ProCare Rx

Insights on the Drugs Pipeline

EXPLORING THE CHANGES IN THE DRUGS MARKET.

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Insights on the Drugs Pipeline | Q2 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 pharmacists, to provide you with continuous evaluation and insights of the drugs market and its impact as it evolves.

Here you will find

- Drug pipeline
- FDA drug approvals
- New indications
- Patent expirations
- Generic approvals
- FDA safety updates/recalls
- Drug shortages

02 Hot Topic

A New Step in the Evolution of Alzheimer's Disease Treatment

Alzheimer's disease continues to be one of the neurodegenerative diseases with the greatest clinical, social, and economic impact worldwide. However, in recent years, it has also become one of the therapeutic areas with the greatest innovation. The introduction of the first disease-modifying therapies marked a landmark change in the management of patients with mild cognitive impairment or mild dementia due to Alzheimer's disease. Now, a new regulatory advancement seeks to reduce one of the major barriers to access to these therapies. On July 13, 2026, the U.S. Food and Drug Administration (FDA) approved a new initial dosing regimen for the subcutaneous formulation of Leqembi (lecanemab-irmb), making it the first anti-amyloid therapy that can be initiated at home by either the patient or a properly trained caregiver. Although this approval does not change the drug's indication or its previously demonstrated efficacy, it represents a significant change in the way patients can initiate treatment and may have important implications for patients, caregivers, healthcare professionals, and healthcare coverage and access systems.

Behind this therapeutic advancement is a disease that continues to represent one of the greatest challenges in modern neurology. Alzheimer's disease remains the most common cause of dementia in the United States and currently affects more than 6.5 million people. Its pathophysiology is characterized by the progressive accumulation of β-amyloid plaques and tau neurofibrillary tangles, leading to neuronal dysfunction, irreversible cognitive decline, and the gradual loss of functional independence. Due to population aging, the prevalence of the disease is expected to continue increasing over the coming decades, significantly increasing its clinical, social, and economic burden.

Currently, the Alzheimer's Association Clinical Practice Guideline (2024) emphasizes the importance of early diagnosis and a comprehensive evaluation to identify, in a timely manner, patients who may benefit from disease-modifying therapies. Specifically for lecanemab, the Prescribing Information states that patients must have confirmed amyloid pathology before initiating treatment.

The introduction of monoclonal antibodies targeting β-amyloid protein has transformed the management of early Alzheimer's disease by becoming the first therapies capable of modifying the course of the disease beyond symptomatic relief. Among these therapies, lecanemab demonstrated clinically meaningful benefits in the pivotal Phase 3 CLARITY AD (Study 301) trial, a confirmatory study that demonstrated a significant slowing of cognitive and functional decline in patients with mild cognitive impairment or mild dementia due to Alzheimer's disease with confirmed amyloid pathology, providing the basis for the FDA's traditional approval of the drug. These findings established lecanemab as one of the first disease-modifying therapies available for this patient population and marked an important change in the therapeutic paradigm of Alzheimer's disease.

02 Hot Topic (cont'd)

As with any therapeutic innovation, clinical benefits are also accompanied by new challenges for medical practice. In the case of amyloid-targeting monoclonal antibodies, the primary safety consideration is Amyloid-Related Imaging Abnormalities (ARIA), a characteristic adverse event associated with this therapeutic class. Clinically, ARIA primarily occurs in two forms: ARIA-E, which is associated with cerebral edema or sulcal effusions, and ARIA-H, which is associated with cerebral microhemorrhages or superficial hemosiderin deposits detected by magnetic resonance imaging (MRI). Although most cases are asymptomatic and resolve over time, some patients may experience headache, confusion, dizziness, visual disturbances, or nausea and, in rare cases, develop serious neurological complications. Therefore, periodic MRI is an essential component of the early detection and timely management of this complication during treatment with lecanemab.

Although ARIA can occur in any patient treated with lecanemab, clinical evidence has shown that the risk is not the same for all patients. One of the factors that most strongly influences its occurrence is the apolipoprotein E ε4 (ApoE ε4) genotype, which is currently considered one of the main predictors of ARIA during treatment. Patients who are ApoE ε4 homozygotes have a significantly higher incidence of symptomatic, serious, and severe ARIA compared with patients who are heterozygotes or noncarriers of the allele. Therefore, the Prescribing Information for lecanemab recommends ApoE ε4 genotyping before initiating treatment, as the results help inform the risk of developing ARIA and guide the clinical evaluation prior to the initiation of therapy.

The new approval marks another step forward in the evolution of Alzheimer's disease treatment by allowing patients to initiate lecanemab therapy at home. This change has the potential to reduce one of the major logistical barriers associated with disease-modifying therapies, provided that the patient or caregiver has received appropriate training for medication administration.

According to the updated Prescribing Information, treatment may be initiated with the subcutaneous formulation, LEQEMBI IQLIK, at a dose of 500 mg administered once weekly using a single-dose autoinjector. After 18 months of treatment, patients may either continue this regimen or transition to a maintenance dose of 360 mg administered once weekly. Prior to this update, treatment initiation required biweekly intravenous infusions administered at specialized infusion centers, resulting in frequent travel, dependence on the availability of infusion centers, and a considerable burden for many patients and their caregivers. With this approval, eligible patients can initiate treatment with the subcutaneous formulation, administered once weekly by either the patient or a properly trained caregiver. Although this update simplifies access to treatment, it does not change the clinical principles that continue to guide the use of lecanemab. Appropriate patient selection, confirmation of amyloid pathology, ARIA risk assessment, and MRI remain essential components of ensuring safe and effective treatment.

Beyond its clinical implications, this approval may also have an important impact on healthcare delivery. The ability to initiate treatment at home may improve access for patients with limited mobility or those who live far from infusion centers, while also reducing part of the burden that treatment places on caregivers and on the infrastructure required for intravenous administration. Nevertheless, this approval does not change the indication or the requirements established in the Prescribing Information for initiating treatment with lecanemab. Eligible patients remain those with mild cognitive impairment or mild dementia due to Alzheimer's disease, confirmed β-amyloid pathology, MRI evaluation, and an ARIA risk assessment before initiating therapy.

02 Hot Topic (cont'd)

The evolution of disease-modifying therapies for Alzheimer's disease demonstrates that therapeutic advances depend not only on the development of new medications, but also on strategies that expand access to treatments whose efficacy has already been demonstrated. The new approval of lecanemab represents precisely this type of advancement by facilitating treatment initiation at home without changing the clinical principles that continue to guide its use. As these therapies are progressively incorporated into clinical practice, the real challenge will be to ensure that greater accessibility is accompanied by appropriate patient selection, individualized risk assessment, and clinical monitoring that maximizes the benefits of treatment without compromising patient safety. This objective will continue to define the responsible use of these therapies in the years to come.

References:

LEQEMBI (lecanemab-irmb) Prescribing Information. Eisai Inc. Revised July 2026.

