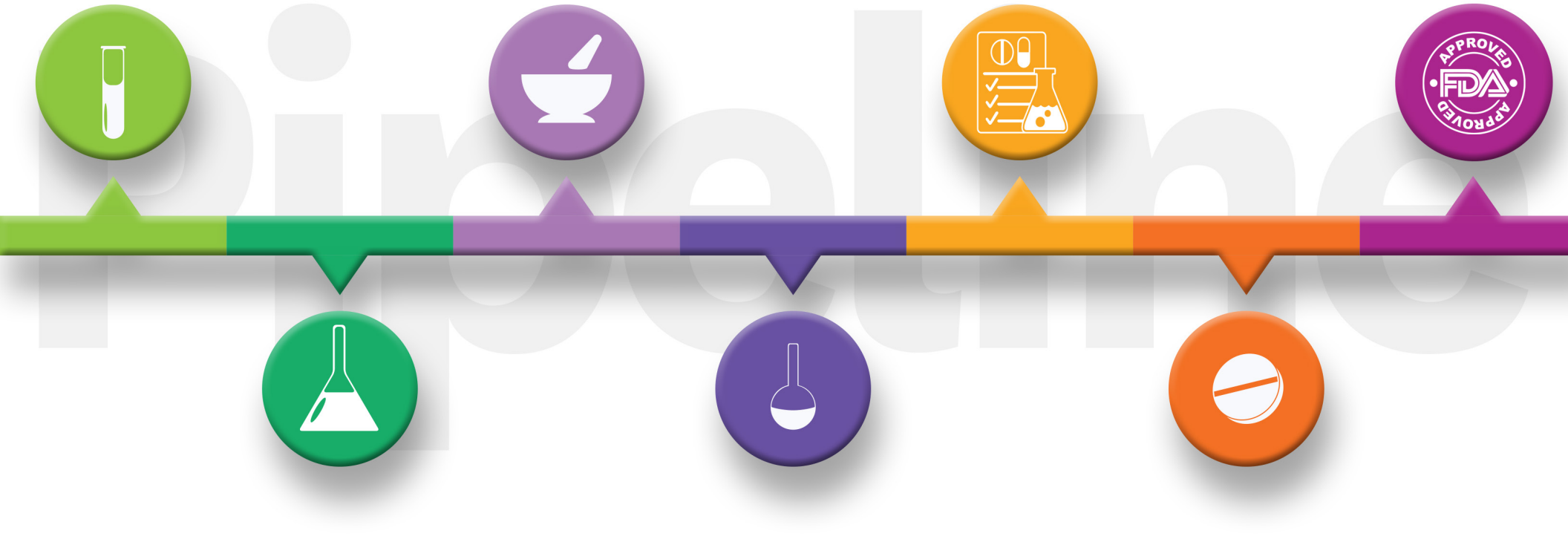

PIPELINE REPORT: JANUARY 2026

AcariaHealth™

Specialty Pharmacy

This quarterly publication is developed by our Clinical Pharmacy Drug Information team to provide additional drug pipeline information and insights to help health care leaders prepare for shifts in prescription drug management.

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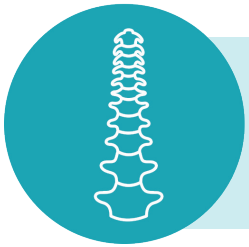
Highlights

APPROVED: WASKYRA *(etuvetidigene autotemcel)* for Wiskott-Aldrich syndrome - projected cost 4.5 million for one time treatment



APPROVED: ITVISMA *(onasemnogene abeparvovec-brve)* for spinal muscular atrophy

APPROVED: WEGOVY *(semaglutide)* oral tablet for obesity and cardiovascular risk reduction

 | Data is current as of 1/25/2026

Recent Specialty Drug Approvals

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC) /Utilizer
CARDIOVASCULAR DISEASE					
MYQORZO™ *aficamten* oral tablet	Cytokinetics, Inc.	Obstructive hypertrophic cardiomyopathy (oHCM)	12/19/2025	· Approved for the treatment of adults with symptomatic oHCM to improve functional capacity and symptoms. · Will compete with CAMZYOS, which is FDA-approved for the same indication. · Projected impact: cost replacement of an existing therapy	Pending launch
ENDOCRINOLOGY					
KYGEVVI™ *doxecitine/ doxribtimine* powder for oral solution	UCB Biosciences Inc.	Thymidine kinase 2 deficiency (TK2d)	11/3/2025	· Approved for the treatment of TK2d in adults and pediatric patients with an age of symptom onset on or before 12 years. · TK2d is an ultra-rare genetic disorder that results in mitochondrial dysfunction leading to inadequate energy production in cells; TK2d may present at all ages and causes progressive and severe muscle weakness, respiratory insufficiency, and is often fatal. · Kygevvi is the first FDA-approved agent for TK2d. · Projected impact: cost increase in a very small population.	Pending launch
REDEMPLO® *plozasiran* SC injection	Arrowhead Pharmaceuticals	Familial chylomicronemia syndrome (FCS)	11/18/2025	· Approved for use as an adjunct to diet to reduce triglycerides in adults with FCS. · Will compete with TRYNGOLZA as a more convenient and much lower cost alternative for the same indication. REDEMPLO is dosed once every 3 months while TRYNGOLZA is dosed once monthly. · Projected impact: cost replacement of an existing therapy.	$60,000/year
ZYCUBO® *copper histidinate* SC injection	Zydus Pharmaceuticals/ Sentynl Therapeutics	Menkes disease	1/12/2026	· Approved for the treatment of Menkes disease in pediatric patients. · Menkes disease is a rare X-linked pediatric disease caused by gene mutations of copper transporter ATP7A. Most Menkes disease patients do not survive past age 3 without treatment. · ZYCUBO is the first FDA-approved treatment for Menkes disease; however, daily injections of copper supplements have been used as an off-label therapy, along with supportive therapies. · Projected impact: new cost in a very small population.	Pending launch

