



Insights on the Drugs Pipeline

EXPLORING THE CHANGES IN THE
DRUGS MARKET.

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**Insights on the Drugs
Pipeline | Q3 2026**

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Overview

ProCare 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

The Evolution of GLP-1 Treatment From Injection to Oral Therapy

Glucagon-like peptide-1 (GLP-1) receptor agonists are incretin-based therapies that have significantly transformed the management of type 2 diabetes mellitus (T2DM) and obesity. These medications enhance glucose-dependent insulin secretion while exerting several complementary metabolic effects, including delayed gastric emptying, suppression of glucagon secretion, and activation of hypothalamic pathways involved in appetite regulation and satiety. Through these mechanisms, GLP-1 receptor agonists can improve glycemic control, promote weight reduction, and, depending on the specific agent and patient population, provide cardiovascular and renal benefits. Consequently, these medications have become an important component of the pharmacologic management of patients with T2DM and obesity.

In addition to their clinical benefits, GLP-1 receptor agonists have a well-established safety profile, although adverse effects must be considered when selecting therapy. The most commonly reported adverse effects are gastrointestinal in nature, including nausea, vomiting, diarrhea, constipation, and abdominal discomfort. These effects are generally more pronounced during treatment initiation and dose escalation and may decrease as patients become accustomed to therapy. Although hypoglycemia is uncommon when GLP-1 receptor agonists are used alone, the risk may increase when they are administered concomitantly with insulin or insulin secretagogues, particularly sulfonylureas. Furthermore, semaglutide-containing products carry a boxed warning regarding the risk of thyroid C-cell tumors and are contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Therefore, although GLP-1 receptor agonists offer substantial therapeutic benefits, their safety profile and individual patient characteristics must be considered when selecting an appropriate treatment.



As the use of GLP-1 receptor agonists has expanded, different formulations and routes of administration have become available, providing clinicians with greater flexibility when tailoring treatment to individual patients. Currently, GLP-1 therapies are available in both oral and injectable formulations, with semaglutide serving as a prominent example of an agent available through both routes. Oral semaglutide is marketed as Ozempic tablets and is indicated for the treatment of T2DM, whereas injectable semaglutide is available as Ozempic and Wegovy, which have different approved indications and dosing regimens. This distinction is clinically important because, although these products contain the same active ingredient, they should not be considered interchangeable solely on the basis of their dosage strengths or route of administration.

Among the available oral formulations, Ozempic tablets provides an alternative for patients who may prefer oral therapy over subcutaneous administration. However, its administration requirements may present challenges for some patients. Conventional oral semaglutide must be taken on an empty stomach upon waking with a limited amount of water, and patients must wait before consuming food, beverages, or other oral medications. Although these instructions are intended to optimize drug absorption, they may be inconvenient for patients who have complex morning routines or take multiple medications. In contrast, injectable semaglutide formulations offer a less frequent administration schedule. Ozempic is administered subcutaneously once weekly and is primarily used in the management of T2DM, with additional cardiovascular and renal risk-reduction indications in appropriate patient populations.

Similarly, Wegovy is administered once weekly and, in combination with a reduced-calorie diet and increased physical activity, is indicated for chronic weight management in eligible patients and for reducing the risk of major adverse cardiovascular events in certain adults with established cardiovascular disease who are overweight or obese.

More recently, the development of newer oral GLP-1 therapies has further expanded the available treatment options. Orforglipron, for example, is an orally administered, nonpeptide GLP-1 receptor agonist that offers a different approach to oral GLP-1 therapy. Unlike oral semaglutide, orforglipron can be administered once daily without regard to meals. This distinction may be particularly relevant for patients who find the administration requirements associated with oral semaglutide difficult to follow. Because orforglipron is a nonpeptide molecule, it does not require the same formulation strategy used to facilitate the gastrointestinal absorption of peptide-based oral semaglutide. As a result, its administration requirements may be simpler, potentially providing patients with greater flexibility in incorporating treatment into their daily routines.

Given the differences among these formulations, the introduction of newer oral GLP-1 therapies raises an important clinical question: what advantages do oral formulations offer compared with established injectable therapies, and what challenges may limit their use? One of the most apparent advantages is the route of administration. Oral therapy provides a needle-free alternative to subcutaneous injections, which may be particularly beneficial for patients who are uncomfortable with needles, have difficulty with injection administration, or simply prefer taking tablets. By eliminating the need for injections, oral formulations may also avoid injection-site reactions and concerns related to injection technique. Consequently, the availability of oral GLP-1 therapy may improve treatment acceptability among certain patient populations. In addition to the route of administration, storage requirements may represent another potential advantage of oral formulations. Oral GLP-1 medications generally do not require refrigeration after dispensing, which may facilitate storage and transportation and provide greater convenience for patients. This characteristic can be especially relevant for individuals who travel frequently or have limited access to appropriate medication storage.

Therefore, when considered together, the needle-free route and simplified storage requirements may make oral therapy an attractive alternative for patients who face barriers associated with injectable medications. Importantly, the potential convenience of oral therapy does not necessarily come at the expense of clinical efficacy. Clinical studies have demonstrated that both oral and injectable semaglutide can produce clinically meaningful reductions in glycated hemoglobin (HbA1c) and body weight in appropriate patient populations. These findings suggest that oral formulations can provide substantial therapeutic benefits while offering an alternative route of administration. However, efficacy alone should not determine formulation selection, as differences in administration frequency and treatment requirements may influence adherence and overall treatment success.

Despite their potential advantages, oral GLP-1 formulations also present several challenges. One important consideration is adherence. Although oral administration may be preferred by some patients, tablets generally require daily administration, whereas injectable formulations such as semaglutide are administered once weekly. Patients may forget to take daily medications or may have difficulty incorporating a medication into their daily routine. Therefore, the assumption that an oral formulation will automatically improve adherence should be avoided. Instead, adherence should be evaluated on an individual basis, considering whether the patient is more likely to consistently follow a daily oral regimen or a weekly injectable regimen. Furthermore, the administration requirements of some oral GLP-1 formulations may reduce their practical convenience. For example, oral semaglutide must be taken under specific conditions related to fasting, water volume, and the timing of subsequent food, beverages, and medications. These requirements may be particularly challenging for patients who take several medications in the morning or have difficulty maintaining a consistent daily schedule. In this regard, newer agents such as orforglipron may provide an advantage because they can be administered without regard to meals. Nevertheless, differences in administration requirements should be carefully considered when determining which formulation is most appropriate for an individual patient. Another consideration involves transitioning between oral and injectable GLP-1 therapies.

Although different formulations may contain the same or similar pharmacologic mechanisms, their dosing regimens are not necessarily directly interchangeable. Therefore, treatment transitions should be guided by the specific product labeling and the patient's clinical circumstances rather than by assuming a direct dose conversion. For newer oral agents, the absence of an established direct conversion pathway to a subcutaneous formulation may also become relevant if a patient's treatment needs change. This consideration further emphasizes the importance of selecting a formulation that aligns with both the patient's current needs and the anticipated long-term treatment plan.