U.S. Food and Drug Administration. FDA approves first at-home starting dose for Alzheimer's disease treatment. July 13, 2026.

U.S. Food and Drug Administration. FDA converts novel Alzheimer's disease treatment to traditional approval. January 6, 2023.

Cummings J, Aisen P, Apostolova LG, et al. Lecanemab: Appropriate Use Recommendations.J Prev Alzheimers Dis.2023;10(3):362-377.

Dickerson BC, Atri A, et al. The Alzheimer's Association clinical practice guideline for the Diagnostic Evaluation, Testing, Counseling, and Disclosure of Suspected Alzheimer's Disease and Related Disorders (DETeCD-ADRD).Alzheimer's & Dementia. 2024.

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?
Belzutifan (Welireg- Merck & Co (MSD), Peloton Therapeutics)	NDA Filed	12/26/2025	Cardiac myosin inhibitor for the treatment of obstructive Hypertrophic cardiomyopathy (HCM); oral
Centanafadine (Otsuka-Otsuka Pharmaceutical Development & Commercialization, Inc.)	NDA Filed	8/12/2025	Dipeptidyl peptidase 1 (DPP1) inhibitor for the treatment of Non-Cystic Fibrosis Bronchiectasis; oral
Deramiocel (Deramiocel-Nippon Shinyaku, Capricor Therapeutics)	BLA Filed	12/16/2025	Long acting IL-5 monoclonal antibody for the treatment of severe eosinophilic asthma and chronic rhinosinusitis with nasal polyps; Subcutaneous (SC every 6 months)
Deramiocel (Deramiocel-Nippon Shinyaku, Capricor Therapeutics)	BLA Filed	8/31/2025	Allogenic stem cell therapy for the treatment of Duchenne muscular dystrophy cardiomyopathy; IV infusion
Garetosmab Regeneron-(Regeneron Pharmaceuticals, Inc.)	NDA Filed	8/21/2025	Antisense medicine designed to reduce the production of prekallikrein (PKK) for the prevention of hereditary angioedema (HAE) attacks in adult and pediatric patients 12 years of age and older; SC injection
Gedatolisib (Gedatolisib-Pfizer, Celcuity)	BLA Filed	6/17/2025	Fully human recombinant FXIIa antagonist monoclonal antibody for the prevention of hereditary angioedema (HAE); SC
Belzutifan (Welireg- Merck & Co (MSD), Peloton Therapeutics)	BLA Filed	7/10/2025	BCMAxCD3 bispecific antibody for the treatment of multiple myeloma; IV

03 Specialty Pipeline (cont'd)

Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Lecanemab (Leqembi- Eisai, Biogen, BioArctic Neuroscience)	BLA Filed	8/24/2026	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
Molgramostim (Molbreevi-PARI, Savara, Fujifilm)	BLA Filed	8/22/2026	Colony stimulating factor for the treatment of autoimmune pulmonary alveolar proteinosis (aPAP); inhalation
Rusfertide (Takeda, Protagonist Therapeutics)	NDA Filed	Q3 2026	First-in-class hepcidin mimetic peptide for the treatment of adults with polycythemia vera; subcutaneous injection
Bevacizumab-vikg. (LYTENAVA™; ONS-5010-Outlook Therapeutics)	BLA Filed	7/29/2026	Treatment of neovascular (wet) age-related macular degeneration; intravitreal.
Vusolimogene Oderparepvec (Replimune Group, Inc)	BLA Filed	8/2/2026	In combination with nivolumab, for the treatment of adult patients with advanced melanoma that has progressed on or after treatment with a PD-1 inhibitor; Intratumoral.
Influenza Virus Vaccine (mRNA-1010,mFlusiva-Moderna, Inc.)	BLA Filed	8/5/2026	Prevention of influenza disease in adults 50 years of age and older; Intramuscular.
Iberdomide (Bristol Myers Squibb)	NDA Filed	8/17/2026	Relapsed or refractory multiple myeloma, in combination with daratumumab and dexamethasone; oral.
Pembrolizumab (Keytruda-Merck & Co., Inc.)	BLA Filed	8/17/2026	In combination with enfortumab vedotin-ejfv as perioperative treatment for patients with muscle invasive bladder cancer who are eligible for cisplatin- containing chemotherapy; intravenous.
Pariglasgene Brecaparvovec (DTX401- Ultragenyx Pharmaceutical Inc.)	BLA Filed	8/23/2026	Treatment of Glycogen Storage Disease Type Ia; intravenous.

03 Specialty Pipeline (cont'd)

Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Dasatinib (Dasynoc- Xspray Pharma AB)	NDA Filed	8/25/2026	Treatment of chronic myeloid leukemia and Philadelphia chromosome positive acute lymphoblastic leukemia; oral.
Bictegravir/Lenacapavir (Gilead Sciences, Inc.)	NDA Filed	8/27/2026	Treatment of HIV-1 infection in virologically suppressed adults to replace a stable antiretroviral regimen; oral.
Lutetium Lu 177 Edotreotide (Raytherity- ITM Isotope Technologies Munich SE)	NDA Filed	8/28/2026	Treatment of adult patients with unresectable or metastatic, well-differentiated gastroenteropancreatic neuroendocrine tumors (GEP-NETs); intravenous.
Finerenone (Kerendia- Bayer AG)	NDA Filed	Sep-26	Treatment of adults with chronic kidney disease (CKD) associated with type 1 diabetes; oral.
Condoliase (Ferring Pharmaceuticals)	BLA Filed	Sep-26	Radicular leg pain associated with lumbar disc herniation; intradiscal injection.
Floretyrosine F18 (Pixclara- Telix Pharmaceuticals Limited)	NDA Filed	9/11/2026	PET imaging for the characterization of recurrent or progressive glioma from treatment related changes in adult and pediatric patients; intravenous.
Zidesamtinib (Jideytro- Nuvalent, Inc.)	NDA Filed	9/18/2026	Treatment of adult patients with locally advanced or metastatic ROS1-positive non small cell lung cancer who have received at least one prior ROS1 tyrosine kinase inhibitor; oral.
Pembrolizumab (Keytruda- Merck & Co., Inc.)	BLA Filed	8/17/2026	In combination with enfortumab vedotin-ejfv as perioperative treatment for patients with muscle invasive bladder cancer who are eligible for cisplatin- containing chemotherapy; intravenous.
Pariglasgene Brecaparvovec (DTX401- Ultragenyx Pharmaceutical Inc.)	BLA Filed	8/23/2026	Treatment of Glycogen Storage Disease Type Ia; intravenous.