 | Data is current as of 1/25/2026

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Recent Specialty Drug Approvals

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC) /Utilizer
HEMATOLOGY					
AQVESME™ *mitapivat* oral tablet	Agios Pharmaceuticals	Thalassemia	12/23/2025	• Approved for the treatment of anemia in adults with α- or β-thalassemia. • The first agent to be FDA-approved for both transfusion-dependent and non-transfusion-dependent thalassemia. REBLOZYL is currently FDA-approved for the treatment of transfusion-dependent β-thalassemia. • Mitapivat is also FDA-approved as PYRUKYND for the treatment of pyruvate kinase deficiency. • Approximately 6,000 adult patients are diagnosed with thalassemia in the U.S. • Projected impact: cost offset by REBLOZYL in the transfusion-dependent β-thalassemia population; incremental cost increase for the small remaining population.	$425,000/year
YARTEMLEA™ *narsoplimab-wuug* IV infusion	Omeros Corporation	Transplant-associated thrombotic microangiopathy (TA-TMA)	12/23/2025	• Approved for the treatment of adult and pediatric patients aged ≥ 2 years with hematopoietic stem cell transplant (HSCT)-associated TMA. • Persistent TMA is a life-threatening complication of HSCT with a reported mortality rate in high-risk patients of > 90%. Yartemlea is the first FDA-approved agent for TA-TMA, though some off-label usage occurs with agents such as SOLIRIS. • Projected impact: cost replacement of existing therapies.	$360,000/ 10-dose treatment course

 | Data is current as of 1/25/2026

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Recent Specialty Drug Approvals

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC) /Utilizer
IMMUNOLOGY					
WASKYRA™ *etuvetidigene autotemcel* IV infusion	Fondazione Telethon	Wiskott Aldrich syndrome (WAS)	12/9/2025	**GENE THERAPY** • Approved for the treatment of pediatric patients aged ≥ 6 months and adults with WAS who have a mutation in the *WAS* gene for whom hematopoietic stem cell transplantation (HSCT) is appropriate and no suitable human leukocyte antigen (HLA)-matched related stem cell donor is available. • WAS is an X-linked primary immunodeficiency disorder caused by mutations in the *WAS* gene which encodes the WAS protein, a cytoskeletal regulator. People with WAS suffer from severe bleeding episodes which can be fatal, along with recurrent and relapsing infections, eczema, increased risk of developing autoimmune diseases and lymphomas. Without treatment, the median survival for WAS patients is 14 years of age. • Current treatment options include supportive therapies for managing and preventing clinical manifestations. The only potentially curative treatment is a hematopoietic stem cell transplant. • The estimated incidence of WAS is 1 to 10 cases per million males worldwide; the condition is rarer in females. • Projected impact: significant cost increase in a small population.	Pending launch (anticipated to be ~$4.5 million/ one-time treatment)

 | Data is current as of 1/25/2026

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Recent Specialty Drug Approvals

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC) /Utilizer
NEUROMUSCULAR DISEASES					
ITVISMA® *onasemnogene abeparvovec-brve* intrathecal injection	Novartis	Spinal muscular atrophy (SMA)	11/25/2025	**GENE THERAPY** • Approved for the treatment of SMA in adult and pediatric patients ≥ 2 years of age with confirmed mutation in SMN1 gene. • ITVISMA has only been studied in pediatric patients; thus, the FDA approval for use in adults is not supported by any evidence of efficacy or safety as established in any clinical trials involving adults. • ITVISMA is an intrathecally delivered alternative formulation of the existing IV ZOLGENSMA product which is currently only FDA-approved for patients with SMA who are < 2 years of age. • Projected impact: cost increase due to use in a broader population than was previously treatable with IV ZOLGENSMA.	$2,586,630/ one-time treatment
ONCOLOGY					
BLENREP® *belantamab mafodotin-blmf* IV infusion	GSK	Multiple myeloma (MM)	10/23/2025	• Approved market re-entry for use in combination with bortezomib and dexamethasone for the treatment of adult patients with relapsed or refractory MM who have received at least two prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent. • BLENREP was previously removed from the market for use as monotherapy for relapsed/refractory MM as 5th-line or later therapy, after failing to demonstrate superiority over the combination of Pomalyst plus dexamethasone in a Phase III confirmatory study. • The FDA re-approval is supported by the results of the Phase III DREAMM-7 and DREAMM-8 trials showing statistically significant efficacy, including improvement in overall survival in DREAMM-7. • Projected impact: cost replacement of existing MM therapies.	$1.22 million/ year for a 70 kg person

 | Data is current as of 1/25/2026

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Recent Specialty Drug Approvals