Finally, gastrointestinal tolerability remains an important consideration regardless of the route of administration. Nausea, vomiting, diarrhea, constipation, and other gastrointestinal adverse effects are among the most common adverse effects associated with GLP-1 receptor agonists. The frequency and severity of these effects may vary according to the specific medication, dose, treatment duration, and patient characteristics. Consequently, although oral formulations may eliminate injection-related concerns, they do not eliminate the class-associated gastrointestinal adverse effects. Patient counseling regarding expected adverse effects and gradual dose escalation may therefore remain essential to improving tolerability and supporting continued treatment. Overall, the development of newer oral GLP-1 receptor agonists represents an important advancement in the management of T2DM and obesity by expanding treatment options beyond injectable therapy. Oral formulations offer a needle-free alternative that may improve convenience, acceptability, and treatment accessibility for patients who are hesitant to use or have difficulty administering injectable medications. Certain newer oral agents may also provide greater flexibility by eliminating some of the administration restrictions associated with earlier oral formulations. Nevertheless, oral therapy is not universally preferable, as daily administration, formulation-specific instructions, gastrointestinal adverse effects, and differences in approved indications may present challenges for certain patients. Conversely, injectable GLP-1 receptor agonists continue to provide established efficacy, less frequent dosing, and important cardiovascular, metabolic, and renal benefits in appropriate patient populations.

References:

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Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Pimicotinib Hydrochloride (EMD Serono (Merck KGaA); Abbisko Therapeutics)	NDA Filed	2H 2026	Pimicotinib is an orally administered, highly selective and potent small-molecule inhibitor of CSF-1R in development for the treatment of tenosynovial giant cell tumor (TGCT); oral
Povetacicept (Vertex; Alpine Immune Sciences)	BLA Filed	11/30/2026	Povetacicept is a fusion protein and dual inhibitor of the BAFF (B cell activating factor) and APRIL (a proliferation inducing ligand) cytokines in development for the treatment of immunoglobulin A nephropathy (IgAN); SC
Remibrutinib (Rhapsido - Novartis)	Supplemental NDA	2H 2026	A kinase inhibitor indicated for the treatment of chronic spontaneous urticaria (CSU) in adult patients who remain symptomatic despite H1 antihistamine treatment. Now, Novartis has submitted a sNDA for Chronic inducible urticaria (CIndU); oral
Mavacamten (Camzyos - Bristol-Myers Squibb; MyoKardia)	Supplemental NDA	9/30/2026	Potential treatment for adolescents (ages 12 years to <18 years) with symptomatic obstructive hypertrophic cardiomyopathy (oHCM); oral
Tirabrutinib Hydrochloride (Velexbu - Gilead; Ono Pharmaceutical; Deciphera)	NDA Filed	12/18/2026	A second generation Bruton tyrosine kinase inhibitor in development for the treatment of relapsed or refractory primary central nervous system lymphoma (PCNSL); oral
Upadacitinib (Rinvoq - AbbVie)	Supplemental NDA; Supplemental NDA	4Q 2026; 02/2027	For the treatment of adult and adolescent patients living with non-segmental vitiligo (NSV), and adult and adolescent patients with severe alopecia areata (AA); oral

Specialty Pipeline (cont'd)

Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Talazoparib Tosylate (Talzenna - Pfizer; Medivation)	Supplemental NDA	4Q 2026	New indication for Talzenna in combination with enzalutamide for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC); oral
Mitapivat (Mitapivat - Agios)	Supplemental NDA	11/1/2026	An oral pyruvate kinase (PK) activator designed for the treatment of adult patients with non-transfusion-dependent and transfusion-dependent alpha- or beta-thalassemia; oral
Molgramostim (Molbreevi - PARI; Savara; Fujifilm)	BLA Filed	11/22/2026	A recombinant human granulocyte-macrophage colony-stimulating factor (rhGM-CSF), is being investigated as a potential treatment for autoimmune pulmonary alveolar proteinosis (aPAP) and other respiratory conditions; Inhalation
Venglustat Malate (Sanofi; Genzyme)	NDA Filed	11/25/2026	An oral glucosylceramide synthase inhibitor (GCSI), for the treatment of neurological manifestations of type 3 Gaucher disease (GD3), a rare lysosomal storage disorder; oral
Neladalkib (GSK; Nuvalent)	NDA Filed	11/27/2026	An anaplastic lymphoma kinase (ALK) selective inhibitor in development for the treatment of ALK-positive non-small cell lung cancer. (NSCLC); oral
Bezuclastinib (Bezuclastinib - Unum Therapeutics; Cogent Biosciences)	NDA Filed	11/30/2026	A selective tyrosine kinase inhibitor in development for the treatment of non-advanced systemic mastocytosis and gastrointestinal stromal tumors; oral
Secukinumab (Cosentyx - Novartis)	Supplemental BLA	2H 2026	A novel biologic option for Polymyalgia rheumatica (PMR), offering clinically meaningful sustained remission and glucocorticoid-sparing benefits; SC

Specialty Pipeline (cont'd)

Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Relugrigine (Relugrigine - Praxis Precision Medicines)	NDA Filed	12/27/2026	Relugrigine is a sodium channel functional state modulator in development for the treatment of SCN2A and SCN8A developmental and epileptic encephalopathies; oral
Risankizumab (Skyrizi - Boehringer Ingelheim; AbbVie)	Supplemental BLA	4Q 2026	An interleukin-23 antagonist indicated for the treatment of moderate-to-severe plaque psoriasis in adults and pediatric patients 6 years of age and older who are candidates for systemic therapy or phototherapy, active psoriatic arthritis in adults and pediatric patients 6 years of age and older, moderately to severely active Crohn's disease in adults, and moderately to severely active ulcerative colitis in adults. The new sBLA seeks to add SC induction as an alternative to the approved IV induction, enabling a fully subcutaneous induction-to-maintenance pathway with q8w SC maintenance dosing; SC
Bepirovirsen (GSK; Ionis Pharmaceuticals)	NDA Filed	10/26/2026	A triple action antisense oligonucleotide in development for the treatment of adults with chronic hepatitis B; SC
Tildrakizumab (Ilumya - Sun; Merck & Co (MSD))	Supplemental BLA	10/29/2026	An interleukin-23 antagonist indicated for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. The new sBLA seeks to add a new indication for the treatment of adults with active psoriatic arthritis; SC
Gefurulimab (AstraZeneca; Alexion)	BLA Filed	2H 2026	An investigational complement C5 inhibitor, is a dual-binding nanobody optimized for subcutaneous self-administration in development as a treatment for AChR-Ab+ gMG (generalized Myasthenia Gravis); SC

Generic Name (Brand Name - Manufacturer)	Current Status	Anticipated Approval	What is this drug being developed for?
Denecimig (Mim8 - Novo; Genmab)	BLA Filed	3Q 2026	An investigational FVIIIa mimetic bispecific antibody in development for the prophylaxis of hemophilia A regardless of inhibitor status; SC
Cemdisiran (Regeneron; Alnylam Pharmaceuticals)	NDA Filed	Nov/2026	An investigational siRNA therapeutic targeting complement factor 5 (C5) in development for the treatment of adult patients with generalized myasthenia gravis who are anti-acetylcholine receptor (AChR) antibody-positive; SC

