Medication Pipeline Report 2026 | Q3

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GLOSSARY:

PO ..... Oral

IV ..... Intravenous

SC ..... Subcutaneous

IM ..... Intramuscular

INH ..... Inhaled

INJ ..... Injectable

TD ..... Transdermal

ID ..... Intradermal

IVT ..... Intravitreal

TOP ..... Topical

OPHT ..... Ophthalmic

IN ..... Intranasal

IA ..... Intra-arterial

IT ..... Intrathecal

OT ..... Otic

CVC ..... Catheter Lock Solution

ICI ..... Intracameral Implant

INTRODUCTION

Welcome to the Judi Rx Pipeline Report. This quarterly publication is developed by our Clinical Pharmacists and is prepared using a wide range of clinical resources. The Judi Rx Pipeline Report is designed to keep you up to date on the latest drug approvals and well-versed on what is to come in the FDA drug pipeline. Our pipeline report is one of the many ways we, at Judi Rx, demonstrate our commitment to providing clients and partners the tools and resources they desire.

WHO WE ARE

Judi Rx is a next generation pharmacy benefits manager, overseeing prescription benefit plans on behalf of employers, unions, and government entities. Determined to transform an outdated model, Judi Rx's mission is to change the way prescription benefits are priced and administered in the US, unlocking enduring social change. Through our platform approach, Judi Rx delivers data-driven insights and actionable strategies that reduce costs, while improving patient outcomes. Our commitment to innovation, technology and service is the reason why Judi Rx is among the fastest-growing PBMs in the country.

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The drug pipeline is subject to change.
Information in this report is current as of:
09/02/2026

TRUTAKNA™ (ATACICEPT) SC, EMD SERONO (MERCK KGAA) VERA THERAPEUTICS

Approval Date	07/07/2026
Indication	Indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression.
Clinical Overview	Immunoglobulin A (IgA) nephropathy (IgAN) is a B-cell–mediated autoimmune kidney disease characterized by the accumulation of IgA. The resulting immune response generates circulating immune complexes that deposit in the kidneys, triggering inflammation and progressive glomerular damage. Over time, this can lead to significant loss of kidney function; an estimated 20% to 50% of patients with IgAN progress to end-stage renal disease (ESRD) requiring dialysis or kidney transplantation within 20 years of diagnosis. IPD estimates the U.S. prevalence to be 329 per 1,000,000 people. The clinical presentation is highly variable, with signs and symptoms that are often silent or easily attributed to other conditions. IgAN can only definitively be diagnosed with a kidney biopsy, which is usually performed once a patient has persistent proteinuria (defined as a urine protein-to-creatinine ratio [UPCR] >0.5 g/g). Kidney transplantation has been the most effective option for patients with ESRD caused by IgAN; however, IgAN recurrence is possible, with a recurrence rate of ~1%–10% each year
Considerations	• Granted FDA accelerated approval, priority review, and breakthrough therapy • First FDA-approved IgAN therapy to inhibit both B-cell activating actor (BAFF) and a proliferation-inducing ligand (APRIL) • Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial
Select Alt Therapies	Voyxact® (sibeprenlimab) SC, Fabhalta™ (iptacopan) PO, Tarpeyo® (budesonide) PO

SARCLISA ESCENA™ (ISATUXIMAB-IRFC) SC ON BODY INJECTOR (OBI), SANOFI

Approval Date	07/09/2026
Indication	Treatment of multiple myeloma in combination with pomalidomide and dexamethasone in certain patients who have received at least 1 prior line of therapy, in combination with carfilzomib and dexamethasone for the treatment relapsed or refractory multiple myeloma in patients who have received 1-3 prior lines of therapy, and in combination with bortezomib, lenalidomide, and dexamethasone for the treatment of certain newly diagnosed patients.
Clinical Overview	Multiple Myeloma (MM) is a type of blood cancer that starts in the plasma cells. It is the second most common hematologic malignancy, affecting about 36,000 newly diagnosed Americans annually, with most cases occurring in older adults, males, and African Americans. MM 5-year survival rate is 63.7%. Treatment consists of combination therapy that includes an immunomodulatory agent, a proteasome inhibitor, corticosteroids, and/or a monoclonal antibody. For eligible patients, initial therapy is often followed by autologous stem cell transplantation and then maintenance therapy to prolong remission.
Considerations	• FDA approved for all approved multiple myeloma indications of the IV formulation of Sarclisa™; orphan drug designation • Maintains clinical efficacy of IV formulation while generally having milder injection-site reactions • Healthcare administered • Shorter administration timed compared to IV (75-200 minutes) compared to 6-20 minutes for SC • First anticancer treatment to be delivered via an automated OBI
Select Alt Therapies	Other cytotoxic chemotherapy in Multiple Myeloma such as: Sarclisa™ (isatuximab) IV, Darzalex® (daratumumab) IV, Darzalex® (daratumumab) SC, Doxil® (doxorubicin hydrochloride) IV, BiCNU® (carmustine) IV, Alkeran™ (melphalan hydrochloride) IV