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC) /Utilizer
KOMZIFTI™ *ziftomenib* oral capsule	Kura Oncology	Acute myeloid leukemia (AML)	11/13/2025	• Approved for the treatment of adults with relapsed or refractory AML with a susceptible nucleophosmin 1 (NPM1) mutation who have no satisfactory alternative options. • In AML, NPM1 mutations are among the most common, representing ~30% of cases. While patients with NPM1 AML have high response rates to frontline therapy, relapse rates are high and survival outcomes are poor. • Projected impact: cost replacement of existing therapies.	$590,083/year
HYRNUO® *sevabertinib* oral tablet	Bayer	Non-small cell lung cancer (NSCLC)	11/19/2025	• Approved for the treatment of adult patients with locally advanced or metastatic non-squamous NSCLC whose tumors have HER2 (ERBB2) tyrosine kinase domain (TKD) activating mutations, as detected by an FDA-approved test, and who have received a prior systemic therapy. • Activating HER2 mutations are found in 2% to 4% of advanced NSCLC cases. • HERNEXEOS and ENHERTU are FDA-approved for the same tumor type in patients with unresectable or metastatic disease. • Projected impact: cost replacement of existing therapies.	$292,000/year
BREYANZI® *lisocabtagene maraleucel* IV infusion	Bristol Myers Squibb	Marginal zone lymphoma (MZL)	12/4/2025	**NEW INDICATION FOR AN EXISTING CAR T-CELL THERAPY** • Approved for the treatment of adult patients with relapsed or refractory MZL who have received at least two prior lines of systemic therapy. • Is the first CAR T-cell therapy to be FDA-approved for MZL, though NCCN guidelines currently include CAR T-cell therapy YESCARTA as another third-line therapy option. • Projected imact: cost replacement of existing therapies.	$531,350/one-time treatment

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Recent Specialty Drug Approvals

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC) /Utilizer
RENAL DISEASES					
VOYXACT® *sibeprenlimab-szsi* SC injection	Otsuka	Immunoglobulin A nephropathy (IgAN)	11/25/2025	• Approved to reduce proteinuria in adults with primary IgAN at risk for disease progression. • TARPEYO, FILSPARI, and VANRAFIA are also FDA-approved for IgAN. • VOYXACT is dosed as a self-administered SC injection every 4 weeks. • Projected impact: cost replacement of existing therapies.	$390,000/ year
RESPIRATORY DISEASES					
JASCAYD® *nerandomilast* oral tablet	Boehringer Ingelheim	Idiopathic pulmonary fibrosis (IPF) and progressive pulmonary fibrosis (PPF)	IPF: 10/7/2025 PPF: 12/19/2025	• Approved for the treatment of IPF and for PPF in adult patients. • Current therapies approved for the treatment of IPF include oral ESBRIET (available as a generic) and OFEV, while OFEV is also FDA-approved for PPF. • Projected impact: cost replacement of existing therapies.	$197,340/year
EXDENSUR® *depemokimab-ulaa* SC injection	GSK	Asthma	12/16/2025	• Approved for add-on maintenance treatment of severe asthma characterized by an eosinophilic phenotype in adult and pediatric patients aged ≥ 12 years. • Will compete with existing biologics already FDA-approved for eosinophilic asthma such as CINQAIR, DUPIXENT, FASENRA, and NUCALA. • EXDENSUR is an ultra-long acting product with one dose administered every 6 months. • Projected impact: cost replacement of existing therapies.	$52,000/year

 | Data is current as of 1/25/2026

Specialty Products on Our Radar

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
DERMATOLOGY						
DISC-1459 *bitopertin* oral therapy	Disc Medicine	Erythropoietic protoporphyria (EPP)	Glycine transporter 1 inhibitor	• Proposed for accelerated approval for the treatment of patients aged ≥ 12 years with EPP, including X-linked protoporphyria. • Would be an oral alternative to SCENESSE implant, which is FDA-approved for the same indication for adults. • This agent was selected by the FDA to be a recipient of the Commissioner's National Priority Voucher which allows for potential FDA approval within 1-2 months of a completed regulatory filing submission.	$350,000/ year	1Q 2026
ENDOCRINOLOGY						
RGX-121 Ⓢ *clemidsogene lanparvovec* intracerebral injection	RegenXBio, Inc.	Mucopolysacch-aridosis type II (MPS II)	Iduronate-2-sulfatase (I2S)-directed gene therapy	**GENE THERAPY** • Proposed for the treatment of MPS II (aka Hunter Syndrome). • MPS II is estimated to occur in approximately 1 in 100,000 to 1 in 170,000 births. • RGX-121 would be the first gene therapy approved for MPS II or any other MPS subtype. • The current disease-modifying therapy for MPS II is enzyme replacement therapy with ELAPRASE administered intravenously; however, ELAPRASE does not reach sufficient brain concentrations to adequately address the cognitive impairment that can occur with the disease.	$3 million/ one-time treatment	2/8/2026

Ⓢ **Expected to cost ≥ $500,000 per member.**

 | Data is current as of 1/25/2026

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Specialty Products on Our Radar