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Biosimilar Pipeline

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Generic Name (Brand Name-Manufacturer)	Reference Biologic	FDA Possible Approval Date
Denosumab (Teva)	Xgeva	2H 2026
Bevacizumab (Henlius)	Avastin	4Q 2026
Pertuzumab (Biocon)	Perjeta	4Q 2026
Aflibercept (Sam Chun Dang Pharm; Fresenius Kabi)	Eylea; Eylea HD	10/2026
Ranibizumab (Lucamzi - Stada; Xbrane; Valorum Biologics)	Lucentis	10/29/2026
Golimumab (Avtos, Teva; Alvogen; Alvotech)	Simponi; Simponi Aria	12/2026
Aflibercept (Teva; Alvogen; Alvotech)	Eylea; Eylea HD	12/2026
Denosumab (Acvybra, Dr. Reddy's Laboratories; Alvogen; Alvotech)	Prolia	12/2026
Abatacept (Dr. Reddy's Laboratories)	Orencia	12/2026
Denosumab (Xbonzy, Dr. Reddy's Laboratories; Alvotech)	Xgeva	12/2026
Omalizumab (Amneal; Kashiv Biosciences)	Xolair	01/2027
Omalizumab (Teva)	Xolair	01/2027
Trastuzumab (Tanvex)	Enhertu	01/2027
Vedolizumab (Teva; Alvogen; Alvotech)	Entyvio	04/2027

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New Drug Entities	Details
Lunsotogene parvec-cwha (Otarmeni)	<p>Dosage Form: Intracochlear infusion</p> <p>Indication: Treatment of pediatric and adult patients with severe-to-profound and profound sensorineural hearing loss (any frequency >90 dB HL) associated with molecularly confirmed biallelic variants in the OTOF gene, preserved outer hair cell function, and no prior cochlear implant in the same ear.</p> <p>Comparables: None</p> <p>Guidelines: Sensorineural Hearing Loss. American Academy of Audiology: Practice Guidelines and Standards. https://www.audiology.org/practice-resources/practice-guidelines-and-standards/</p>
Allogeneic regulatory T cell immunotherapy with HSPC and T cells-vldq (Tregzi)	<p>Dosage Form: Intravenous infusion</p> <p>Indication: Use in matched donor hematopoietic stem cell transplantation with myeloablative preparative regimen, for hematopoietic and immunologic reconstitution and to improve chronic graft-versus-host disease-free survival, in the treatment of adults with hematological malignancies.</p> <p>Comparables: None</p> <p>Guidelines: Chronic graft-versus-host disease. National Comprehensive Cancer Network (NCCN) Version 3.2025. https://www.nccn.org/guidelines/guidelines-detail?category=3&id=1501</p>
Atacicept-vymj (Trutakna)	<p>Dosage Form: Subcutaneous injection</p> <p>Indication: A B-lymphocyte stimulator (BLyS)-specific inhibitor and A Proliferation Inducing Ligand (APRIL) blocker indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression.</p> <p>Comparables: Voyxact (sibeprenlimab-szsi), Filspari (sparsentan)</p> <p>Guidelines: The Kidney Disease: Improving Global Outcomes (KDIGO) 2025 Clinical Practice Guideline for the Management of Immunoglobulin A Nephropathy. https://kdigo.org/wp-content/uploads/2025/09/KDIGO-2025-IgAN-IgAV-Guideline.pdf</p>

New Drug Entities	Details
Baxdrostat (Baxfendy)	<p>Dosage Form: Tablets</p> <p>Indication: Is an aldosterone synthase inhibitor indicated for the treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adults who are not adequately controlled on other agents.</p> <p>Comparables: Tryvio, generic MRAs mineralocorticoid, Spirolactone</p> <p>Guidelines: Hypertension. 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: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines</p>
Bulevirtide-gmod (Hepcludex)	<p>Dosage Form: Subcutaneous Injection</p> <p>Indication: Treatment of chronic hepatitis delta virus (HDV) infection in adults without cirrhosis or with compensated cirrhosis.</p> <p>Comparables: Pegasys (peginterferon alfa-2a)</p> <p>Guidelines: Chronic hepatitis delta virus (HDV). 2025 American Gastroenterological Association. https://gastro.org/clinical-guidance/management-of-hepatitis-delta-virus/</p>
Ensitrelvir (Xocova)	<p>Dosage Form: Tablets</p> <p>Indication: Post-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and adolescents 12 years of age and older following contact with an individual who has COVID-19.</p> <p>Comparables: Paxlovid (nirmatrelvir/ritonavir)</p> <p>Guidelines: COVID-19. 2026 IDSA Guidelines on the Treatment and Management of Patients with COVID-19. https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/</p>
Finafloxacin (Xtoro)	<p>Dosage Form: Otic Suspension: finafloxacin 0.3%</p> <p>Indication: Is a quinolone antimicrobial indicated for the treatment of acute otitis externa (AOE) with or without an otowick, caused by susceptible strains of <i>Pseudomonas aeruginosa</i> and <i>Staphylococcus aureus</i> in patients age 1 year and older.</p> <p>Comparables: Ciprofloxacin/dexamethasone otic 0.3%–0.1%, Ofloxacin otic solution 0.3%</p> <p>Guidelines: Acute Otitis Externa. American Academy of Otolaryngology-Head and Neck Surgery Foundation. https://journals.sagepub.com/doi/full/10.1177/0194599813517083</p>

New Drug Entities	Details
Marnetegrane autotemcel (Kresladi)	<p>Dosage Form: Intravenous infusion</p> <p>Indication: Is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of pediatric patients with severe leukocyte adhesion deficiency-I (LAD-I) due to biallelic variants in ITGB2 without an available human leukocyte antigen (HLA)-matched sibling donor for allogeneic hematopoietic stem cell transplant.</p> <p>Comparables: None</p> <p>Guidelines: Severe leukocyte adhesion deficiency-I (LAD-I). International clinical consensus on leukocyte adhesion deficiency-I: Modified Delphi analysis. https://pmc.ncbi.nlm.nih.gov/articles/PMC13091988/</p>
Pivekimab Sunirine-PVZY (Decnupaz)	<p>Dosage Form: Intravenous infusion</p> <p>Indication: Is a CD123-directed antibody and alkylating agent conjugate indicated for the treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN).</p> <p>Comparables: Elzonris (tagraxofusp-erzs)</p> <p>Guidelines: Acute Myeloid Leukemia. National Comprehensive Cancer Network (NCCN) Version 5.2026- July 15, 2026. https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf</p>
Sonrotoclax (Beqalzi)	<p>Dosage Form: Tablets</p> <p>Indication: Is a BCL-2 inhibitor indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor.</p> <p>Comparables: Jaypirca (pirtobrutinib), Breyanzi (lisocabtagene maraleucel)</p> <p>Guidelines: Mantle cell lymphoma (MCL). National Comprehensive Cancer Network (NCCN) Version 4.2026 - May 20, 2026. https://www.nccn.org/patients/guidelines/content/PDF/Mantle-patient-guideline.pdf</p>
Tebipenem pivoxil (Utebzi)	<p>Dosage Form: Tablets</p> <p>Indication: Is a penem antibacterial indicated for the treatment of complicated urinary tract infections (cUTI), including pyelonephritis, caused by the following susceptible microorganisms: Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae species complex, Klebsiella oxytoca, and Enterococcus faecalis in adult patients who have limited or no alternative oral treatment options.</p> <p>Comparables: Ertapenem, Imipenem/Cilastatin</p> <p>Guidelines: Complicated Urinary Tract Infections (cUTI). IDSA 2025 Guideline Update on Complicated Urinary Tract Infections. https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/</p>