03 Specialty Pipeline (cont'd)

Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Levacetylleucine (Aqneursa-IntraBio Inc.)	NDA Filed	9/19/2026	Treatment of ataxia-telangiectasia in adult and pediatric patients; oral.
Rebisufligene Etisparvovec (Ultragenyx Pharmaceutical Inc.)	BLA Filed	9/19/2026	Treatment of patients with Sanfilippo syndrome type A (MPS IIIA); intravenous.
Zilganersen (Ionis Pharmaceuticals, Inc.)	NDA Filed	9/22/2026	Treatment of children and adults with Alexander disease; intrathecal.

04 Biosimilar Pipeline

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

Generic Name (Brand Name-Manufacturer)	Reference Biologic	FDA Possible Approval Date
Bevacizumab (Henlius)	Avastin	Q4: 2026
Bevacizumab (AstraZeneca, Fujifilm Kyowa Kirin, Centus Biotherapeutics)	Avastin	Q4: 2026
Aflibercept (Sam Chun Dang Pharm, Fresenius Kabi)	Eylea	Pending Approval Date
Trastuzumab (Tanvex)	Herceptin	Pending Approval Date
Insulin Lispro (Prandilin-Sandoz, Gan & Lee)	Humalog	Pending Approval Date
Insulin Glargine (Basalin- Sandoz, Gan & Lee)	Lantus	Pending Approval Date
Ranibizumab (Lupin)	Lucentis	FDA Approval Date: 6/2/2026
Pegfilgrastim (Lapelga- Apotex, Accord, Intas)	Neulasta	Pending Approval Date
Insulin Aspart (Amphastar)	Novolog	Pending Approval Date
Insulin Aspart (Rapilin-Sandoz, Gan & Lee)	Novolog	Pending Approval Date
Abatacept (Dr. Reddy's Laboratories)	Orencia	Q4: 2026
Denosumab (Osqay-Alken Labs, Ascend, Enzene)	Prolia	Pending Approval Date
Denosumab (Alken Labs, Ascend, Enzene)	Xgeva	Pending Approval Date
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
Adifamilast (Adquey)	**Dosage Form:** Ointment 1% (10 mg difamilast/g) **Indication:** Topical treatment of mild to moderate atopic dermatitis in adults and pediatric patients ≥2 years of age. **Comparables:** Crisaborole (Eucrisa), Roflumilast (Zoryve), Tacrolimus ointment (Protopic), Pimecrolimus cream (Eidel). **Guidelines:** Atopic Dermatitis. American Academy of Dermatology (AAD) Guidelines of Care for the Management of Atopic Dermatitis. https://www.aad.org/member/clinical-quality/guidelines/atopic-dermatitis
Insulin icodec-abae (Awiqli Flextouch)	**Dosage Form:** Injection 700 units/mL (U-700) solution in FlexTouch prefilled pen (1mL, 1.5mL and 3mL) presentations. **Indication:** Adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. **Comparables:** Tresiba (insulin degludec), Toujeo (insulin glargine U-300) **Guidelines:** Standards of Care in Diabetes 2026. American Diabetes Association (ADA). https://diabetesjournals.org/care/article/49/Supplement_1/S183/163934/9-Pharmacologic-Approaches-to-Glycemic-Treatment

06 New Drug Formulations

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

New Drug Formulations	Details
Darunavir/cobicistat (Prezcobix PED)	**New Dosage Form:** Tablets for oral suspension Darunavir 600mg/cobicistat 90mg dispersible tablet. **Indication:** Treatment of HIV-1 infection, in combination with other antiretroviral agents, in treatment-naïve and treatment experienced pediatric ≥3 years of age weighing ≥15kg with no darunavir resistance associated substitutions. **Comparables:** Prezcobix tablets, Prezista oral suspension **Guidelines:** Pediatric HIV Infection. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. NIH. Updated June 25, 2026. https://clinicalinfo.hiv.gov/sites/g/files/mnhszr391/files/guidelines/documents/pediatric-arv/drug-information-protease-inhibitors-darunavir-pediatric-arv.pdf

06 New Drug Formulations (cont'd)

New Drug Formulations	Details
Paliperidone palmitate (Erzofri)	**New Dosage form:** Extended-release injectable suspension. Extended-release injectable suspension: 39 mg/0.25 mL, 78 mg/0.5mL, 117 mg/0.75mL, 156 mg/mL,234 mg/1.5 mL, 351 mg/2.25 mL. **Indication:** Is a second-generation antipsychotic indicated for treatment of schizophrenia in adults, and treatment of schizoaffective disorder in adults as monotherapy, and as an adjunct to mood stabilizers or antidepressants. **Comparables:** injectable long-acting Invega® products Invega Sustenna®, Trinza™and Hafyera™, which are administered as IM injections. Invega tablets are also available generically **Guidelines:** American Psychiatric Association (APA): Practice guideline for the treatment of patients with schizophrenia, 3rd edition (2020)
Octreotide acetate (Bynfezia Pen)	**New Dosage form:** Injection, for subcutaneous use. Injection: 7,000 mcg/2.8 mL (2,500 mcg/ mL) octreotide (as acetate) in a 2.8 mL single-patient-use prefilled pen. **Indication:** Is a somatostatin analog "New Formulation" or New Manufacturer: For subcutaneous use for the following indications: • Acromegaly: To reduce blood levels of growth hormone (GH) and insulin growth factor 1 (IGF-1; somatomedin C) in acromegaly patients who have had inadequate response to or cannot be treated with surgical resection, pituitary irradiation, and bromocriptine mesylate at maximally tolerated doses. • Carcinoid Tumors: For the symptomatic treatment of patients with metastatic carcinoid tumors where it suppresses or inhibits the severe diarrhea and flushing episodes associated with the disease. • Vasoactive Intestinal Peptide Tumors (VIPomas): For the treatment of profuse watery diarrhea associated with VIP-secreting tumors. **Comparables: Octreotide** **Guidelines: Neuroendocrine and Adrenal tumors.National Comprehensive Cancer Network (NCCN) (Version 2.2024)**

07 New Indications

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

New Indications	Details
Suzetrigine (Journavx)	For the addition of the Indication: treatment of moderate to severe post operative pain in adults.
Posaconazole (Noxafil)	For the expansion of the treatment population: inclusion of pediatric patients for the treatment of invasive aspergillosis with NOXAFIL injection and delayed-release tablets, and for the addition of the Indication: treatment of invasive aspergillosis with NOXAFIL powder for delayed-release oral suspension in pediatric patients 2 years of age and older weighing 10 kg to 40kg.
Deucravacitinib (Sotyktu)	For the addition of the Indication: treatment of adults with active psoriatic arthritis (PsA).
Rizatriptan (RizaFilm)	For the expansion of the treatment population: acute treatment of migraine with or without aura in pediatric patients 6 to 11 years of age, with the addition of a 5 mg strength.
Imiglucerase (Cerezyme)	For the addition of the Indication: treatment of type 3 Gaucher disease in adult and pediatric patients, and for the expansion of the treatment population: treatment of type 1 Gaucher disease in pediatric patients younger than 2 years of age.
Etonogestrel (Nexplanon)	For the extension of the duration of use: extending the approved duration of use of NEXPLANON from 3 years to 5 years.
Daratumumab and hyaluronidase fihj (Darzalex Faspro)	For the addition of the Indication: DARZALEX FASPRO in combination with bortezomib, lenalidomide, and dexamethasone (VRd) for newly diagnosed multiple myeloma (ndmm) in adults who are ineligible for autologous stem cell transplantation.
Amivantamab and hyaluronidase-lpuj (Rybrevant Faspro)	For the addition of the Indication: RYBREVANT FASPRO as monotherapy for adults with locally advanced or metastatic EGFR exon 20 insertion mutation positive non small cell lung cancer (NSCLC) after progression on platinum based chemotherapy.