REVTORPYK™ (GEDATOLISIB) IV, PFIZER, CELCUITY

Approval Date	07/15/2026
Indication	In combination with fulvestrant, with or without palbociclib, for the treatment of adults with hormone receptor (positive (HR+), human epidermal growth factor receptor 2 (HER2)-negative (HER2−) locally advanced or metastatic breast cancer (BC) without a detected PIK3CA mutation following progression on or after at least one line of endocrine therapy (ET) in the metastatic setting.
Clinical Overview	Hormone receptor-positive (HR+), HER2-negative (HER2−) breast cancer is the most common subtype of breast cancer, accounting for approximately 70% of cases. In the United States, more than 320,000 women are expected to be diagnosed with breast cancer in 2026, corresponding to approximately 225,000 new HR+/HER2− cases annually. HR+/HER2− tumors are driven by estrogen and/or progesterone signaling and do not overexpress HER2. While many patients are diagnosed with early-stage disease, recurrence can occur years after diagnosis, and metastatic disease remains incurable. Patients may present with a breast lump, breast swelling, nipple discharge, skin changes, or axillary lymphadenopathy.
Considerations	• Granted priority review from FDA • First and only FDA-approved therapy that inhibits all class I PI3K isoforms (α, β, δ, γ) and mTOR complexes mTORC1 and mTORC2 • Severe hyperglycemia has been reported; fasting glucose levels and A1C should be tested at baseline, with optimal glucose control achieved prior to each gedatolisib infusion.
Select Alt Therapies	This is a first in class medication, but there are many medications currently used to treat HR+/HER2- breast cancer such as Endocrine Therapies, CDK4/6 Inhibitors, Kinase Inhibitors, Immune Checkpoint Inhibitors, etc.

JIDEYTRO™ (ZIDESAMTINIB) PO, NUVALENT

Approval Date	07/22/2026
Indication	Treatment of adults with locally advanced or metastatic ROS1-positive non-small cell lung cancer (NSCLC) who have previously received a ROS1 tyrosine kinase inhibitor.
Clinical Overview	Non-small cell lung cancer (NSCLC) accounts for approximately 80% to 85% of all lung cancer cases and represents a heterogeneous group of malignancies arising from epithelial cells of the lung. NSCLC is generally classified into three major histologic subtypes: adenocarcinoma, squamous cell carcinoma, and large cell carcinoma. The treatment landscape for NSCLC has evolved substantially with the development of biomarker-driven targeted therapies and immune checkpoint inhibitors. Broad molecular profiling is now standard of care, particularly for patients with non-squamous NSCLC, to identify actionable driver mutations that may guide therapy selection. Lung cancer is by far the leading cause of cancer death in the US, accounting for about 1 in 5 of all cancer deaths. Each year, more people die of lung cancer than of colon, breast, and prostate cancer combined. Overall, the chance that a person will develop lung cancer in their lifetime is about 1 in 19.
Considerations	• It is a next-generation, ROS1-selective tyrosine kinase inhibitor designed to address resistance mutations improve central nervous system (CNS) penetrations while minimizing off-target TRK inhibition • Received FDA Breakthrough Therapy and Orphan Drug Designation • Recommended to monitor creatinine phosphokinase (CPK) level at baseline, every 2 weeks during first month of treatment, then every 1 to 2 months and as clinically indicated
Select Alt Therapies	Augtyro® (repotrectinib) PO, Ibtrozi® (taletrectinib) PO, Rozlytrek® (entrectinib) PO, Xalkori® (crizotinib) PO