New Drug Entities	Details
Veligrotug-vvze (Lumvoa)	<p>Dosage Form: Intravenous infusion</p> <p>Indication: Is an insulin-like growth factor-1 receptor inhibitor indicated for the treatment of thyroid eye disease regardless of thyroid eye disease activity or duration.</p> <p>Comparables: Teprotumumab-trbw (Tepezza)</p> <p>Guidelines: Thyroid eye disease.2026 American Academy of Ophthalmology. https://eyewiki.org/Thyroid_Eye_Disease#Management</p>
Vepdegestrant (Veppanu)	<p>Dosage Form: Tablets</p> <p>Indication: Is a heterobifunctional protein degrader indicated for the treatment of adults with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, estrogen receptor-1 (ESR1)-mutated advanced or metastatic breast cancer, as detected by an FDA-authorized test, with disease progression following at least one line of endocrine therapy.</p> <p>Comparables: Faslodex (fulvestrant), Orserdu (elacestrant) and Inluriyo (imlunestrant)</p> <p>Guidelines: Metastatic Breast Cancer. National Comprehensive Cancer Network (NCCN) Version 3.2026 - May 8, 2026. https://www.nccn.org/patients/guidelines/content/PDF/stage_iv_breast-patient.pdf</p>

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New Drug Formulations

Details

Anifrolumab-fnia (Saphnelo)

New Dosage Form: Injection for subcutaneous use. Injection: 120 mg/0.8 mL in a single-dose prefilled syringe or single dose autoinjector (SAPHNELO PEN).

Indication: Is a type I interferon (IFN) receptor antagonist indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy.

Comparables: Belimumab (Benlysta)

Guidelines: Systemic lupus erythematosus (SLE). 2025 American College of Rheumatology (ACR) Guideline for the Treatment of Systemic Lupus Erythematosus. <https://assets.contentstack.io/v3/assets/bltee37abb6b278ab2c/bltdf97323a3723de0f/lupus-guideline-sle-2025.pdf>

Beclomethasone dipropionate/formoterol fumarate/glycopyrrolate (Trimbow)

New Dosage Form: New Combination. Beclomethasone dipropionate (BDP) (an inhaled corticosteroid [ICS]), formoterol fumarate (FF) (a long acting beta2-adrenergic agonist [LABA]), and glycopyrrolate (G) (an anticholinergic)

Indication: Is a combination of beclomethasone dipropionate (BDP) (an inhaled corticosteroid [ICS]), formoterol fumarate (FF) (a long acting beta2-adrenergic agonist [LABA]), and glycopyrrolate (G) (an anticholinergic) indicated for the maintenance treatment of asthma in adult patients aged 18 years and older.

Comparables: Trelegy Ellipta (fluticasone furoate / umeclidinium / vilanterol), Breztri Aerosphere (budesonide / glycopyrrolate / formoterol fumarate)

Guidelines: Asthma Management and Prevention. 2026 Summary Guide for Asthma Management and Prevention For Adults, Adolescents, and Children 6-11 years. [HTTPS://ginasthma.org/wp-content/uploads/2026/07/GINA-Summary-Guide-2026-WEB-WMS.pdf](https://ginasthma.org/wp-content/uploads/2026/07/GINA-Summary-Guide-2026-WEB-WMS.pdf)

New Drug Formulations	Details
Cefepime and zidebactam (Zaynich)	<p>New Dosage Form: New Combination: Cefepime, a cephalosporin antibacterial, and zidebactam, a beta-lactamase inhibitor and non-beta-lactam antibacterial</p> <p>Indication: Is a combination of cefepime, a cephalosporin antibacterial, and zidebactam, a beta-lactamase inhibitor and non-beta-lactam antibacterial indicated for the treatment of adult patients with complicated urinary tract infections (cUTI) including pyelonephritis caused by designated susceptible microorganisms.</p> <p>Comparables: Avycaz (ceftazidime 2 grams and avibactam 0.5 grams), Recarbrio (imipenem 500 mg, cilastatin 500 mg, and relebactam 250 mg), Vabomere (meropenem 2 grams and vaborbactam 2 grams), Zerbaxa (ceftolozane 1 gram / tazobactam 0.5 gram), Carbapenems (e.g., Meropenem), Aminoglycosides (e.g., Amikacin)</p> <p>Guidelines: Complicated Urinary Tract Infections (cUTI). IDSA 2025 Guideline Update on Complicated Urinary Tract Infections. https://www.idsociety.org/practice-guideline/complicated-urinary-tract-infections/</p>
Doravirine and islatravir (Idvynso)	<p>New Dosage Form: New Combination: doravirine, a HIV-1 nonnucleoside reverse transcriptase inhibitor (NNRTI), and islatravir, a nucleoside analog reverse transcriptase inhibitor (NRTI)</p> <p>Indication: Is a two-drug combination of doravirine, a HIV-1 nonnucleoside reverse transcriptase inhibitor (NNRTI), and islatravir, a nucleoside analog reverse transcriptase inhibitor (NRTI), and is indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of virologic treatment failure and no known substitutions associated with resistance to doravirine.</p> <p>Comparables: Delstrigo, Dovato, Biktarvy</p> <p>Guidelines: HIV. 2026 Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV. https://clinicalinfo.hiv.gov/sites/g/files/mnhszr391/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf</p>

New Drug Formulations	Details
Isatuximab-irfc (Sarclisa Escena)	<p>New Dosage Form: Injection for subcutaneous use. Injection: 100 mg/5 mL (20 mg/mL) solution in single-dose vial, 500 mg/25 mL (20 mg/mL) solution in single-dose vial.</p> <p>Indication: Is a CD38-directed cytolytic antibody indicated:</p> <ul style="list-style-type: none"> • in combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 1 prior line of therapy including lenalidomide and a proteasome inhibitor. • in combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy. • in combination with bortezomib, lenalidomide and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplant (ASCT). <p>Comparables: Daratumumab and hyaluronidase-fihj (Darzalex Faspro), Isatuximab-irfc (Sarclisa)</p> <p>Guidelines: Multiple Myeloma. National Comprehensive Cancer Network (NCCN) Version 2.2027 - September 24, 2026. https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf</p>
Nilotinib (Cavhanza)	<p>New Dosage Form: Orally Disintegrating Tablets</p> <p>Indication: Is a kinase inhibitor indicated for the treatment of:</p> <ul style="list-style-type: none"> • Adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. • Adult patients with chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib. <p>Comparables: Danziten (nilotinib tablets), Tasigna / Generic (nilotinib capsules).</p> <p>Guidelines: Chronic Myeloid Leukemia. National Comprehensive Cancer Network (NCCN) Version 1.2026 - July 16, 2025. https://www.nccn.org/patients/guidelines/content/PDF/cml-patient.pdf</p>

New Drug Formulations	Details
Ruxolitinib extended-release (Jakafi XR)	<p>New Dosage Form: Extended-release tablets: 11 mg, 22 mg, 33 mg, 44 mg and 55 mg. Other dosage: JAKAFI tablets: 5 mg, 10 mg, 15 mg, 20 mg and 25 mg.</p> <p>Indication: Is a kinase inhibitor indicated for treatment of:</p> <ul style="list-style-type: none">• intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis in adults.• polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea.• steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older.• chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older. <p>Comparables: Jakafi</p> <p>Guidelines: Myeloproliferative Neoplasms. National Comprehensive Cancer Network (NCCN) Version 3.2026 - September 18,2026. https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf</p>
Trabectedin (Evdia)	<p>New Dosage Form: Injection: 1 mg/20 mL (0.05 mg/mL) solution in a single dose vial</p> <p>Indication: Is an alkylating drug indicated for the treatment of adult patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen</p> <p>Comparables: Trabectedin (Yondelis)</p> <p>Guidelines: Soft Tissue Sarcoma. National Comprehensive Cancer Network (NCCN) Version 5.2026 - July 23, 2026. https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf</p>