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
TRANSCON® CNP *navepegritide* SC injection	Ascendis Pharmaceuticals	Achondroplasia	C-type natriuretic peptide	• Proposed for the treatment of children with achondroplasia. • Dosed SC once weekly. • Would compete with VOXZOGO which is dosed SC once daily for the same indication.	$400,000/ year	2/28/2026
DNL310 Ⓢ *tividenofusp alfa* IV infusion	Denali Therapeutics	MPS II	Enzyme replacement therapy	• Proposed for accelerated approval for the treatment of patients with MPS II (aka Hunter Syndrome). • MPS II is estimated to occur in approximately 1 in 100,000 to 1 in 170,000 births. • The current disease-modifying therapy for MPS II is enzyme replacement therapy with ELAPRASE administered intravenously; however, ELAPRASE does not reach sufficient brain concentrations to adequately address the cognitive impairment that can occur with the disease. DNL310 is a brain-penetrant therapy that may better address the neurological manifestations of MPS II.	$500,000/ year	4/5/2026
NASP Ⓢ *pegadricase/sirolimus* IV infusion	Sobi/Cartesian Therapeutics	Gout	pegadriase: pegylated uricase enzyme sirolimus: immuno-suppressant	• Proposed for the treatment of chronic refractory gout. • Would compete with KRYSTEXXA for the same indication.	$750,000/ year	6/27/2026

Ⓢ **Expected to cost ≥ $500,000 per member.**

 | Data is current as of 1/25/2026

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Specialty Products on Our Radar

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
HEMATOLOGY						
KRESLADI Ⓢ *marnetegragene autotemcel* IV infusion	Rocket Pharmaceuticals, Inc.	Leukocyte adhesion deficiency-I (LAD-I)	Lentiviral vector-based gene therapy	**GENE THERAPY** · LAD-I is a rare genetic condition that results in recurrent life-threatening bacterial and fungal infections that respond poorly to antibiotics and require frequent hospitalizations. · LAD-I is estimated to occur in ~1 in every 1 million people worldwide. · Bone marrow transplant is the only available curative therapy, but mortality in patients with severe LAD-I remains at 60-75% prior to the age of 2 and survival beyond the age of 5 is uncommon.	$3-4 million/ one-time treatment	3/28/2026
CASGEVY® Ⓢ *exagamglogene autotemcel* IV infusion	Vertex	Sickle cell disease (SCD) and transfusion-dependent β-thalassemia (TDT)	CRISPR-edited gene therapy	**NEW INDICATIONS FOR AN EXISTING GENE THERAPY** · Proposed for the treatment of patients 5-11 years of age with sickle cell disease (SCD) and recurrent vaso-occlusive crises (VOCs) or with TDT. · CASGEVY is currently FDA-approved for the treatment of patients ≥ 12 years of age with SCD and TDT. · Within the expanded age range of 5 to 11-year-olds with TDT, CASGEVY will compete with ZYNTEGLO which is FDA-approved for TDT in adult and pediatric patients with data supporting use in patients as young as 4 years of age. · These expanded indications were selected by the FDA to receive the Commissioner's National Priority Voucher which allows for potential FDA approval within 1-2 months of a completed regulatory filing submission. The manufacturer has indicated an intent to complete that filing during 1H 2026.	$2.2 million/ one-time treatment	1H 2026

Ⓢ **Expected to cost ≥ $500,000 per member.**

 | Data is current as of 1/25/2026

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Specialty Products on Our Radar

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
HEPATOLOGY						
GSK2330672 *linerixibat* oral tablet	GSK	Primary biliary cholangitis (PBC)	Inhibitor of the ileal bile acid transporter	• Proposed for the treatment of cholestatic pruritus in patients with PBC. • Ursodeoxycholic acid, IQIRVO and LIVDELZI are currently used for the treatment of PBC. • Cholestatic pruritus is a serious condition that can be debilitating, with patients experiencing sleep disturbance, fatigue, impaired quality of life.	$200,000/ year	3/24/2026
HEPCLUDEX® *bulevirtide* SC injection	Gilead	Hepatitis delta virus (HDV) infection	Viral entry inhibitor	• Would be the first FDA-approved agent for this indication. • Has been studied as monotherapy as well as combination therapy with pegylated interferon; previously monotherapy with pegylated interferon products has been used off-label for HDV. • Daily subcutaneous injection.	$250,000/ year	3Q 2026
INFECTIOUS DISEASES						
MK-8591 *islatravir* oral therapy	Merck	Human immunodeficiency virus-1 (HIV-1) infection	Nucleoside reverse transcriptase translocation inhibitor (NRTTI)	• Proposed for use in combination with PIFELTRO for the treatment of adults with HIV-1 infection that is virologically suppressed on antiretroviral therapy. • If approved the combination would be the first FDA-approved two-drug regimen without an integrase inhibitor.	$30,000/year	4/28/2026

 | Data is current as of 1/25/2026

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Specialty Products on Our Radar