07 New Indications (cont'd)

New Indications	Details
Acalabrutinib (Calquence)	For the addition of the combination regimen: CALQUENCE in combination with venetoclax for the treatment of adult patients with chronic lymphocytic leukemia (CLL) or small lymphocytic lymphoma (SLL).
Pembrolizumab (Keytruda)	For the addition of the Indication: KEYTRUDA in combination with paclitaxel, with or without bevacizumab, for the treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express PD-L1 (CPS≥1) and who have received one or two prior systemic treatment regimens.
Pembrolizumab and berahyaluronidase alfa-pmph (Keytruda QLEX)	For the addition of the Indication: KEYTRUDA QLEX in combination with paclitaxel, with or without bevacizumab, for the treatment of adult patients with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal carcinoma whose tumors express PD-L1 (CPS≥1) and who have received one or two prior systemic treatment regimens.
Encorafenib (Braftovi)	For the addition of the Indication: BRAFTOVI in combination with cetuximab and fluorouracil based chemotherapy for BRAF V600E mutation positive metastatic colorectal cancer.
Zongertinib (Hernexeos)	For the addition of the Indication: HERNEXEOS for the treatment of adult patients with unresectable or metastatic non-squamous non-small cell lung cancer (NSCLC) harboring HER2 (ERBB2) tyrosine kinase domain activating mutations.
Somapacitan-beco (Sogroya) - Growth Hormone	For the addition of the Indication: treatment of pediatric patients 2.5 years and older with short stature born small for gestational age (SGA) and with no catch-up growth by 2 years of age, growth failure associated with Noonan syndrome (NS), Idiopathic Short Stature (ISS).
Teclistamab-cqyv (Tecvayli)	For the conversion from accelerated to traditional approval: TECVAYLI as monotherapy for adults with relapsed or refractory multiple myeloma who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent and an anti-CD38 monoclonal antibody; and for the addition of the Indication: TECVAYLI in combination with daratumumab hyaluronidase fihj for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least one prior line of therapy, including a proteasome inhibitor and an immunomodulatory agent.
Secukinumab (Cosentyx)	For the expansion of the treatment population: treatment of moderate-to severe hidradenitis suppurativa in pediatric patients 12 years of age and older.

07 New Indications (cont'd)

New Indications	Details
Setmelanotide (Imcivree)	For the addition of the Indication: reduction of excess body weight and long term maintenance of weight reduction in adults and pediatric patients 4 years of age and older with acquired hypothalamic obesity.
Nivolumab (Opdivo)	For the addition of the Indication: OPDIVO in combination with doxorubicin, vinblastine, and dacarbazine (AVD) for previously untreated Stage III or IV classical Hodgkin lymphoma (cHL) in adult and pediatric patients 12 years of age and older; and for the conversion from accelerated to traditional approval: OPDIVO as monotherapy for relapsed or refractory classical Hodgkin lymphoma (cHL) in adults.
Diclofenac epolamine (Licart)	For the expansion of the treatment population: topical treatment of acute pain due to minor strains, sprains and contusions in pediatric patients 6 to less than 17 years of age.
Elexacaftor/tezacaftor/ivacaftor; ivacaftor (Trikafta)	For the expansion of the Indication: treatment of cystic fibrosis (CF) in adult and pediatric patients 2 years of age and older with at least one CFTR gene variant that is responsive based on clinical and/or in vitro data or results in CFTR protein production.
Pembrolizumab (Keytruda)	For the update of the Indication: selection of patients with esophageal or gastroesophageal junction cancer based on PD-L1 (CPS ≥1) expression.
Pembrolizumab and berahyaluronidase alfa-pmph (Keytruda Qlex)	For the addition of the Indication: treatment of esophageal or gastroesophageal junction cancer in patients whose tumors express PD-L1 (CPS ≥1).
Sparsentan (Filspari)	For the addition of the Indication: reduction of proteinuria in adult and pediatric patients 8 years of age and older with focal segmental glomerulosclerosis (FSGS) without nephrotic syndrome.
Ustekinumab (Stelara)	For the addition of the Indication: treatment of pediatric patients 2 years of age and older with moderately to severely active Crohn's disease.
Dupilumab (Dupixent)	For the addition of the Indication: treatment of allergic fungal rhinosinusitis (AFRS) in adult and pediatric patients 6 years and older with a history of sino-nasal surgery.

08 In-Market Brand

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

In-Market Brands	Details
Fibrinogen, human-chmt (Fesilty)	**Dosage Form:** Lyophilized powder for IV injection: 1g/single-dose vial. **Indication:** Treatment of acute bleeding episodes in pediatric and adult patients with congenital fibrinogen deficiency (hypofibrinogemia or afibrinogenemia). Not indicated for dysfibrinogenemia. Comparables: RiaSTAP® (fibrinogen concentrate), Fibryga®, cryoprecipitate, fresh frozen plasma (FFP). **Guidelines:** Congenital Fibrinogen Deficiency. Guidelines for the Diagnosis and Management of the Rare Coagulation Disorders. UKHCDO/BCSH. https://onlinelibrary.wiley.com/doi/full/10.1111/bjh.13058
Copper histidinate (Zycubo)	**Dosage Form:** Subcutaneous injection: 2.9 mg copper histidinate (equivalent to 0.5mg elemental copper)/single-dose vial. **Indication: T**reatment of Menkes disease in pediatric patients. Comparables: Compounded copper histidinate; copper chloride (investigational/ historical use). None FDA-approved. **Guidelines:** Menkes Disease. GeneReviews®: Menkes Disease. https://www.ncbi.nlm.nih.gov/books/NBK1413/
Navepegritide (Yuviwel)	**Dosage Form:** For Injection 1.3mg, 2.8mg and 5.5mg lyophilized powder in single-dose vial for reconstitution (subcutaneous use). **Indication:** To increase linear growth in pediatric patients ≥2 years of age with achondroplasia and open epiphyses. **Comparables:** Voxzogo® (vosoritide) **Guidelines:** Achondroplasia. Health Supervision for People with Achondroplasia. American Academy of Pediatrics (AAP). https://publications.aap.org/pediatrics/article/145/6/e20201010/76908/Health-Supervision-for-People-With-Achondroplasia?autologincheck=redirected
Relacorilant (Lifyorli)	**Dosage Form:** Capsules 25mg and 100mg. **Indication:** In combination with nab-paclitaxel for the treatment of adults with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received 1-3 prior systemic treatment regimens, at least one of which included bevacizumab. **Comparables:** Elahere® (mirvetuximab soravtansine-gynx), bavacizumab (Avastin®) **Guidelines:** Ovarian Cancer. NCCN Clinical Practice Guidelines in Oncology: Ovarian Cancer. https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1453