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New Indications	Details
Afamitresgene autoleucel (Tecelra)	For the expansion of the treatment population: inclusion of pediatric patients 12 years of age and older with unresectable or metastatic synovial sarcoma who have received prior chemotherapy therapy.
Atezolizumab (Tecentriq)	For the addition of the Indication: as adjuvant treatment of adult patients with Muscle Invasive Bladder Cancer (MIBC) after cystectomy who have circulating tumor DNA molecular residual disease (ctDNA MRD) as determined by an FDA-authorized test.
Atezolizumab and hyaluronidase-tqjs (Tecentriq Hybreza)	For the addition of the Indication: as adjuvant treatment of adult patients with Muscle Invasive Bladder Cancer (MIBC) after cystectomy who have circulating tumor DNA molecular residual disease (ctDNA MRD) as determined by an FDA-authorized test.
Belzutifan (Welireg)	For the addition of the Indication: in combination with lenvatinib, is indicated for the treatment of adult patients with advanced ccRCC following a programmed death receptor-1 (PD-1) or programmed death-ligand 1 (PD-L1) inhibitor.
Benralizumab (Fasenra)	For the addition of the Indication: treatment of adult and pediatric patients aged 12 years and older with hypereosinophilic syndrome (HES) without an identifiable nonhematologic secondary cause.
Capivasertib (Truqap)	For the addition of the Indication: in combination with abiraterone and prednisone for the treatment of adult patients with metastatic androgen pathway modulation-naïve or sensitive (mAPMN/S) prostate cancer that is PTEN-deficient as detected by an FDA-authorized test.
Dasiglucagon (Zegalogue)	For the expansion of the treatment population: treatment of severe hypoglycemia in adults and pediatric patients with diabetes who weigh at least 20 kg.

New Indications	Details
Datopotamab deruxtecan-dlnk (Datroway)	For the addition of the Indication: <ul style="list-style-type: none"> adult patients with locally advanced or metastatic epidermal growth factor receptor (EGFR)-mutated non-small cell lung cancer (NSCLC) who have received prior EGFR-directed therapy and platinum-based chemotherapy adult patients with unresectable or metastatic triple-negative breast cancer (TNBC) who are not candidates for PD-1/PD-L1 inhibitor therapy
Decitabine and cedazuridine (Inqovi)	For the addition of the Indication: in combination with venetoclax for the treatment of newly diagnosed acute myeloid leukemia (AML) in adults 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy.
Dextromethorphan HBr / bupropion HCl (Auvelity)	For the addition of the Indication: treatment of agitation associated with dementia due to Alzheimer's disease
Durvalumab (Imfinzi)	For the addition of the Indication: in combination with Bacillus Calmette-Guérin (BCG) for the treatment of adult patients with BCG-naïve, high-risk non-muscle-invasive bladder cancer (NMIBC).
Eculizumab-aagh (Epysqli)	For the addition of the Indication: treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.
Eculizumab-aeeb (Bkemv)	For the addition of the Indication: treatment of neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin-4 (AQP4) antibody positive.
Efgartigimod alfa and hyaluronidase-qvfc (Vyvgart Hytrulo)	For the update of the Indication: treatment of generalized myasthenia gravis (gMG) in adult patients removing the prior qualifier of adult patients who are anti-acetylcholine receptor (AChR) antibody positive.
Efgartigimod alfa-fcab (Vyvgart)	For the update of the Indication: treatment of generalized myasthenia gravis (gMG) in adult patients removing the prior qualifier of adult patients who are anti-acetylcholine receptor (AChR) antibody positive.
Enfortumab vedotin-ejfv (Padcev)	For the update of the Indication: In combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph, as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment, is indicated for the treatment of adult patients with muscle invasive bladder cancer (MIBC).

New Indications	Details
Exagamglogene autotemcel (Casgevy)	For the addition of the Indication: treatment of sickle cell disease (SCD) with recurrent vaso-occlusive crises and transfusion dependent thalassemia (TDT) in patients ages 2 to <12 years.
Fam-trastuzumab deruxtecan-nxki; herein referred to as T-DXd (Enhertu)	For the addition of the Indication: <ul style="list-style-type: none"> • as neoadjuvant treatment of adult patients with HER2-positive (IHC 3+ or ISH+) Stage II or III breast cancer, as determined by an FDA authorized test followed by a taxane, trastuzumab, and pertuzumab (THP) • as adjuvant treatment of adult patients with HER2-positive (IHC 3+ or ISH+) breast cancer who have residual invasive disease following neoadjuvant trastuzumab (with or without pertuzumab) and taxane based treatment.
Guselkumab (Tremfya)	For the addition of the treatment: inclusion of a radiographic response section for the treatment of adults with moderately to severely active psoriatic arthritis for the 100 mg administered by subcutaneous injection at Week 0, Week 4, and every 8 weeks thereafter dosing regimen.
Ipilimumab (Yervoy)	For the update of the Indication: in combination with nivolumab, is indicated for the treatment of adult and pediatric patients 12 years and older with unresectable or metastatic microsatellite instability-high (MSIH) or mismatch repair deficient (dMMR) colorectal cancer (CRC) as determined by an FDA authorized test.
Lecanemab-irmb (Leqembi IQLIK)	For the update of the Indication: New starting dosage regimen subcutaneous (under the skin) formulation of Leqembi (lecanemab-irmb).
Linacotide (Linzess)	For the expansion of the treatment population: functional constipation (FC) in pediatric patients 2 years of age and older.
Marstacimab-hncq (Hypavzi)	For the update of the Indication: <ul style="list-style-type: none"> • hemophilia A (congenital factor VIII deficiency) with or without factor VIII inhibitors, or • hemophilia B (congenital factor IX deficiency) with or without factor IX and for the expansion of the treatment population: routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adults and pediatric patients 6 years of age and older inhibitors.
Ocrelizumab (Ocrevus)	For the addition of the Indication: Relapsing-remitting MS, in pediatric patients 10 years of age and older who weigh 25 kg or more.