LYTENAVA™ (BEVACIZUMAB) IVT, OUTLOOK THERAPEUTICS

Approval Date	07/24/2026
Indication	Treatment of neovascular (wet) age-related macular degeneration (AMD) [wAMD].
Clinical Overview	Wet age-related macular degeneration is a condition of the eye that causes blurred vision or decreases central vision. Symptoms usually worsen quickly and may include difficulty adjusting to low light levels, a need for brighter lights when reading, visual distortions, and difficulty recognizing faces. This disease is most common in those ≥50 years old and accounts for 20% of all age-related macular degeneration. Diabetic retinopathy (DR) and diabetic macular edema are caused from damage overtime to the structures of the retina. DR and macular edema are major complications of diabetes with about 75% of people with type I diabetes developing DR and 25% of those with diabetes developing macular edema. Blockage to a vein that carries blood away from the retina can lead to a retinal vein occlusion (RVO). RVOs can cause swelling of the macula leading to blurry vision and even vision loss.
Considerations	• First and only FDA-approved ophthalmic formulation of bevacizumab for this indication in the United States. Repackaged bevacizumab was used prior. • Administered as a monthly intravitreal injection by a qualified physician • Anticipated wholesale acquisition cost (WAC) of approximately $500 to $1,000 per injection
Select Alt Therapies	Beovu® (brolucizumab) IVT, Eylea® (aflibercept) and biosimilars IVT, Lucentis® (ranibizumab) and biosimilars IVT, Vabysmo™ (faricimab) IVT

XIMRIXBY® (RITUXIMAB- CDXX) IV, DR. REDDY'S LABORATORIES, FRESENIUS KABI

Approval Date	07/31/2026
Indication	Non-Hodgkin's Lymphoma, Chronic Lymphocytic Leukemia, Rheumatoid Arthritis (RA) in combination with methotrexate in adult patients with moderately-to severely active RA who have inadequate response to one or more TNF antagonist therapies, and Granulomatosis with Polyangiitis (GPA) (Wegener's Granulomatosis) and Microscopic Polyangiitis (MPA) in adult patients in combination with glucocorticoids.
Clinical Overview	Non-Hodgkin's Lymphoma is a type of cancer that starts in the lymphatic system and is characterized by painless swelling of the lymph nodes, night sweats, unexplained fevers, unintentional weight loss, chest pain, or trouble breathing. There are an estimated 79,320 new cases in 2026 with a 5-year survival rate of 74.3%. Chronic Lymphocytic Leukemia is a type of blood cancer that starts in the bone marrow and is slow progressing. The rate of new cases is 4.8 per 100,000 people. RA is chronic, systemic, autoimmune inflammatory disorder that affects approximately 1.5 million Americans. RA is characterized by dysregulated inflammatory processes in the synovium of the joint that eventually leads, if uncontrolled to destruction of joints due to erosion of cartilage and bone, with resulting pain and joint deformities. Granulomatosis with Polyangiitis is an autoimmune disease that causes vasculitis and forms clusters of cells called granulomas.
Considerations	• Interchangeable biosimilar to Rituxan® • Orphan Drug Designation from FDA
Select Alt Therapies	Rituxan® (rituximab) IV and other Rituxan biosimilars: Riabni™ (rituximab-arrx) IV, Ruxience® (rituximab-pvvr) IV, Truxima® (rituximab-abbs) IV

ORZEYFUL™ (OVEPOREXTON) PO, TAKEDA

Approval Date	08/05/2026
Indication	Adults with narcolepsy type 1.
Clinical Overview	Narcolepsy is a chronic sleep disorder characterized by excessive daytime sleepiness. Narcolepsy type 1 is differentiated by patients also having cataplexy, a sudden episode of muscle weakness usually triggered by intense emotions. While the exact cause is unknown, it involves low levels of hypocretin, also called orexin, which helps control sleep-wake cycles. Underlying causes for narcolepsy include autoimmune reactions, genetic factors, and secondary causes such as brain injuries. An estimated 1 in 2,000 Americans are affected with either narcolepsy type 1 or 2, but it is believed around 50% are undiagnosed.
Considerations	• First-in-class orexin receptor 2 (OX2R) agonist
Select Alt Therapies	Xywav™ (calcium, magnesium, potassium, sodium oxybates) PO, Lumryz™ (sodium oxybate) PO, Wakix® (pitolisant) PO, Xyrem® (sodium oxybate) PO, armodafinil PO, modafinil PO, and off-label antidepressants