08 In-Market Brand (cont'd)

In-Market Brands	Details
Pivmecillinam (Pivya)	**Dosage Form:** Film-coated tablet 185mg pivmecillinam (equivalent to 20mg pivmecillinam hydrochloride). **Indication:** Treatment of uncomplicated urinary tract infection (uUTI) in women ≥18 years of age caused by susceptible isolates of Escherichia coli, Proteus mirabilis, and Staphylococcus saprophyticus. **Comparables:** Nitrofurantoin (Macrobid®), Trimethoprim/Sulfametoxazole (Bactrim®), Fosfomycin (Monurol®). **Guidelines:** Acute Uncomplicated Cystitis and Pyelonephritis in Women. IDSA Clinical Practice Guideline (2010 Update; published 2011). https://www.idsociety.org/practice-guideline/uncomplicated-cystitis-and-pyelonephritis-uti/
Lerodalcibep-liga (Lerochol)	**Dosage Form:** Injection 300mg/1.2mL (250mg/mL) solution in a single- dose prefilled syringe for subcutaneous use. **Indication:** Adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C) in adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH). **Comparables:** Repatha® (evolocumab), Praluent® (alirocumab), Leqvio® (inclisiran) **Guidelines:** 2026 ACC/AHA/AACVPR/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Dyslipidemia. https://www.ahajournals.org/doi/10.1161/CIR.0000000000001423
Doxecitine and doxribtimine (Kygevvi)	**Dosage Form:** Powder for oral solution 2g doxecitine and 2g doxribtimine per packet. **Indication:** Treatment of thymidine kinase 2 deficiency (TK2d) in adults and pediatric patients with an age of symptom onset on or before 12 years. **Comparables:** None **Guidelines:** Gene Reviews- TK2 Related Mitochondrial DNA Maintenance Defect, Myopathic Form. https://www.ncbi.nlm.nih.gov/books/NBK114628/
Orforglipron (Foundayo)	**Dosage Form:** Film-coated tablets 0.8mg, 2.5mg, 5.5mg, 9mg, 14.5mg and 17.8mg. **Indication:** Adjunct to a reduced-calorie diet and increased physical activity to reduce excess body weight and maintain long-term weight reduction in adults with obesity or adults with overweight with at least one weight-related comorbidity. **Comparables:** Wegovy® (semaglutide), Zepbound® (tirzepatide), Saxenda® (liraglutide). **Guidelines:** Obesity Management for the Treatment of Type 2 Diabetes. Standards of Care in Diabetes 2026. American Diabetes Association (ADA). https://diabetesjournals.org/care/article/49/Supplement_1/S166/163915/8-Obesity-and-Weight-Management-for-the-Prevention

08 In-Market Brand (cont'd)

In-Market Brands	Details
Carbachol and brimonidine tartrate (Yuvezzi)	**New Dosage Form:** Ophthalmic solution carbachoal 2.75% and brimonidine tartrate 0.1% in a single-dose vial. **Indication:** Combination of a cholinergic agonist and an alpha-adrenergic receptor agonist indicated for the treatment of presbyopia in adults. **Comparables:** Vuity® (pilocarpine HCl ophthalmic solution 1.25%), Qlosi (pilocarpine HCl ophthalmic solution 0.4%). **Guidelines:** Refractive Errors Preferred Practice Pattern. American Academy of Ophthalmology (AAO), 2022. https://www.aao.org/education/preferred-practice-pattern/refractive-errors-ppp-2022
Folic Acid (Quiofic)	**New Dosage Form:** Oral Solution 0.2mg/mL (1mg/5mL) **Indication:** Folate analog indicated for the treatment of megaloblastic anemias due to folic acid deficiency in adult and pediatric patients. **Comparables:** Folvite® (folic acid tablets), generic folic acid tablets. **Guidelines:** Cobalamin and Folate Disorders. Guidelines for the Diagnosis and Treatment of Cobalamin and Folate Disorders. British Society for Haematology (BSH), 2014. https://onlinelibrary.wiley.com/doi/10.1111/bjh.12959
Etoposide (Avopef)	**New Dosage Form:** Injection 100mg/5mL (20mg/mL) multiple- dose vial for intravenous use. **Indication:** In combination with other chemotherapy and/or immunotherapy for the treatment of refractory testicular cancer and small cell lung cancer (SCLC) in adults. **Comparables:** Toposar® (etoposide injection), generic etoposide injection. **Guidelines:** Small Cell Lung Cancer. NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer 2026. https://www.nccn.org/guidelines/guidelines-detail?category=1&id=1462
Fluorouracil (Favlyxa)	**New Dosage Form:** Injection 250mg/10mL (25mg/mL) single-dose vial for intravenous use. **Indication:** Treatment of adenocarcinoma of the colon and rectum, breast, stomach and pancreas. **Comparables:** Adrucil® (fluorouracil injection), generic fluorouracil injection. **Guidelines:** Colon Cancer. NCCN Clinical Practice Guidelines in Oncology 2026. https://www.nccn.org/guidelines/guidelines-detail?id=1428

