

Generic name (Brand Name)	Presentation	Posting Date	Related Information
Amphetamine variations: Amphetamine Aspartate Monohydrate, Amphetamine Sulfate, Dextroamphetamine Sulfate, Dextroamphetamine Saccharate	Tablet: 1.25mg, 1.875mg, 2.5mg, 3.125mg, 3.75mg, 5mg, 7.5mg, 20mg, 30mg	3/17/2026	Expected estimated availability within 3 months of most strengths (June 2026)
Azacitidine (Vidaza)	Injection: 100mg vial	3/18/2026	Product on backorder. Recovery date to be determined.
Carboplatin	Injection: 10mg/mL, 600mg,60mL	3/27/2026	Limited supply available. Estimated recovery by June 2026.
Clonazepam (Klonopin)	Tablet: 0.5mg, 1mg	3/17/2026	Estimated recovery by April 2026.
Crmolyn Sodium Concentrate (Gastrocrom)	Concentrate for oral solution: 100mg/5mL	3/2/2026	Limited availability.
Desmopressin Acetate Spray (DDVAP)	Nasal Spray: 10ug	3/17/2026	Next replenishment expected by late March 2026.
Dexamethasone Sodium Phosphate (Decadron)	Injection: 4mg/mL, 10mg,mL	3/17/2026	Temporarily on backorder. Next replenishment expected by April 2026.
Fentanyl Citrate/ Fentanyl Citrate Preservative Free	Injection: 0.5mg/mL, 250mcg/5mL, 1000mcg/20mL	3/17/2026	Some lots to be available by March and April 2026.
Flurazepam Hydrochloride	Capsule: 15mg, 30mg	1/14/2026	Delay is due to manufacturing delays at the contract manufacturing facility. Anticipated delivery by Q4 2026.

12 Shortages (New)

Generic name (Brand Name)	Presentation	Posting Date	Related Information
Hydroxycobalamin (Vitamin B12)	Injection: 100mcg/mL, 30mL multidose vail	3/16/2026	Supply is expected to return by June 2026.
Ketorolac Tromethamine (Toradol)	Injection: 15mg/1mL, 30mg/1mL, 60mg/2mL	3/27/2026	The 30mg/1mL is expected by April 2026. Other formulations are still in to be determined status with an estimated recovery date of June 2027.
Lydocaine Hydrochloride (Xylocaine)	Injection: 5mg/mL, 10mg/mL, 15mg/mL, 20mg/mL	3/27/2026	Expected recovery to be determined.
Lisdexamfetamine Dimesylate (Vyvanse)	Capsule: 10mg, 20mg, 30mg, 40mg, 50mg, 60mg, 70mg	3/17/2026	Expected recovery to be determined.
Lorazepam (Ativan)	Injection: 2mg/mL, 4mg/mL	3/13/2026	Expected recovery to be determined.
Methotrexate Sodium Preservative Free	Injection: 25mg/mL	3/16/2026	Estimated recovery for January 2027.
Methylphenidate Hydrochloride Extended Release (Concerta, Relexxi)	Tablet: 10mg, 18mg, 20mg, 27mg, 36mg, 45mg, 54mg, 63mg, 72mg	3/16/2026	Limited availability. Estimated recovery is still to be determined.
Methylprednisolone Acetate (Depo-Medrol)	Injection: 40mg/mL, 80mg/mL	3/18/2026	On backorder. Expected recovery to be determined.
Midazolam Hydrochloride (Versed)	Injection: 1mg/mL, 5mg/mL, 50mg/10mL	3/17/2026	Estimated availability by April 2026.

12 Shortages (New)

Generic name (Brand Name)	Presentation	Posting Date	Related Information
Penicillin G Benzathine (Bicillin L-A)	Injection: 1200000 [iU]/2 mL, 2400000 [iU]/4 mL, 600000 [iU]/1 mL	3/27/2026	Next delivery expected by August 2026. Expected recovery by December 2026.
Promethazine Hydrochloride (Phenergan)	Injection: 25mg/mL, 50mg/mL	3/12/2026	The 50mg/mL is expected to be available by April 2026.
Quinapril Hydrochloride (Accupril)	Tablet: 5mg, 10mg, 20mg, 40mg	3/2/2026	Information unavailable.
Rifampin (Rifadin)	Capsule: 150mg, 300mg	3/2/2026	On allocation status.
Riluzole (Tiglutik)	Oral suspension: 50mg/10mL	3/16/2026	Next release not available at this time.

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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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