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
NEPHROLOGY						
atacicept SC injection	Vera Therapeutics	Immunoglobulin A nephropathy (IgAN)	Anti-B-cell activating factor (BAFF) and A proliferation-inducing ligand (APRIL) antibody	• Proposed for the treatment of adults with IgAN. • Would compete with other FDA-approved therapies for IgAN including TARPEYO, FILSPARI, FABHALTA, and VANRAFIA.	$250,000/ year	7/7/2026
NEUROMUSCULAR DISEASES						
SRK-015 *apitegromab* IV infusion	Scholar Rock	Spinal muscular atrophy (SMA)	Myostatin activation inhibitor	• Proposed for the treatment of spinal muscular atrophy (SMA) in patients who are receiving SMN-targeted treatments. • Would be the first muscle-directed therapy approved for SMA. • When used as intended as adjunctive therapy, SRK-015 would increase the total cost of care over the existing cost for SMN-targeted treatments. • In late September 2025 the FDA declined to approve apitegromab, citing observations identified during a routine general site inspection of a third-party manufacturing facility. The FDA did not cite any other approvability concerns, including apitegromab's efficacy and safety data.	$400,000/ year	Pending BLA re-submission
TRANSLARNA® Ⓢ *ataluren* oral therapy	PTC Therapeutics	Duchenne muscular dystrophy (DMD)	Protein restoration therapy	• Proposed for the treatment of nonsense mutation DMD (nmDMD). • It is estimated that nonsense mutations account for approximately 13% of DMD cases. • A specific FDA approval date for TRANSLARNA has yet to be announced after the original estimated date of 4/30/2025 has passed, with uncertainty around an ultimate FDA approval.	$750,000/ year	1Q 2026

Ⓢ **Expected to cost ≥ $500,000 per member.**

 | Data is current as of 1/25/2026

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Specialty Products on Our Radar

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
ONCOLOGY						
YESCARTA® Ⓢ *axicabtagene ciloleucel* IV infusion	Gilead	Primary central nervous system lymphoma (pCNSL)	CAR T-cell therapy	**NEW INDICATION FOR AN EXISTING CAR T-CELL THERAPY** • Proposed for the treatment of patients with relapsed or refractory pCNSL. • Would be the first CAR T-cell therapy to gain this indication. • Currently pCNSL is called out as a Limitation of Use in the Yescarta Prescribing Information. • The estimated annual incidence of pCNSL in the U.S. is 1,500 cases. pCNSL is most likely to be seen in the elderly and in people with a compromised immune system.	$503,580/ one-time treatment	February 2026
ORCA-T *hematopoietic stem cells and T cells* IV infusion	Orca Bio	Acute myeloid leukemia (AML), acute lymphoblastic leukemia, and myelodysplastic syndrome	Allogeneic stem cell and T-cell immunotherapy	**CELL THERAPY** • Potential competitor to conventional allogeneic hematopoietic stem cell transplants, with the potential for lower rates of graft vs. host disease.	$450,000/ one-time treatment	4/6/2026
RP1 Ⓢ *vusolimogene oderparepvec* intratumoral injection	Replimune	Melanoma	Immunotherapy	• Proposed for use in combination with nivolumab for the treatment of patients with unresectable Stage IIIb-IV cutaneous melanoma whose disease progressed on an anti PD-1 and an anti-CTLA-4 containing regimen or who are not candidates for treatment with an anti-CTLA-4 therapy.	$500,000/ course of therapy	4/10/2026
BGB-11417 *sonrotoclax* oral therapy	BeOne Medicines	Mantle cell lymphoma (MCL)	B-cell lymphoma 2 (BCL2) inhibitor	• Proposed for the treatment of adult patients with relapsed or refractory MCL who have received prior treatment with a BTK inhibitor. • MCL is a rare subtype of aggressive B-cell non-Hodgkin lymphoma that accounts for approximately 5% of all non-Hodgkin lymphoma cases.	$250,000/ year	5/26/2026

Ⓢ **Expected to cost ≥ $500,000 per member.**

 | Data is current as of 1/25/2026

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Specialty Products on Our Radar

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
ARV-471 *vepdegestrant* oral therapy	Pfizer/Arvinas	Breast cancer	Selective estrogen receptor degrader (SERD)	• Proposed as monotherapy for the treatment of adults with estrogen receptor (ER) positive/human epidermal growth factor receptor 2 (HER2) negative (ER+/HER2-), estrogen receptor 1 (ESR1)-mutated advanced or metastatic breast cancer previously treated with endocrine-based therapy. • Would compete with INLURIYO and ORSERDU which are FDA-approved for the same indication.	$300,000/ year	6/5/2026
ADI-PEG 20 *pegargiminase* IV infusion	Polaris Group	Malignant pleural mesothelioma	Arginine depleter	• Proposed for the treatment of malignant pleural mesothelioma with non-epithelioid histology, in combination with a platinum agent and pemetrexed.	$300,000/ year	6/9/2026
AZD9833 *camizestrant* oral therapy	AstraZeneca	Breast cancer	SERD	• Proposed for use in combination with a cyclin-dependent kinase (CDK) 4/6 inhibitor as first-line treatment of patients with hormone receptor (HR)-positive, HER2-negative advanced breast cancer whose tumors have an emergent ESR1 mutation. • Would compete with INLURIYO and ORSERDU which are FDA-approved for the same tumor type.	$300,000/ year	2Q 2026
CORT125134 *relacorilant* oral therapy	Corcept Therapeutics	Ovarian cancer	Glucocorticoid II (GR-II) receptor antagonist	• Proposed for the treatment of platinum-resistant ovarian cancer in combination with nab-paclitaxel. • Would compete with standard of care antineoplastic agents for ovarian cancer. • A previously pursued indication for the treatment of patients with endogenous hypercortisolism (Cushing's syndrome) has received a Complete Response Letter from the FDA due to inadequate evidence of a favorable benefit-risk assessment in hypercortisolism.	$250,000/ year	7/11/2026

 | Data is current as of 1/25/2026

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Specialty Products on Our Radar