08 In-Market Brand (cont'd)

In-Market Brands	Details
Desmopressin acetate (Desmoda)	**New Dosage Form:** Oral Solution 0.05mg/mL. **Indication:** Management of central diabetes insipidus as antidiuretic replacement therapy in adults and pediatric patients. **Comparables:** DDAVP® Tablets, DDAVP Nasal Spray, Desmopressin injection, Generic desmopressin tablets. **Guidelines:** Central Diabetes Insipidus. Diagnosis and Management of Central Diabetes Insipidus in Adults. Journal of Clinical Endocrinology & Metabolism (JCEM). 2022. https://pmc.ncbi.nlm.nih.gov/articles/PMC9516129/
Atomoxetine (Atoncy)	**New Dosage Form:** Oral Solution 4mg/mL **Indication:** Selective norepinephrine reuptake inhibitor (SNRI) indicated for the treatment of attention-deficit/hyperactivity disorder (ADHD) in adults and pediatric patients 6 years of age and older. **Comparables:** Strattera® capsules, generic atomoxetine capsules. **Guidelines:** Attention-Deficit/Hyperactivity Disorder. Clinical Practice Guideline for the Diagnosis, Evaluation and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. American Academy of Pediatrics (AAP). 2019. https://publications.aap.org/pediatrics/article/144/4/e20192528/81590/Clinical-Practice-Guideline-for-the-Diagnosis?autologincheck=redirected
Semaglutide (Wegovy HD)	**New Dosage Form:** Injection 7.2mg/0.75mL single-dose prefilled pen for subcutaneous use. **Indication:** In combination with a reduced calorie diet and increased physical activity to reduce excess body weight and maintain long term weight reduction in adults with obesity, or overweight with at least one weight related comorbidity. **Comparables:** Wegovy® 2.4mg, Zepbound® (tirzepatide). **Guidelines:** Obesity Management for the Treatment of Type 2 Diabetes. Standards of Care in Diabetes 2026. American Diabetes Association (ADA). https://diabetesjournals.org/care/article/49/Supplement_1/S166/163915/8-Obesity-and-Weight-Management-for-the-Prevention
Amlodipine (Sdamlo)	**New Dosage Form:** Oral Solution 2.5mg, 5mg and 10mg single-dose bottles (reconstituted before administration). **Indication:** Calcium Channel Blocker indicated for the treatment of hypertension in adults and pediatric patients ≥6 years of age and coronary artery disease (chronic stable angina, vasospastic angina and angiographically documented CAD) in adults. **Comparables:** Norliqva® oral solution, Katerzia® oral suspension, Norvasc® tablets. **Guidelines:** High Blood Pressure. 2025 AHA/ACC/AANP/AAPA/ABC/ACCP/ACPM/AGS/AMA/ASPC/NMA/PCNA Guideline for the Prevention, Detection, Evaluation and Management of High Blood Pressure in Adults. https://www.ahajournals.org/doi/10.1161/CIR.0000000000001356

08 In-Market Brand (cont'd)

In-Market Brands	Details
Tizanidine (Ontralfy)	**New Dosage Form:** Oral Solution 2mg/5mL. **Indication:** Central alpha-2 adrenergic agonist indicated for the treatment of spasticity in adults. **Comparables:** Zanaflex® Tablets, Zanaflex® Capsules **Guidelines:** Spasticity Assessment and Management. American Academy of Physical Medicine and Rehabilitation (AAPM&R) Consensus Guidance. 2024. https://onlinelibrary.wiley.com/doi/abs/10.1002/pmrj.13211
Sildenafil (Vybrique)	**New Dosage Form:** Oral film 25mg, 50mg, 75mg and 100mg. **Indication:** Phosphodiesterase type 5 (PDE5) inhibitor indicated for the treatment of erectile dysfunction in adult men. **Comparables:** Viagra® tablets, generic sildenafil tablets. **Guidelines:** Erectile Dysfunction. American Urological Association (AUA) Guideline. 2018. https://www.auanet.org/guidelines-and-quality/guidelines/erectile-dysfunction-(ed)-guideline
Lisdexamfetamine dimesylate (Arynta)	**New Dosage Form:** Oral Solution 10mg/mL. **Indication:** Central nervous system (CNS) stimulant indicated for the treatment of attention-deficit/hyperactivity disorder (ADHD) in adults and pediatric patients ≥6 years of age and moderate to severe binge eating disorder (BED) in adults. **Comparables:** Vyvanse® capsules, Vyvanse® chewable tablets. **Guidelines:** Attention-Deficit/Hyperactivity Disorder. Clinical Practice Guideline for the Diagnosis, Evaluation and Treatment of Attention-Deficit/Hyperactivity Disorder in Children and Adolescents. American Academy of Pediatrics (AAP). 2019. https://publications.aap.org/pediatrics/article/144/4/e20192528/81590/Clinical-Practice-Guideline-for-the-Diagnosis
Milsaperidone (Bysanti)	**Dosage Form:** Tablets 1mg, 2mg, 4mg, 6mg, 8mg, 10mg and 12mg. **Indication:** Treatment of schizophrenia in adults; acute treatment of manic or mixed episodes associated with bipolar I disorder in adults. **Comparables:** Fanapt® (Iloperidone) **Guidelines:** Schizophrenia. American Psychiatric Association (APA) Practice Guideline for the Treatment of Patients with Schizophrenia. https://www.psychiatry.org/psychiatrists/practice/clinical-practice-guidelines/schizophrenia

08 In-Market Brand (cont'd)

In-Market Brands	Details
Icotrokinra (Icotyde)	**Dosage Form:** Tablet 200mg **Indication:** Treatment of moderate to severe plaque psoriasis in adults and pediatric patients ≥12 years of age weighing at least 40kg who are candidates for systemic therapy or phototherapy. **Comparables:** Sotyku® (deucravacitinib), Otezla® (apremilast) **Guidelines:** Plaque Psoriasis. Joint American Academy of Dermatology-National Psoriasis Foundation (AAD-NPF) Guidelines of Care for the Management and Treatment of Psoriasis. https://www.aad.org/member/clinical-quality/guidelines/psoriasis
Linerixibat (Lynavoy)	**Dosage Form:** Tablet 40mg Indication: Treatment of cholestatic pruritus associated with primary biliary cholangitis (PBC) in adults patients. **Comparables:** Livdelzi® (seladelpar), Iqirvo® (elafibranor), Ocaliva® (obeticholic acid) **Guidelines:** Primary Biliary Cholangitis. AASLD Practice Guidance: Primary Biliary Cholangitis (2021 Update) https://journals.lww.com/hep/fulltext/10.1002/hep.32117~primary-biliary-cholangitis-2021-practice-guidance-update
Tividenofusp alfa-eknm (Avlayah)	**Dosage Form:** For injection 150mg lyophilized powder in a single-dose vial for reconstitution and further dilution (IV infusion). **Indication:** Treatment of neurologic manifestations of Hunter syndrome (Mucopolysaccharidosis type II, MPS II) in presymptomatic or symptomatic pediatric patients weighing at least 5kg prior to advanced neurologic impairment. Comparables: Elaprase® (idursulfase). **Guidelines:** Mucopolysaccharidosis type II (Hunter syndrome). Treatment of Mucopolysaccharidosis type II (Hunter syndrome): A Delphi Derived Practice Resource of the American College of Medical Genetics and Genomics (ACMG).

09 New Generics

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

Generic Name	ANDA Applicants	Brand Name	ANDA Approval Date	ANDA Indications
Azilsartan Kamedoxomil	Lupin, Wilshire Pharmaceuticals (AG)	Edarbi	6/17/2026, 4/27/2026	For the treatment of hypertension in adults to lower blood pressure, as monotherapy or in combination with other antihypertensive agents.
Beclomethasone Dipropionate	Amneal	QVAR 40, QVAR 80	3/18/2026	For the maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older.
Bimatoprost	Amneal, Mankind Pharma	Lumigan (0.01%)	4/1/2026, 3/18/2026	For the reduction of elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension.
Bosutinib Monohydrate	MSN Laboratories, Alembic	Bosulif (tablet)	6/13/2026, 6/11/2026	For the treatment of adult patients with newly diagnosed chronic phase Philadelphia chromosome-positive chronic myelogenous leukemia and for the treatment of adult patients with chronic, accelerated, or blast phase Ph+ CML with resistance or intolerance to prior therapy.
Brivaracetam	Zydus, Micro Labs	Briviact (injection)	3/1/2026	For the treatment of partial onset seizures in patients 1 month of age and older.
Cladribine	Hopewell Pharma	Mavenclad (tablet)	4/29/2026	For the treatment of relapsing forms of multiple sclerosis, including relapsing remitting disease and active secondary progressive disease, in adults.