New Indications	Details
Olezarsen (Tryngolza)	For the addition of the Indication: To reduce TG and the risk of acute pancreatitis in adults with severe hypertriglyceridemia (sHTG: TG greater than or equal to 500 mg/dL).
Olopatadine and mometasone (Ryaltris)	For the expansion of the treatment population: Extends the indication for Ryaltris nasal spray to pediatric patients 6 years of age and older for the treatment of symptoms of seasonal allergic rhinitis.
Palbociclib (Ibrance)	For the addition of the Indication: in combination with trastuzumab, with or without pertuzumab, and endocrine therapy for the maintenance treatment of adult patients with HR-positive, HER2-positive locally advanced or metastatic breast cancer following induction treatment.
Pembrolizumab (Keytruda)	For the update of the Indication: in combination with enfortumab vedotin-ejfv, as neoadjuvant treatment and then continued after cystectomy as adjuvant treatment, is indicated for the treatment of adult patients with muscle invasive bladder cancer (MIBC).
Pembrolizumab (Keytruda)	For the update of the Indication: in combination with belzutifan, is indicated for the adjuvant treatment of adult patients with ccRCC at intermediate-high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions.
Pembrolizumab (Keytruda)	For the update of the Indication: in combination with sacituzumab govitecan-hziy, for the first-line treatment of adult patients with unresectable locally advanced or metastatic TNBC whose tumors express PD-L1 (CPS ≥ 10) as determined by an FDA-authorized test.
Pembrolizumab and berahyaluronidase alfa-pmph (Keytruda Qlex)	For the update of the indication: in combination with belzutifan, is indicated for the adjuvant treatment of adult patients with ccRCC at intermediate high or high risk of recurrence following nephrectomy or following nephrectomy and resection of metastatic lesions.
Pembrolizumab and berahyaluronidase alfa-pmph (Keytruda Qlex)	For the update of the indication: in combination with sacituzumab govitecan-hziy, for the first-line treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (TNBC) whose tumors express PD-L1 (CPS ≥ 10) as determined by an FDA-authorized test.

New Indications	Details
Pembrolizumab and berahyaluronidase alfa-pmph (Keytruda Qlex)	For the update of the Indication: in combination with enfortumab vedotin-ejfv (Padcev, Astellas Pharma) as neoadjuvant treatment (before surgery) followed by adjuvant treatment after cystectomy (surgery to remove the bladder) for adults with muscle invasive bladder cancer (MIBC).
Risankizumab-rzaa (Skyrizi)	For the expansion of treatment population: <ul style="list-style-type: none"> inclusion of pediatrics patients 6 years of age and older with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy inclusion of pediatric patients 6 years of age and older with active psoriatic arthritis
Roflumilast (Zoryve)	For the expansion of the treatment population: inclusion pediatric patients 2 years of age and older with plaque psoriasis, including intertriginous areas. For the addition of Indication: ZORYVE cream, 0.05%, is indicated for the topical treatment of mild to moderate atopic dermatitis in pediatric patients 2 to 5 years of age.
Sacituzumab govitecan-hziy (Trodelvy)	For the update of the Indication: First Line: <ul style="list-style-type: none"> As a single agent for the first-line treatment of adult patients with unresectable locally advanced or metastatic triple negative breast cancer (TNBC) who are not candidates for PD-1 or PD-L1 inhibitor-based therapy. In combination with pembrolizumab or pembrolizumab and berahyaluronidase alfa-pmph for the first-line treatment of adult patients with unresectable locally advanced or metastatic TNBC whose tumors express PD-L1 (CPS $\geq$ 10) as determined by an FDA-authorized test. Second line or Later: <ul style="list-style-type: none"> For the treatment of adult patients with unresectable locally advanced or mTNBC who have received two or more prior systemic therapies, at least one of them for metastatic disease.
Secukinumab (Cosentyx)	For the expansion of the treatment population: inclusion of pediatric patients 12 years of age and older with active ankylosing spondylitis (AS).
Selexipag (Uptravi)	For the addition of the Indication: in pediatric patients aged 2 years and older. UPTRAVI reduces NT-proBNP and is expected to delay disease progression and reduce the risk of hospitalization for PAH.
Tocilizumab-aazg (Tyenne)	For the expansion of treatment population: inclusion of hospitalized pediatric patients aged 2 years and older with coronavirus disease 2019 (COVID-19) who are receiving systemic corticosteroids and require supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).

New Indications	Details
Zenocutuzumab-zbco (Bizengri)	For the addition of the Indication: adults with advanced, unresectable or metastatic cholangiocarcinoma harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy.

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Atacicept-vymj (Trutakna)

Dosage Form: Subcutaneous injection**Indication:** A B-lymphocyte stimulator (BLyS)-specific inhibitor and A Proliferation Inducing Ligand (APRIL) blocker indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression.**Comparables:** Voyxact (sibeprenlimab-szsi), Filspari (sparsentan)**Guidelines:** The Kidney Disease: Improving Global Outcomes (KDIGO) 2025 Clinical Practice Guideline for the Management of Immunoglobulin A Nephropathy.<https://kdigo.org/wp-content/uploads/2025/09/KDIGO-2025-IgAN-IgAV-Guideline.pdf>

Baxdrostat (Baxfendy)

Dosage Form: Tablets**Indication:** Is an aldosterone synthase inhibitor indicated for the treatment of hypertension in combination with other antihypertensive drugs, to lower blood pressure in adults who are not adequately controlled on other agents.**Comparables:** Tryvio, generic MRAs mineralocorticoid, Spirolactone**Guidelines:** Hypertension. 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: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines

Bulevirtide-gmod (Hepcludex)

Dosage Form: Subcutaneous Injection**Indication:** Treatment of chronic hepatitis delta virus (HDV) infection in adults without cirrhosis or with compensated cirrhosis.**Comparables:** Pegasys (peginterferon alfa-2a)**Guidelines:** Chronic hepatitis delta virus (HDV). 2025 American Gastroenterological Association. <https://gastro.org/clinical-guidance/management-of-hepatitis-delta-virus/>

Ensitrelvir (Xocova)

Dosage Form: Tablets**Indication:** Post-exposure prophylaxis of coronavirus disease 2019 (COVID-19) in adults and adolescents 12 years of age and older following contact with an individual who has COVID-19.**Comparables:** Paxlovid (nirmatrelvir/ritonavir)**Guidelines:** COVID-19. 2026 IDSA Guidelines on the Treatment and Management of Patients with COVID-19. <https://www.idsociety.org/practice-guideline/covid-19-guideline-treatment-and-management/>

In-Market Brands	Details
Finafloxacin (Xtoro)	<p>Dosage Form: Otic Suspension: finafloxacin 0.3%</p> <p>Indication: Is a quinolone antimicrobial indicated for the treatment of acute otitis externa (AOE) with or without an otowick, caused by susceptible strains of <i>Pseudomonas aeruginosa</i> and <i>Staphylococcus aureus</i> in patients age 1 year and older.</p> <p>Comparables: Ciprofloxacin/dexamethasone otic 0.3%–0.1%, Ofloxacin otic solution 0.3%</p> <p>Guidelines: Acute Otitis Externa. American Academy of Otolaryngology-Head and Neck Surgery Foundation. https://journals.sagepub.com/doi/full/10.1177/0194599813517083</p>
Sonrotoclax (Beqalzi)	<p>Dosage Form: Tablets</p> <p>Indication: Is a BCL-2 inhibitor indicated for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL) after at least two lines of systemic therapy, including a Bruton's tyrosine kinase (BTK) inhibitor.</p> <p>Comparables: Jaypirca (pirtobrutinib), Breyanzi (lisocabtagene maraleucel)</p> <p>Guidelines: Mantle cell lymphoma (MCL). National Comprehensive Cancer Network (NCCN) Version 4.2026 - May 20, 2026. https://www.nccn.org/patients/guidelines/content/PDF/Mantle-patient-guideline.pdf</p>
Veligrotug-vvze (Lumvoa)	<p>Dosage Form: Intravenous infusion</p> <p>Indication: Is an insulin-like growth factor-1 receptor inhibitor indicated for the treatment of thyroid eye disease regardless of thyroid eye disease activity or duration.</p> <p>Comparables: Teprotumumab-trbw (Teppezza)</p> <p>Guidelines: Thyroid eye disease.2026 American Academy of Ophthalmology. https://eyewiki.org/Thyroid_Eye_Disease#Management</p>
Vepdegestrant (Veppanu)	<p>Dosage Form: Tablets</p> <p>Indication: Is a heterobifunctional protein degrader indicated for the treatment of adults with estrogen receptor (ER)-positive, human epidermal growth factor receptor 2 (HER2)-negative, estrogen receptor-1 (ESR1)-mutated advanced or metastatic breast cancer, as detected by an FDA-authorized test, with disease progression following at least one line of endocrine therapy.</p> <p>Comparables: Faslodex (fulvestrant), Orserdu (elacestrant) and Inluriyo (imlunestrant)</p> <p>Guidelines: Metastatic Breast Cancer. National Comprehensive Cancer Network (NCCN) Version 3.2026 - May 8, 2026. https://www.nccn.org/patients/guidelines/content/PDF/stage_iv_breast-patient.pdf</p>