TUDRIQEV™ (VUSOLIMOGENE ODERPAREPVEC) ITU, REPLIMUNE

Approval Date	08/06/2026
Indication	In combination with nivolumab for the treatment of certain patients with unresectable advanced cutaneous melanoma.
Clinical Overview	Melanoma is the fifth most common cancer in the United States and the most lethal form of skin cancer. Cutaneous melanoma originates from melanocytes and accounts for approximately 94% of melanoma cases. Unresectable advanced cutaneous melanoma refers to disease that cannot be surgically removed due to extensive local growth or metastatic spread. Approximately 112,000 new invasive melanoma cases are expected in the U.S. in 2026, with over 8,500 deaths projected. Treatment of advanced disease has been transformed by immunotherapies and targeted therapies, leading to substantial improvements in long-term survival.
Considerations	• Granted FDA Accelerated Approval • First FDA-approved oncolytic viral immunotherapy for patients with anti-PD-1-refractory advanced cutaneous melanoma • Continued approval may be contingent upon verification of clinical benefit in the ongoing randomized Phase 3 IGNYTE-3 confirmatory trial
Select Alt Therapies	Trisenox® (arsenic trioxide) IV, eribulin mesylate IV, Imlygic® (talimogene laherparepvec) Inj, Lonsurf® (trifluridine, tipiracil) PO, Yondelis® (trabectedin yondelis) IV

ZENBEXUS™ (IBERDOMIDE) PO, CELGENE, BRISTOL-MYERS SQUIBB

Approval Date	08/13/2026
Indication	In combination with daratumumab, hyaluronidase-fihj, and dexamethasone for the treatment of adult patients with multiple myeloma who have received at least 1 prior line of therapy including a proteasome inhibitor and an immunomodulatory agent.
Clinical Overview	Multiple Myeloma (MM) is a type of blood cancer that starts in the plasma cells. It is the second most common hematologic malignancy, affecting about 36,000 newly diagnosed Americans annually, with most cases occurring in older adults, males, and African Americans. MM 5-year survival rate is 63.7%. Treatment consists of combination therapy that includes an immunomodulatory agent, a proteasome inhibitor, corticosteroids, and/or a monoclonal antibody. For eligible patients, initial therapy is often followed by autologous stem cell transplantation and then maintenance therapy to prolong remission.
Considerations	• Received priority review and orphan drug designation from FDA • First in class cereblon-modulating protein degrader
Select Alt Therapies	First in class medication; standard of care consists of combination therapy with an immunomodulatory agent, a proteasome inhibitor, corticosteroids, and/or a monoclonal antibody.

GENGLYCOS™ (PARIGLASGENE BRECAPARVOVEC) IV, ULTRAGENYX

Approval Date	08/19/2026
Indication	Glycogen storage disease type 1a (GSDIa)
Clinical Overview	GSDIa is an ultra-rare, genetic metabolic disorder that affects approximately 1,500-2,500 patients in the U.S. It is caused by missing glucose-6-phosphatase (G6PC) enzymes, resulting in reduced glucose control, severe hypoglycemia episodes, and other serious complications. Patients with GSDIa are typically required to carefully manage their nutritional intakes, including daily dietary supplementation of cornstarch to maintain glucose levels. Genglycos™ targets the root cause of GSDIa by delivering a functional G6PC gene to the liver, and is the first treatment approved for GSDIa.
Considerations	• One-time gene therapy that is not curative but functions as a long-term functional treatment that fixes main symptoms of the disease. • Accelerated approval from FDA
Select Alt Therapies	Genglycos™ is the first treatment approved for GSD1a.

PASATRU™ (GARETOSMAB) IV, REGENERON

Approval Date	08/19/2026
Indication	Adults with disease flare-ups of Fibrodysplasia ossificans progressiva (FOP).
Clinical Overview	Fibrodysplasia ossificans progressiva (FOP) is an ultra-rare genetic disease characterized by extra skeletal bone formation in muscle and soft tissue. It is thought to affect ~400 people in the US. Disease flare-up symptoms can include inflammation which will look like red or purple lumps that are painful and warm to the touch.
Considerations	• Received Breakthrough Therapy, Fast Track, Orphan Drug and Priority Review designations • Competitor Sohonos® is approved for patients as young as age 8 for girls and 10 for boys
Select Alt Therapies	Sohonos® (palovarotene) PO