09 New Generics (cont'd)

Generic Name	ANDA Applicants	Brand Name	ANDA Approval Date	ANDA Indications
Cyclophosphamide	Nexus	Cyclophosphamide (injection) (Dr. Reddy's)	3/9/2026	For the treatment of malignant diseases, including malignant lymphomas, leukemias, multiple myeloma, neuroblastoma, adenocarcinoma of the ovary, retinoblastoma and breast cancer.
Dapagliflozin Propanediol	Biocon, Teva, Lupin, Aizant Drug Research Solutions, Alkem Labs, Aurobindo, Inventia Healthcare, MSN Laboratories, Ajanta Pharma, Alembic, Cipla, Macleods, Sandoz, Zydus	Farxiga	4/6/2026	For the treatment of type 2 diabetes mellitus to improve glycemic control, to reduce the risk of hospitalization for heart failure, to reduce the risk of cardiovascular death and hospitalization for heart failure in patients with heart failure and to reduce the risk of sustained eGFR decline, end stage kidney disease, cardiovascular death and hospitalization for heart failure in patients with chronic kidney disease.
Dapagliflozin; Metformin Hydrochloride	Alkem Labs, Aurobindo, Lupin, Macleods, MSN Laboratories, Sun	Xigduo XR	4/8/2026	For the treatment of type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycemic control in adults when treatment with both dapagliflozin and metformin is appropriate.
Deflazacort	Upsher-Smith	Emflaza (oral suspension)	6/3/2026	For the treatment of Duchenne muscular dystrophy in patients 5 years of age and older.
Eltrombopag Olamine	Zenara, Dr. Reddy's Laboratories	Promacta (12.5 mg), Promacta (25 mg), Promacta (50 mg), Promacta (75 mg)	4/27/2026, 3/19/2026	For the treatment of thrombocytopenia in adult and pediatric patients with chronic immune thrombocytopenia, thrombocytopenia in patients with chronic hepatitis C to allow interferon based therapy and severe aplastic anemia in appropriate patients.
Emtricitabine; Rilpivirine Hydrochloride; Tenofovir Disoproxil Fumarate	Laurus Labs	Complera	3/17/2026	For the treatment of HIV-1 infection as complete regimen in adults and pediatric patients meeting the approved labeling criteria.

09 New Generics (cont'd)

Generic Name	ANDA Applicants	Brand Name	ANDA Approval Date	ANDA Indications
Eribulin Mesylate	XGen Pharma	Halaven	4/3/2026	For the treatment of adults with metastatic breast cancer who have previously received at least two chemotherapeutic regimens for metastatic disease and for treatment of adults with unresectable or metastatic liposarcoma who have received a prior anthracycline containing regimen.
Estrogens Conjugated	Prasco (AG)	Premarin (tablets)	4/2/2026	For the treatment of moderate to severe vasomotor symptoms associated with menopause, moderate to severe vulvar and vaginal atrophy due to menopause, hypoestrogenism due to hypogonadism, castration or primary ovarian failure, prevention of postmenopausal osteoporosis and palliative treatment of advanced androgen dependent carcinoma of the prostate and advanced breast cancer in appropriately selected patients.
Ferric Citrate	Teva	Auryxia	3/12/2026	For the treatment of iron deficiency anemia in adults with chronic kidney disease not on dialysis and for the control of serum phosphorus levels in adults with chronic kidney disease on dialysis.
Fluorometholone	DifGen	FML (suspension)	5/18/2026	For the treatment of corticosteroid responsive inflammation of the palpebral and bulbar conjunctiva, cornea and anterior segment of the globe.
Fluticasone Propionate	Glenmark	Flovent HFA	3/24/2026	For the maintenance treatment of asthma as prophylactic therapy in patients 4 years of age and older.

09 New Generics (cont'd)

Generic Name	ANDA Applicants	Brand Name	ANDA Approval Date	ANDA Indications
Glycerol Phenylbutyrate	MSN Laboratories, Aurobindo, Teva	Ravicti	4/17/2026, 4/16/2026	For the chronic management of adult and pediatric patients with urea cycle disorders who cannot be managed by dietary protein restriction and or amino acid supplementation alone.
Halobetasol Propionate	Lacer (AG)	Ultravate (lotion)	3/16/2026	For the topical treatment of plaque psoriasis in patients 12 years of age and older.
Hydrocortisone Sodium Succinate	Apotex, Zydus	Solu-Cortef	6/15/2026, 6/2/2026	For the treatment of adrenocortical insufficiency and as adjunctive therapy in severe allergic, inflammatory, rheumatic, dermatologic, endocrine, gastrointestinal, hematologic, ophthalmic, respiratory and others conditions responsive to corticosteroids.
Ipratropium Bromide	Armstrong Pharmaceuticals	Atrovent HFA	3/13/2026	For the maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease, including chronic bronchitis and emphysema.
Lacosamide	Glenmark	Vimpat (injection)	3/20/2026	For the treatment of partial onset seizures in patients 1 month of age and older, and as adjunctive therapy for primary generalized tonic clonic seizures in patients 4 years of age and older.
Liraglutide Recombinant	Biocon	Victoza	6/2/2026	For the treatment of type 2 diabetes mellitus in adults and pediatric patients 10 years of age and older as an adjunct to diet and exercise and to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease.
Liraglutide Recombinant	Biocon	Saxenda	5/15/2026	For chronic weight management as an adjunct to a reduced calorie diet and increased physical activity in appropriate adult and pediatric patients.
Metformin Hydrochloride; Sitagliptin Phosphate	Apotex, Sandoz	Janumet	5/28/2026	For the treatment of type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycemic control in adults.