In-Market Brands	Details
Anifrolumab-fnia (Saphnelo)	<p>New Dosage Form: Injection, for subcutaneous use. Injection: 120 mg/0.8 mL in a single-dose prefilled syringe or single dose autoinjector (SAPHNELO PEN).</p> <p>Indication: Is a type I interferon (IFN) receptor antagonist indicated for the treatment of adult patients with moderate to severe systemic lupus erythematosus (SLE), who are receiving standard therapy.</p> <p>Comparables: Belimumab (Benlysta)</p> <p>Guidelines: Systemic lupus erythematosus (SLE). 2025 American College of Rheumatology (ACR) Guideline for the Treatment of Systemic Lupus Erythematosus. https://assets.contentstack.io/v3/assets/bltee37abb6b278ab2c/bltdf97323a3723de0f/lupus-guideline-sle-2025.pdf</p>
Doravirine and islatravir (Idvynso)	<p>New Dosage Form: New Combination: doravirine, a HIV-1 nonnucleoside reverse transcriptase inhibitor (NNRTI), and islatravir, a nucleoside analog reverse transcriptase inhibitor (NRTI)</p> <p>Indication: Is a two-drug combination of doravirine, a HIV-1 nonnucleoside reverse transcriptase inhibitor (NNRTI), and islatravir, a nucleoside analog reverse transcriptase inhibitor (NRTI), and is indicated as a complete regimen for the treatment of HIV-1 infection in adults to replace the current antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen with no history of virologic treatment failure and no known substitutions associated with resistance to doravirine.</p> <p>Comparables: Delstrigo, Dovato, Biktarvy</p> <p>Guidelines: HIV. 2026 Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents With HIV. https://clinicalinfo.hiv.gov/sites/g/files/mnh5zr391/files/guidelines/documents/adult-adolescent-arv/guidelines-adult-adolescent-arv.pdf</p>
Isatuximab-irfc (Sarclisa Escena)	<p>New Dosage Form: Injection for subcutaneous use. Injection: 100 mg/5 mL (20 mg/mL) solution in single-dose vial, 500 mg/25 mL (20 mg/mL) solution in single-dose vial.</p> <p>Indication: Is a CD38-directed cytolytic antibody indicated:</p> <ul style="list-style-type: none"> • in combination with pomalidomide and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least 1 prior line of therapy including lenalidomide and a proteasome inhibitor. • in combination with carfilzomib and dexamethasone, for the treatment of adult patients with relapsed or refractory multiple myeloma who have received 1 to 3 prior lines of therapy. • in combination with bortezomib, lenalidomide and dexamethasone, for the treatment of adult patients with newly diagnosed multiple myeloma who are not eligible for autologous stem cell transplant (ASCT). <p>Comparables: Daratumumab and hyaluronidase-fihj (Darzalex Faspro), Isatuximab-irfc (Sarclisa)</p> <p>Guidelines: Multiple Myeloma. National Comprehensive Cancer Network (NCCN) Version 2.2027 - September 24, 2026. https://www.nccn.org/professionals/physician_gls/pdf/myeloma.pdf</p>

In-Market Brands	Details
Nilotinib (Cavhanza)	<p>New Dosage Form: Orally Disintegrating Tablets</p> <p>Indication: Is a kinase inhibitor indicated for the treatment of:</p> <ul style="list-style-type: none"> • Adult patients with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase. • Adult patients with chronic phase (CP) and accelerated phase (AP) Ph+ CML resistant to or intolerant to prior therapy that included imatinib. <p>Comparables: Danziten (nilotinib tablets), Tasigna / Generic (nilotinib capsules)</p> <p>Guidelines: Chronic Myeloid Leukemia. National Comprehensive Cancer Network (NCCN) Version 1.2026 - July 16, 2025. https://www.nccn.org/patients/guidelines/content/PDF/cml-patient.pdf</p>
Ruxolitinib extended-release (Jakafi XR)	<p>New Dosage Form: Extended-release tablets: 11 mg, 22 mg, 33 mg, 44 mg and 55 mg. Other dosage: JAKAFI tablets: 5 mg, 10 mg, 15 mg, 20 mg and 25 mg.</p> <p>Indication: Is a kinase inhibitor indicated for treatment of:</p> <ul style="list-style-type: none"> • intermediate or high-risk myelofibrosis, including primary myelofibrosis, post-polycythemia vera myelofibrosis, and post-essential thrombocythemia myelofibrosis in adults. • polycythemia vera in adults who have had an inadequate response to or are intolerant of hydroxyurea. • steroid-refractory acute graft-versus-host disease in adult and pediatric patients 12 years and older. • chronic graft-versus-host disease after failure of one or two lines of systemic therapy in adult and pediatric patients 12 years and older. <p>Comparables: Jakafi</p> <p>Guidelines: Myeloproliferative Neoplasms. National Comprehensive Cancer Network (NCCN) Version 3.2026 - September 18, 2026. https://www.nccn.org/professionals/physician_gls/pdf/mpn.pdf</p>
Trabectedin (Evdia)	<p>New Dosage Form: Injection: 1 mg/20 mL (0.05 mg/mL) solution in a single dose vial</p> <p>Indication: Is an alkylating drug indicated for the treatment of adult patients with unresectable or metastatic liposarcoma or leiomyosarcoma who received a prior anthracycline-containing regimen</p> <p>Comparables: Trabectedin (Yondelis)</p> <p>Guidelines: Soft Tissue Sarcoma. National Comprehensive Cancer Network (NCCN) Version 5.2026 - July 23, 2026. https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf</p>

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Generic Name	ANDA Applicants	Brand Name	ANDA Approval Date	ANDA Indications
Dextromethorphan Hydrobromide; Quinidine Sulfate	Sun, Hetero, Actavis	Nuedexta	7/30/2026	Indicated for the treatment of pseudobulbar affect (PBA).
Sugammadex Sodium	Zydus, Tamarang, Sun, Sandoz, Qilu Pharmaceutical (Hainan), Mylan, MSN Laboratories, Lupin, Hikma, Gland Pharma, Dr. Reddy's Laboratories, B. Braun, Aspiro Pharma, Sterisience, Fresenius Kabi	Bridion	7/28/2026	Indicated for the reversal of neuromuscular blockade induced by rocuronium bromide and vecuronium bromide in adult and pediatric patients undergoing surgery.
Rifapentine	Macleods	Priftin	7/27/2026	<ul style="list-style-type: none"> Is a rifamycin antimycobacterial drug indicated in patients 12 years of age and older for the treatment of active pulmonary tuberculosis (TB) caused by Mycobacterium tuberculosis in combination with one or more antituberculosis (anti-TB) drugs to which the isolate is susceptible. Indicated for the treatment of latent tuberculosis infection (LTBI) caused by M. tuberculosis in combination with isoniazid in patients 2 years of age and older at high risk of progression to TB disease.