RASONQUE™ (DARAXONRASIB) PO, REVOLUTION MEDICINES

Approval Date	08/26/2026
Indication	Metastatic pancreatic adenocarcinoma who have received at least one prior systemic therapy or who are not candidates for multiagent systemic therapy
Clinical Overview	Pancreatic cancer is the fourth leading cause of cancer deaths in the U.S. Surgery is the only chance at a curative therapy. Most patients are diagnosed late in their disease and are usually not eligible for pancreatectomy and therefore are treated with chemotherapy. Initial non-surgical therapy for nonmetastatic, locally advanced, unresectable pancreatic cancer is usually chemotherapy and radiation.
Considerations	• First in class oral inhibitor of the RAS GTPase family • Received Orphan Drug and Priority Review designations • Does not require RAS mutation testing but 97% of study enrollees had a documented RAS mutation
Select Alt Therapies	Eloxatin® (oxaliplatin) IV, leucovorin IV, irinotecan IV, Gemzar® (gemcitabine) IV, Keytruda® (pembrolizumab) IV

MIMRYLO™ (RUSFERTIDE) SC, TAKEDA, PROTAGONIST THERAPEUTICS

Approval Date	08/28/2026
Indication	Erythrocytosis in adults with polycythemia vera (PV)
Clinical Overview	Polycythemia vera (PV) is a chronic myeloproliferative neoplasm. PV causes elevated red blood cells, which differentiates it from other myeloproliferative diseases, leading to increased blood viscosity and a heightened risk of thrombotic events. PV presents itself in all age groups. In the United States, PV affects an estimated 65,000 people, with an annual incidence of approximately 0.5 to 4 cases per 100,000 individuals. Current treatment focuses on reducing thrombotic risk and controlling blood counts through phlebotomy, low-dose aspirin, and cytoreductive therapies when needed.
Considerations	• Received Priority Review and Orphan Drug designations
Select Alt Therapies	Hydroxyurea PO, Besremi® (ropeginterferon alfa-2b) SC, Jakafi® (ruxolitinib) PO

LIPFENDRA® (ENLICITIDE DECANOATE) PO, MERCK & CO (MSD)

Approval Date	07/15/2026
Indication	Adults with hypercholesterolemia, including heterozygous familial hypercholesterolemia (HeFH), as an adjunct to diet and exercise to reduce low-density lipoprotein cholesterol (LDL-C).
Clinical Overview	Dyslipidemia is defined as an imbalance of lipids, including total cholesterol, low-density lipoprotein cholesterol (LDL-C), triglycerides, and high-density lipoprotein cholesterol (HDL-C), and remains a highly prevalent and clinically significant therapeutic area. According to the American Heart Association (AHA), dyslipidemia remains highly prevalent in the United States, with 10% of adults 20 years of age and older, or nearly 25 million people, having total cholesterol levels of ≥240 mg/dL between 2021 and 2023, with approximately 26% having LDL-C levels of at least 130 mg/dL, and about 14% having HDL-C levels below 40 mg/dL. Dyslipidemia contributes to atherosclerotic cardiovascular disease (ASCVD), including sudden cardiac death, acute myocardial infarction, and stroke, while severe hypertriglyceridemia (SHTG) and familial chylomicronemia syndrome (FCS) are associated with acute and recurrent pancreatitis. Utilization pressure is expected to continue moving away from legacy statin only management and toward increased adjunctive higher cost nonstatin therapies, including PCSK9 inhibitors, inclisiran, bempedoic acid, emerging oral PCSK9 inhibitors, and targeted therapies for SHTG and FCS.
Considerations	• First and only once-daily oral PCSK9 inhibitor approved in the U.S. • Received Priority Review from FDA • Specifically used as an adjunct to diet and exercise
Select Alt Therapies	Statin therapies, PCSK9 Injection therapies (Repatha™ (evolocumab) SC, Praluent® (alirocumab) SC, Lerochol™ (lerodalcibep-liga) SC)

GARZULYS™ (INSULIN ASPART-FSAN) IV, SC, NANJING KING-FRIEND BIOCHEMICAL PHARMACEUTICAL , MEITHEAL, TONGHUA DONGBAO PHARMACEUTICAL, XENTRIA, EMERGE BIOSCIENCE

Approval Date	07/24/2026
Indication	Improve glycemic control in adults and pediatric patients with diabetes mellitus
Clinical Overview	Diabetes is a chronic, progressive, metabolic disorder characterized by persistently high blood glucose (hyperglycemia) due to inadequate levels of insulin in the body. According to the American Diabetes Association (ADA), more than 40 million people in the United States (12% of the U.S. population) currently have diabetes. Based on etiology and symptoms, diabetes can be broadly classified into three main types: type 1 diabetes (T1D), type 2 diabetes (T2D), and gestational diabetes (GD). Insulin is a mainstay of diabetes treatment and is frequently used as part of diabetes technology.
Considerations	• Interchangeable biosimilar of Novolog®
Select Alt Therapies	Novolog® (insulin aspart) SC, Kirsty™ (insulin aspart-xjhz) SC, Merilog™ (insulin aspart-szjj) SC