10 Recall Notifications

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

Date	Drug Name	Reason for Recall	Company Name
4/28/2026	Webcol Large Alcohol Prep Pads (70% isopropyl alcohol)	Voluntary recall of select lots due to microbial contamination identified as Paenibacillus phoenicis.	Cardinal Health
4/29/2026	Tandem Mobi Insulin Pumps	Correction issued because affected software versions may incorrectly detect a false motor failure (Malfunction 12), causing the pump to stop insulin delivery.	Tandem Diabetes Care
5/1/2026	Omnipod 5 Pods	Pods from certain lots may have a small tear in the internal tubing that delivers insulin, causing insulin leakage inside the Pod and under-delivery of insulin.	Insulet

11 Safety Notifications

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

Safety Notification

FDA announced a labeling correction for all TRUE METRIX Blood Glucose Monitoring Systems after determining that the current Owner's Booklets/System Instructions for Use did not adequately emphasize that users should seek immediate medical attention if an E-5 error code was received while experiencing symptoms of hyperglycemia. The E-5 error code may indicate either an extremely high blood glucose value (greater than 600mg/dL) or a test strip error. Failure to promptly seek medical 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 one death associated with the E-5 error code. The labeling and instructions for use are being updated to better guide patients and caregivers.

FDA updated the labeling for capecitabine and fluorouracil to strengthen warnings about the risks associated with dihydropyrimidine dehydrogenase (DPD) 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 increased 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 initiating treatment unless immediate therapy is necessary, advises avoiding use in patients with complete DPD deficiency, and recommends individualized dosing for patients with partial DPD deficiency. The FDA will continue to monitor this safety issue and evaluate the need for additional regulatory actions.

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, including 2 fatalities, and determined that many cases did not respond to traditional antiseizure medications but resolved after vitamin B6 administration. Based on the available evidence, the FDA concluded there is reasonable evidence of a causal association between drug products containing carbidopa/levodopa and vitamin B6 deficiency associated seizures. The agency now recommends evaluating baseline vitamin B6 levels before treatment, periodic monitoring during therapy, and considering vitamin B6 supplementation as needed, particularly at higher doses.

FDA issued a Drug Safety Communication to alert healthcare professionals and patients about serious postmarketing cases of drug-induced liver injury (DILI), including fatal cases, associated with Tavneos (avacopan). Some cases involved vanishing bile duct syndrome (VBDS), a rare condition that may result in permanent liver damage. Although hepatotoxicity was previously described in the prescribing information, the FDA identified DILI and VBDS with fatal outcomes as new safety concerns. The agency recommends routine liver function monitoring, prompt discontinuation of Tavneos in patients with signs or symptoms of liver injury, and referral to a hepatologist if abnormalities persist. The FDA will continue to monitor this safety issue and provide updates as additional information becomes available.

12 Shortages

Generic name (Brand Name)	Presentation	Date of Update	Related Information
Activated Charcoal (Actidose, Actidose Aqua)	Oral Suspension, 208 mg/1 mL	5/15/2026	Discontinuation of the manufacture of the drug.
Aprepitant (Emend)	Powder for Oral Suspension, 125mg	4/8/2026	To be discontinued in approximately November 2026.
Azithromycin (Zithromax)	Tablet: 500 mg, 250 mg	4/9/2026	Discontinuation of the manufacture of the drug.
Crinecerfont (Crenessity)	Capsule: 25mg	4/28/2026	Neurocrine is discontinuing only the 25 mg soft gel capsule dose strength (NDC 70370-5025-01). The 50mg and 100mg soft gel capsule dose strength (NDC 70370-5050-1 and 70370-5100-1), and 50 mg/mL oral solution will continue to be marketed (NDC 70370-5250-1).
Dacomitinib (Vizimpro)	Tablet: 15 mg, 30 mg, 45mg.	6/8/2026	Discontinuation of the manufacture of the drug.
Donepezil Hydrochloride; Memantine Hydrochloride (Namzaric)	Capsule, Extended Release: 10 mg; 28 mg, 10 mg; 14 mg.	6/15/2026	Discontinuation of the manufacture of the drug.
Emtricitabine (Emtriva)	Capsule: 200mg	6/17/2026	Product expected to be available until March 2027.
Emtricitabine (Emtriva)	Oral Solution: 10 mg/1 mL	6/17/2026	Product expected to be available until March 2027.

12 Shortages (Cont'd)

Generic name (Brand Name)	Presentation	Date of Update	Related Information
Etravirine (Intelence)	Tablet: 100mg	4/28/2026	Discontinuation of the manufacture of the drug.
Icatibant Acetate Injection (Firazyr)	Injection: 10 mg/1 mL	5/7/2026	Discontinuation of the manufacturer of the drug.
Icosapent Ethyl (Vascepa)	Capsule: 1g	4/1/2026	Discontinuation of the manufacture of the drug.
Idelalisib (Zydelig)	Tablet: 100mg, 150mg	4/7/2026	Discontinuation in the manufacturing of the drug.
Ketorolac Tromethamine (Toradol)	Tablet: 10mg	4/20/2026	Discontinuation of the manufacture of the drug.
Lamotrigine (Lamictal XR)	Tablet, Extended Release: 25 mg, 50 mg, 100 mg, 200 mg, 250, 300mg	4/29/2026	Discontinuation of the manufacture of the drug.
Leflunomide (Arava)	Tablet: 10 mg, 20 mg, 100 mg	6/8/2026	Discontinuation of the manufacture of the drug.
Liraglutide Injection (Victoza, Saxenda)	Injection: 6 mg/1 mL	5/14/2026	Discontinuation of the manufacture of the drug.
Lorlatinib (Lorbrena)	Tablet: 25mg	6/15/2026	Supply expected to exhaust 6/30/2026; NDC 0069-0227-01 25 mg; 30 tablets bottle with a child-resistant closure will continue to be manufactured; Discontinuation of the manufacture of this presentation.

12 Shortages (Cont'd)

Generic name (Brand Name)	Presentation	Date of Update	Related Information
Nitrofurantoin (Furadantin)	Oral suspension: 25 mg/5 mL	4/10/2026	Discontinuation of the manufacture of the drug.
Nitroglycerin (Rectiv)	Ointment: 0.4%	4/14/2026	Discontinuation of the manufacture of the drug.
Palbociclib (Ibrance)	Capsule: 75mg, 100mg	4/22/2026	Discontinuation of the manufacturing of the capsule presentation. 75 mg Tablet NDC 0069-0284-03 will continue to be manufactured., Discontinuation of the manufacturing of the capsule presentation. 100 mg Tablet NDC 0069-0486-03 will continue to be manufactured.
Semaglutide (Rybelsus)	Tablet: 3mg, 7mg, 14mg	6/4/2026	Discontinuation of the manufacture of the drug. These products will be replaced by Ozempic (semaglutide) tablets.
Sulconazole Nitrate (Exelderm)	Solution: 1.0% 5 mL, 1.0% 30 mL	5/8/2026	Discontinuation of the manufacture of the drug, Discontinuation of the manufacture of the drug. Manufactured for JG Pharma.
Tiagabine Hydrochloride (Gabitril)	Tablet: 2mg, 4mg, 12mg, 16mg	4/15/2026	Discontinuation of the manufacture of the drug.
Ursodiol (Actigall)	Capsule: 300 mg	4/6/2026	Discontinuation of the manufacture of the drug.

ProCare Rx

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