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
ITM-11 *^{177}Lu-edotreotide* IV infusion	ITM Isotope Technologies Munich	Gastroentero-pancreatic neuroendocrine tumors (GEP-NETs)	Radio-pharmaceutical	• GEP-NETs are rare types of tumors originating in the pancreas or other parts of the gastrointestinal tract. Due to their heterogeneity and unique characteristics, early diagnosis is difficult, increasing the likelihood of metastatic disease and severely limiting treatment options.	$350,000/ year	8/28/2026
NVL-520 *zidesamtinib* oral tablet	Nuvalent, Inc.	Non-small cell lung cancer (NSCLC)	Brain-penetrant ROS-1 inhibitor	• Proposed for the treatment of adult patients with locally advanced or metastatic ROS1-positive NSCLC who received at least 1 prior ROS1 tyrosine kinase inhibitor.	$350,000/ year	9/18/2026
OPHTHALMOLOGY						
RAXONE® *idebenone* oral tablet	Chiesi Global Rare Diseases	Leber's hereditary optic neuropathy (LHON)	Benzoquinone	• LHON is a genetic mitochondrial disorder that damages retinal ganglion cells, resulting in rapid vision loss. • Fewer than 50,000 individuals in the U.S. are believed to have LHON, with males being ~4 to 5 times more likely than females to experience vision loss from the disease.	$300,000/ year	2/28/2026
VRDN-001 *veligrotug* IV infusion	Viridian Therapeutics	Thyroid eye disease	Anti-insulin-like growth factor-1 receptor antibody	• Would compete with TEPEZZA which is also FDA-approved for the same indication. • VRDN-001 is administered with fewer infusions and with a shorter infusion time than TEPEZZA.	$450,000/ treatment course	6/30/2026

 | Data is current as of 1/25/2026

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Specialty Products on Our Radar

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
OTOLOGY						
DB-OTO Ⓢ intracochlear injection	Regeneron	Congenital deafness	Otoferlin-directed gene therapy	**GENE THERAPY** • Proposed for the treatment of patients with otoferlin-related congenital hearing loss. • Otoferlin-related hearing loss is ultra-rare, affecting 20-50 newborns per year in the U.S. • This agent was selected by the FDA to be a recipient of the new Commissioner's National Priority Voucher which allows for potential FDA approval within 1-2 months of a completed regulatory filing submission.	$1.5 million/ one-time treatment/ear	1Q 2026
RESPIRATORY DISEASES						
N115 *sodium pyruvate* intranasal spray	EmphyCorp Inc.	Idiopathic pulmonary fibrosis (IPF)	Anti-oxidative agent	• Proposed to reduce coughing in patients with IPF. • Current therapies approved for the treatment of IPF include oral ESBRIET, OFEV, and JASCAYD.	$150,000/ year	1Q 2026
INO-3107 intramuscular injection	Inovio	Recurrent respiratory papillomatosis (RRP)	T-cell-mediated immunotherapy	• Proposed for the treatment of RRP in adults. • RRP is a debilitating and rare disease caused primarily by HPV-6 and/or HPV-11 that is characterized by the development of small, wart-like growths, or papillomas, in the respiratory tract. Repeated surgical interventions may be required to address each new recurrence. • PAPZIMEOS is also FDA-approved for adults with RRP.	$450,000/ one-time course of therapy	10/30/2026