SIMTRIYO™ (CENTANAFADINE) PO, OTSUKO

Approval Date	07/24/2026
Indication	Attention deficit hyperactivity disorder (ADHD) in certain adults and pediatric patients 6 years of age and older
Clinical Overview	Attention deficit hyperactivity disorder is one of the most common neuropsychiatric disorders in childhood. The CDC estimates that 7 million (11.4%) children in the United States (age 3 to 17 years) have a diagnosis of ADHD (according to 2022 data). Although typically thought of as a childhood disease, many patients will require treatment into adulthood. Prevalence estimates of adult ADHD are highly variable but is approximately 6% of the U.S. adult population (approximately 15.5 million people). Treatment recommendations for patients with ADHD vary based on age and include behavioral changes, cognitive therapy, and pharmacotherapy. Pharmacotherapy options include stimulant and nonstimulant medications.
Considerations	• Boxed warning regarding suicidal ideation and behaviors • Potential for abuse, misuse and addiction • Received Priority Review Designation • First and only approved norepinephrine, dopamine, serotonin reuptake inhibitor (NDSRI)
Select Alt Therapies	Unknown current place in therapy as awaiting scheduling from DEA; current standard treatment includes stimulant medications (ex. Adderall® (amphetamine-dextroamphetamine) PO) and nonstimulant medications (ex. Strattera® (atomoxetine) PO).

MFLUSIVA® (MRNA-1010 INFLUENZA VACCINE) IM, MODERNA

Approval Date	08/05/2026
Indication	Active immunization for the prevention of influenza disease caused by influenza virus subtype A and type B in persons aged 50 years and older.
Clinical Overview	Influenza (flu) is a contagious viral respiratory infection caused primarily by influenza A and B viruses. It affects the nose, throat, and lungs and can cause symptoms such as fever, cough, fatigue, muscle aches, and sore throat. Influenza is a major public health concern in the United States, causing millions of illnesses each year and leading to substantial hospitalizations and deaths, particularly among older adults, young children, and individuals with chronic conditions. The virus spreads mainly through respiratory droplets from coughing, sneezing, or talking. Annual vaccination remains the most effective strategy for preventing infection and reducing the risk of severe complications.
Considerations	• Approved in time for 2026-2027 flu season • Approval for persons 65 years of age or older is currently under accelerated approval • First mRNA flu vaccine
Select Alt Therapies	Audenz™ IM, Fluad® Trivalent IM, Afluria® Trivalent IM, Fluarix® Trivalent IM, Flublok® Trivalent IM, Flucelvax® Trivalent IM, Flulaval® Trivalent IM, FluMist® Nasal Spray, Fluzone® Trivalent IM

BIXLENVO™ (BICTEGRAVIR SODIUM; LENACAPAVIR SODIUM) PO, GILEAD

Approval Date	08/27/2026
Indication	Human immunodeficiency virus 1 (HIV-1) 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
Clinical Overview	HIV is a virus that attacks the body's immune system, specifically CD4 T cells, making it harder to fight infections and certain cancers. If left untreated, HIV can progress to acquired immunodeficiency syndrome (AIDS), the most advanced stage of infection. HIV is primarily transmitted through sexual contact, sharing injection drug equipment, or from parent to child during pregnancy, childbirth, or breastfeeding. Approximately 1.2 million people in the United States are living with HIV, and an estimated 31,800 new infections occur each year. Early initiation of combination antiretroviral therapy (ART) is the standard treatment for all patients with HIV.
Considerations	• Requires a 2-day oral initiation dose with Sunlenca® (lenacapavir) • Received Priority Review • Wholesale acquisition cost (WAC) at $55,140 annually
Select Alt Therapies	Preferred first line regimens for HIV include: Biktarvy® (bictegravir/emtricitabine/tenofovir alafenamide) PO, Dolutegravir + emtricitabine/tenofovir (TAF or TDF) (Truvada® or Descovy®) PO, Dovato®(dolutegravir/lamivudine) PO