New Generics (cont'd)

Generic Name	ANDA Applicants	Brand Name	ANDA Approval Date	ANDA Indications
Metformin Hydrochloride; Sitagliptin Phosphate	PH Health	Janumet XR	7/24/2026	Is a combination of sitagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, and metformin hydrochloride (HCl), a biguanide indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
Dimethyl Sulfoxide	Stira	RIMSO-50	7/24/2026	Indicated for the symptomatic relief of patients with interstitial cystitis.
Oxymetazoline Hydrochloride	Mayne Pharma (AG), Sun	Rhofade	7/15/2026	Is an alpha1A adrenoceptor agonist indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.
Tapentadol Hydrochloride	Novitium	Nucynta (oral solution)	7/13/2026	Indicated for the management of acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate in adults.
Ferric Carboxymaltose	Sandoz, Mylan	Injectafer	7/1/2026	Indicated for the treatment of: iron deficiency anemia (IDA) in: adult and pediatric patients 1 year of age and older who have either intolerance or an unsatisfactory response to oral iron. adult patients who have non-dialysis dependent chronic kidney disease. iron deficiency in adult patients with heart failure and New York Heart Association class II/III to improve exercise capacity.
Methylphenidate	Neos Therapeutics (AG)	Cotempla XR-ODT	7/1/2026	Is a central nervous system (CNS) stimulant indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in pediatric patients 6 to 17 years of age.

New Generics (cont'd)

Generic Name	ANDA Applicants	Brand Name	ANDA Approval Date	ANDA Indications
Ascorbic Acid; Biotin; Cholecalciferol; Cyanocobalamin; Dexpanthenol; Folic Acid; Niacinamide; Pyridoxine; Riboflavin; Thiamine; Tocopherol Acetate; Vitamin A; Vitamin K	Apotex	Infuvite Pediatric	6/24/2026	Is a combination of vitamins indicated for the prevention of vitamin deficiency in pediatric patients up to 11 years of age receiving parenteral nutrition.

Recall Notifications

Date	Drug Name	Reason for Recall	Company Name
7/18/2026	Cetirizine Hydrochloride Tablets USP 5mg	Potential cross contamination with Ranitidine	Unique Pharmaceutical Laboratories
8/10/2026	Tyenne Injection 400 mg/20 mL vial	Due to Presence of Glass Particles	Fresenius Kabi
8/21/2026	Thyroid Tablets, USP 30 mg	Potential for the Product to be Superpotent	Vitruvias Therapeutics, Inc

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Notices

Safety Notification

FDA announced that it has approved changes to the Drugs Facts Label of the over-the-counter (OTC) weight loss drug, alli (orlistat) 60 mg capsules, to warn of risks of acute kidney injury, which is a rare side effect of the medication. The labeling now advises consumers to ask a health care provider before using alli if they have ever had kidney disease or kidney stones. The labeling changes also tell consumers to stop using alli and ask a doctor if they develop symptoms of kidney injury or kidney stones, such as back or groin pain, painful urination, blood in the urine, feet and leg swelling, or less frequent urination. The risk of renal (kidney) injury is now described consistently across the labeling for all FDA approved orlistat products, including those available OTC and those available in a higher strength by prescription.

Generic name (Brand Name)	Presentation	Date of Update	Related Information
Aspirin (Aspirin)	Suppository 300mg	7/23/2026	Discontinuation of the manufacture of the drug.
Disopyramide Phosphate (Norpace CR)	Extended release capsule: 100mg, 150mg	8/24/2026	Discontinuation of the manufacture of the drug.
Fluticasone Propionate and Salmeterol Xinafoate (Advair HFA)	Aerosol Inhaler: 45ug;21ug , 115ug;21ug , 230ug;21ug	7/27/2026	The anticipated date that GSK will cease distribution of the presentation is approximately December 31, 2026. The 120 dose presentation of this product will still be available.
Glyburide (Diabeta)	Tablet: 1.25mg, 2.5mg, 5mg	8/10/2026	A business decision was made to discontinue manufacture of the drug.
Glycerol Phenylbutyrate (Ravicti)	Oral Liquid 1.1g/1mL	9/1/2026	Discontinuation in the manufacturing of the drug product.
Hydromorphone Hydrochloride (Hydromorphone Hydrochloride)	Suppository 3mg	7/23/2026	Discontinuation of the manufacture of the drug.
Insulin Glargine-aglr (Rezvoglar)	Injection 100iU/1mL	9/1/2026	A business decision was made to discontinue manufacture of the drug. Distribution projected to end June 2027. If patients or prescribers have any questions, the Lilly Answers Center (1-800-545-5979) is available Monday through Friday from 9am to 8pm for assistance.

Shortages (Cont'd)

Generic name (Brand Name)	Presentation	Date of Update	Related Information
Insulin Lispro Protamine and Insulin Lispro (Humalog Mix 75/25)	Injection 100iU/1mL	9/1/2026	A business decision was made to discontinue manufacture of the drug. Distribution projected to end June 2027. If patients or prescribers have any questions, the Lilly Answers Center (1-800-545-5979) is available Monday through Friday from 9am to 8pm for assistance.
Ivermectin (Stromectol)	Tablet 3mg	9/29/2026	Product will be discontinued on 10/31/2026.
Liraglutide (Saxenda)	Injection 6mg/1mL	8/25/2026	Product will be available until discontinuation in January 2027; Discontinuation of the manufacture of the drug.
Lopinavir and Ritonavir (Kaletra)	Oral solution: 80mg/1mL;20mg/1mL Tablets: 100mg;25mg , 200mg;50mg	7/24/2026	Discontinuation of the manufacture of the drug.
Medroxyprogesterone Acetate (Provera)	Tablet: 10mg, 2.5mg	8/31/2026	Discontinuation of the manufacture of the drug; Withdrawal from sale expected September 2026.
Mesalamine (Pentasa)	Extended release capsule: 250mg, 500mg	9/16/2026	Product is anticipated to be available until December 31, 2027.
Morphine Sulfate (Morphine Sulfate)	Suppository: 5mg, 10mg, 20mg, 30mg	7/23/2026	Discontinuation of the manufacture of the drug.
Ritonavir (Norvir)	Oral powder: 100mg Tablet 100mg	7/24/2026	Discontinuation of the manufacture of the drug.

Shortages (Cont'd)

Generic name (Brand Name)	Presentation	Date of Update	Related Information
Rivaroxaban (Xarelto)	Suspension 155mg	9/18/2026	Business Decision.
Belladonna and Opium (Belladonna and Opium)	Suppository: 16.2mg;60mg , 16.2mg;30mg	7/23/2026	Discontinuation of the manufacture of the drug.

ProCare Rx

DRUG INFORMATION CENTER:

1-877-741-7470

druginfo@ProCare Rx.com



ACCREDITED

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

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