Ⓢ **Expected to cost ≥ $500,000 per member.**

 | Data is current as of 1/25/2026

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Biosimilars

Drug Name & Administration Method	Manufacturer(s)	Biosimilar Reference Drug	Indication(s)	Status/Estimated Approval	Biosimilar Currently Launched?	Comments
ENDOCRINOLOGY						
OSVYRTI® *denosumab-desu* SC injection	Accord	PROLIA®	Osteoporosis and prevention of fractures related to cancer therapy	FDA approval: 10/29/2025	Yes - BILDYOS, CONEXXENCE, JUBBONTI, STOBOCLO, BILPREVDA, BOMYNTRA, OSENVELT, OSPOMYV, WYOST	· 8th PROLIA biosimilar after CONEXXENCE, STOBOCLO, JUBBONTI, OSPOMYV, BILDYOS, BOSAYA, ENOBY.
JUBEREQ® *denosumab-desu* SC injection	Accord	XGEVA®	Skeletal-related bone events in patients with cancer; hypercalcemia of malignancy	FDA approval: 10/29/2025	Yes - BILDYOS, CONEXXENCE, JUBBONTI, STOBOCLO, BILPREVDA, BOMYNTRA, OSENVELT, OSPOMYV, WYOST	· 8th XGEVA biosimilar after BOMYNTRA, OSENVELT, WYOST, XBRYK, BILPREVDA, AUKELSO, XTRENBO.
BONCRESA™ *denosumab-mobz* SC injection	Amneal	PROLIA®	Osteoporosis and prevention of fractures related to cancer therapy	FDA approval: 12/19/2025	Yes - BILDYOS, CONEXXENCE, JUBBONTI, STOBOCLO, BILPREVDA, BOMYNTRA, OSENVELT, OSPOMYV, WYOST	· 9th PROLIA biosimilar after CONEXXENCE, STOBOCLO, JUBBONTI, OSPOMYV, BILDYOS, BOSAYA, ENOBY, OSVYRTI.
OZILTUS™ *denosumab-mobz* SC injection	Amneal	XGEVA®	Skeletal-related bone events in patients with cancer; hypercalcemia of malignancy	FDA approval: 12/19/2025	Yes - BILDYOS, CONEXXENCE, JUBBONTI, STOBOCLO, BILPREVDA, BOMYNTRA, OSENVELT, OSPOMYV, WYOST	· 9th XGEVA biosimilar after BOMYNTRA, OSENVELT, WYOST, XBRYK, BILPREVDA, AUKELSO, XTRENBO, JUBEREQ.
AVT03 *denosumab* SC injection	Alvotech	PROLIA®, XGEVA®	Osteoporosis and fractures due to bone metastasis; skeletal-related bone events	BLA is under FDA review (BsUFA date: 1Q 2026)	Yes - BILDYOS, CONEXXENCE, JUBBONTI, STOBOCLO, BILPREVDA, BOMYNTRA, OSENVELT, OSPOMYV, WYOST	· Would be a subsequent denosumab biosimilar, after multiple others.

 | Data is current as of 1/25/2026

CONTINUED

Biosimilars

Drug Name & Administration Method	Manufacturer(s)	Biosimilar Reference Drug	Indication(s)	Status/Estimated Approval	Biosimilar Currently Launched?	Comments
TVB-009P *denosumab* SC injection	Teva	PROLIA®, XGEVA®	Osteoporosis and fractures due to bone metastasis; skeletal-related bone events	BLA is under FDA review (BsUFA date: 1Q 2026)	Yes - BILDYOS, CONEXXENCE, JUBBONTI, STOBOCLO, BILPREVDA, BOMYNTRA, OSENVELT, OSPOMYV, WYOST	· Would be a subsequent denosumab biosimilar, after multiple others.
HEMATOLOGY						
ARMLUPEG™ *pegfilgrastim-unne* SC injection	Lupin Pharmaceuticals	NEULASTA®	Chemotherapy-induced neutropenia; myelosuppressive doses of radiation	FDA approval: 11/28/2025	Yes - FULPHILA, FYLNETRA, NYVEPRIA, STIMUFEND, UDENYCA, ZIEXTENZO	· 7th biosimilar to NEULASTA after FULPHILA, UDENYCA, ZIEXTENZO, NYVEPRIA, FYLNETRA, STIMUFEND.
IMMUNOLOGY						
BAT2506 *golimumab* SC and IV injections	BioThera Solutions	SIMPONI®	Rheumatoid arthritis (RA), psoriatic arthritis (PsA), polyarticular juvenile idiopathic arthritis (pJIA), ankylosing spondylitis (AS), ulcerative colitis (UC)	BLA is under FDA review (BsUFA date: 5/16/2026)	No	· Would be one of the first FDA-approved biosimilars to SIMPONI. · The submitted BLA included a request for interchangeable status.
ADL-018 *omalizumab* SC injection	Kashiv Biosciences/ Amneal	XOLAIR®	Persistent asthma; chronic rhinosinusitis with nasal polyps (CRSwNP), chronic spontaneous urticaria	BLA is under FDA review (BsUFA date: 3Q 2026)	No	· Would be a subsequent XOLAIR biosimilar, after OMLYCLO.
NEUROLOGY						
TYRUKO® *natalizumab-sztn* IV infusion	Sandoz	TYSABRI®	Multiple sclerosis; Crohn's disease	FDA approval: 8/24/2023 Market launch: 10/20/2025	Yes - TYRUKO	· Recent market launch of the first FDA-approved biosimilar to TYSABRI.

 | Data is current as of 1/25/2026

CONTINUED

Biosimilars

Drug Name & Administration Method	Manufacturer(s)	Biosimilar Reference Drug	Indication(s)	Status/Estimated Approval	Biosimilar Currently Launched?	Comments
OPHTHALMOLOGY						
EYDENZELT® *aflibercept-boav* intraocular injection	Celltrion	EYLEA®	Wet age-related macular degeneration (AMD), macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy	FDA approval: 10/2/2025	Yes - PAVBLU	• 6th EYLEA biosimilar, after AHZANTIVE, ENVEEZU, OPUVIZ, PAVBLU, and YESAFILI.
NUFYMCO™ *ranibizumab-leyk* intravitreal injection	Formycon AG	EYLEA®	Wet AMD, macular edema following retinal vein occlusion, diabetic macular edema, diabetic retinopathy, myopic choroidal neovascularization	FDA approval: 12/18/2025	Yes - BYOOVIZ, CIMERLI	• 3rd LUCENTIS biosimilar, after BYOOVIZ and CIMERLI. NUFYMCO was granted interchangeable status.
AVT06 *aflibercept* intraocular injection	Alvotech	EYLEA®	Wet AMD	BLA is under FDA review (BsUFA date: 1Q 2026)	Yes - PAVBLU	• Would be a subsequent EYLEA biosimilar, after AHZANTIVE, ENVEEZU, OPUVIZ, PAVBLU, and YESAFILI.