BRAND NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	APPROVAL DATE
Casgevy® (exagamglogene autotemcel)	Vertex, CRISPR Therapeutics	IV	Patients 2 years and olde with Sickle Cell Disease (SCD) with recurrent vaso-occlusive crises (VOCs) and transfusion-dependent β-thalassemia (TDT)	07/01/2026
Wilate® (coagulation factor VIII (human); von willebrand factor)	Octapharma	IV	Treatment of certain conditions in adult and pediatric patients with von Willebrand disease and in adult an pediatric patients 12 years of age and older with hemophilia A	07/02/2026
Ryaltris™ (mometasone furoate; olopatadine hydrochloride)	Glenmark	PO	Seasonal allergic rhinitis in children aged 6 to 11 years.	07/07/2026
Sodium Bicarbonate (sodium bicarbonate)	Amneal	IV	Metabolic Acidosis Poisoning	07/09/2026
Keytruda Qlex™ (berahyaluronidase alfa; pembrolizumab)	Merck & Co (MSD), Alteogen	SC	Adult patients with muscle invasive bladder cancer (MIBC) in combination with enfortumab vedotin-ejfv (Padcev)	07/10/2026
Padcev® (enfortumab vedotin)	Pfizer, Astellas, Seattle Genetics, Agensys, Seagen	IV	Adult patients with muscle invasive bladder cancer (MIBC) in combination with Keytruda Qlex™ or Keytruda® IV	07/10/2026
Keytruda® IV (pembrolizumab)	Merck & Co (MSD)	IV	Adult patients with muscle invasive bladder cancer (MIBC) in combination with enfortumab vedotin-ejfv (Padcev)	07/10/2026
Leqembi® Iqlik® (lecanemab)	Eisai, Biogen, BioArctic Neuroscience	New Formulation: SC autoinjector	Alzheimer's Disease	07/13/2026
Furoscix® ReadyFlow (furosemide)	MannKind Corporation, scPharmaceuticals	New formulation: SC autoinjector	Treatment of edema in pediatric patients weighing 43 kg and above and in adult patients with chronic heart failure or chronic kidney disease, including the nephrotic syndrome.	07/23/2026
Tylenol® with Naproxen (acetaminophen; naproxen)	Kenvue	PO	Pain	07/24/2026

BRAND NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	APPROVAL DATE
Gwyn Lo™ (ethinyl estradiol; norelgestromin)	Viatris	TD	Pregnancy Prevention	07/28/2026
Qlonilik™ (clonidine hydrochloride)	CMP Pharma	PO	Hypertension	07/29/2026
Glycophos® (sodium glycerophosphate)	Fresenius Kabi	IV	Nutritional Deficiency	07/29/2026
Pluvicto® (lutetium Lu 177 vipivotide tetraxetan)	Novartis, Endocyte, Advanced Accelerator Applications	IV	Prostate Cancer	07/31/2026
Imaavy™ IV (nipocalimab)	Momenta, Johnson & Johnson (Janssen)	IV	Warm antibody autoimmune hemolytic anemia (WAIHA)	08/24/2026
Tivicay PD® (dolutegravir sodium)	ViiV Healthcare	PO	HIV-1	08/25/2026
Tevimbra® IV (tislelizumab)	BeiGene, BeOne Medicines	IV	Esophageal cancer, Gastric cancer, and Gastric, Gastroesophageal Junction, or Esophageal Adenocarcinoma	08/25/2026
Vobrig (leuprolide acetate)	Sun Pharmaceutical	TBD	Central precocious puberty in children	08/26/2026
Mounjaro™ (tirzepatide)	Eli Lilly	SC	Reduce cardiovascular mortality in patients with type 2 diabetes (T2D)	08/27/2026
Besremi™ (ropeginterferon alfa-2b)	PharmaEssentia, AOP Orphan	SC	Thrombocythemia	08/28/2026

PIPELINE NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	PENDING FDA APPROVAL DATE
brepocitinib	Pfizer, Roivant, Priovant Therapeutics	PO, TOP	Dermatomyositis	3Q 2026
tavapadon	Pfizer, AbbVie, Cereve Therapeutics	PO	Parkinson's Disease	3Q 2026
apixaban	TAHO	PO	Reduce risk of stroke and embolism in nonvalvular Afib	3Q 2026
denecimig	Novo Nordisk, Genmab	SC	Hemophilia A prophylaxis in adults and pediatrics	3Q 2026
follitropin alfa; lutropin alfa	EMD Serono (Merck KGaA)	SC	Female infertility - Multiple follicle development	3Q 2026
pimicotinib hydrochloride	EMD Serono (Merck KGaA), Abbisko Therapeutics	PO	Tenosynovial giant cell tumor (TGCT)	2H 2026
baricitinib tablet	Eli Lilly, Incyte	PO	Pediatric patients with alopecia areata	2H 2026
baricitinib oral suspension	Eli Lilly	PO	Pediatric patients with alopecia areata	2H 2026
camizestrant	AstraZeneca	PO	HR+/HER2- Breast cancer	2H 2026

PIPELINE NAME (generic name)	COMPANY	ROUTE OF ADMINISTRATION	INDICATION(S)	PENDING FDA APPROVAL DATE
orforglipron calcium	Eli Lilly, Chugai	PO	Type 2 diabetes	2H 2026
COVID-19 Vaccine, mRNA	Pfizer, BioNTech, Shanghai Fosun Pharmaceutical	IM	COVID-19	2H 2026
respiratory syncytial virus vaccine, adjuvanted	GSK	IM	Respiratory syncytial virus (RSV)	2H 2026
gefurulimab	AstraZeneca, Alexia	SC	Myasthenia gravis	2H 2026
secukinumab	Novartis	SC	Polymyalgia rheumatica	2H 2026
insulin efsitora alfa	Eli Lilly	SC	Type 2 diabetes	2H 2026
tirzepatide	Eli Lilly	SC	Reduce cardiovascular mortality in patients with type 2 diabetes	2H 2026
remibrutinib	Novartis	PO	Chronic inducible urticaria (CIndU)	2H 2026
ustekinumab SC	Johnson & Johnson (Janssen)	SC	Ulcerative Colitis	08/2026
rusfertide	Takeda, Protagonist Therapeutics	SC	Polycythemia vera	08/2026

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ustekinumab IV	Johnson & Johnson (Janssen)	IV	Ulcerative Colitis	08/2026
bictegravir; lenacapavir	Gilead	PO	HIV-1 Infection	08/27/2026
ropeginterferon alfa-2b	PharmaEssentia, AOP Orphan	SC	Thrombocytopenia	08/30/2026
apixaban	Lupin	PO	Prophylaxis of deep vein thromboembolism in surgical patients, reduce risk of stroke and embolism in nonvalvular Afib	09/2026
condoliase	Ferring Pharmaceuticals, Seikagaku	Other	Lumbar disc herniation	09/2026
finerenone	Bayer	PO	Diabetic neuropathy	09/2026
sevabertinib	Bayer	PO	Non-small cell lung cancer (NSCLC)	09/2026
potassium bicarbonate; potassium citrate	Advicenne	PO	Renal tubular acidosis	09/03/2026
floretyrosine F18	Telix	IV	Diagnosis imaging in glioma	09/11/2026
rebisufligene etisparvovec	Ultragenyx, Abeona Therapeutics	IV	Mucopolysaccharidosis type IIIA	09/19/2026

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levacetylleucine	IntraBio	PO	Ataxia Telangiectasia	09/19/2026
sotatercept	Bristol-Myers Squibb, Merck & Co (MSD), Celgene, Acceleron	SC	Pulmonary arterial hypertension	09/21/2026
zilganersen	Ionis Pharmaceuticals	IT	Alexander disease (AxD)	09/22/2026
zilurgisertib	Incyte, Mirum Pharmaceuticals	PO	Fibrodysplasia ossificans progressiva (FOP)	09/26/2026
lirafugratinib	Elevar Therapeutics, Relay Therapeutics	PO	Biliary tract cancer	09/27/2026
obinutuzumab	Roche, Genentech, Biogen	IV	Nephrotic syndrome	09/27/2026
tiratricol	PledPharma, Egetis Therapeutics, Rare Thyroid Therapeutics	PO	MCT8 deficiency (Allan Herndon Dudley syndrome)	09/28/2026
aminolevulinic acid hydrochloride	Biofrontera	TOP	Basal cell carcinoma	09/28/2026
mavacamten	Bristol-Myers Squibb, MyoKardia	PO	Hypertrophic cardiomyopathy	09/30/2026
apitegromab	Scholar Rock	IV	Spinal muscular atrophy	09/30/2026

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aflibercept	Sam Chun Dang Pharm, Freseniu Kabi	IA	Diabetic macular edema, diabetic retinopathy, macular edema following retinal vein occlusion, wet age-related macular degeneration	10/2026
hydrocortisone acetate	Cristcot	PR	Ulcerative colitis	10/2026
pertuzumab	Biocon	IV	HER2+ breast cancer	4Q 2026
bevacizumab	Henlius	IV	Cervical cancer, Colorectal cancer, Glioblastoma multiforme, Kidney cancer, Non-small cell lung cancer, Ovarian cancer	4Q 2026