Generic Specialty Agents

Recent Approvals			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**MARKET LAUNCH DATE**
glycerol phenylbutyrate	RAVICTI®	Endo	10/20/2025
lomustine	GLEOSTINE®	Carnegie	11/14/2025
cladribine	MAVENCLAD® (tablets)	Apotex	11/26/2025
Pipeline Agents			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**ANTICIPATED LAUNCH DATE**
rilpivirine hydrochloride	EDURANT®	Somerset Therapeutics; Strides	1Q 2026
treprostinil	TYVASO®	Actavis/Teva	1Q 2026
pomalidomide	POMALYST®	Dr. Reddy's Laboratories; Cipla; Deva Holdings; MSN Laboratories; Sandoz; Synthon/Alvogen; USV	March 2026
nintedanib esylate	OFEV®	Accord; Glenmark	4/2/2026
melphalan hydrochloride	EVOMELA®	Alembic; Gland Pharma; Lupin	6/1/2026
macitentan	OPSUMIT®	Alembic; Aurobindo; Laurus Labs; MSN Laboratories; Mylan/Viatris; Seasons Biotechnology; Sun; Teva; Amneal	2Q 2026
tofacitinib (tablet)	XELJANZ®	Prinston Pharma Inc.; Zydus	2Q 2026
selexipag (tablet and intravenous)	UPTRAVI®	Alembic; MSN Laboratories; Vgyaan	October 2026
riociguat	ADEMPAS®	Alembic; MSN Laboratories; Teva	4Q 2026

Includes generic agents with > 50% launch probability

 | Data is current as of 1/25/2026

Glossary

Term	Definition
ADC	antibody-drug conjugate
ALL	acute lymphoblastic leukemia
allo-HSCT	allogeneic hematopoietic stem cell transplantation
AMD	age-related macular degeneration
AML	acute myeloid leukemia
apoC-III	apolipoprotein C-III
AS	ankylosing spondylitis
BCG	Bacillus Calmette-Guérin
BCL2	B-cell lymphoma 2
BCMA	B-cell maturation antigen
BLA	biologics license application
BsUFA	Biosimilar User Fee Act
CAR T-cell	chimeric antigen receptor T-cell
CD	Crohn's disease
CDK	cyclin-dependent kinase
CHE	chronic hand eczema
CIS	carcinoma in situ
CKD	chronic kidney disease
CRSwNP	chronic rhinosinusitis with nasal polyps
CSU	chronic spontaneous urticaria
DED	dry eye disease
DLBCL	diffuse large B-cell lymphoma
DMD	Duchenne muscular dystrophy
DPP1	dipeptidyl peptidase 1
EBV+ PTLD	Epstein-Barr virus positive post-transplant lymphoproliferative disease
EGFR	epidermal growth factor receptor
ER	estrogen receptor
ESR1	estrogen receptor-1
FCS	familial chylomicronemia syndrome
FDA	Food and Drug Administration
FL	follicular lymphoma
GEP-NET	Gastroenteropancreatic neuroendocrine tumor
GLP-1	glucagon-like peptide-1
GR-II	glucocorticoid II

Term	Definition
HAE	hereditary angioedema
HDV	hepatitis delta virus
HeFH	heterozygous familial hypercholesterolemia
HER	human epidermal growth factor receptor
HFpEF	heart failure with preserved ejection fraction
HIV-1	human immunodeficiency virus-1
HLA	human leukocyte antigen
HPV	human papillomavirus
HR	hormone receptor
HSCT	hematopoietic stem cell transplantation
I2S	iduronate-2-sulfatase
ICS	inhaled corticosteroids
IgAN	Immunoglobulin A nephropathy
IPF	idiopathic pulmonary fibrosis
ITP	immune thrombocytopenia
IV	intravenous
LAD-I	leukocyte adhesion deficiency-I
LDL-C	low-density lipoprotein cholesterol
LHON	Leber's hereditary optic neuropathy
MACE	major adverse cardiovascular event
MASH	metabolic dysfunction–associated steatohepatitis
MCL	mantle cell lymphoma
MM	multiple myeloma
MPS II	mucopolysaccharidosis type II
MZL	marginal zone lymphoma
NCFB	non-cystic fibrosis bronchiectasis
nmDMD	nonsense mutation Duchenne muscular dystrophy
NMIBC	non-muscle invasive bladder cancer
NPM1	nucleophosmin 1
nrSPMS	non-relapsing secondary progressive multiple sclerosis
NRTTI	nucleoside reverse transcriptase translocation inhibitor
NSCLC	non-small cell lung cancer
oHCM	obstructive hypertrophic cardiomyopathy
PAD	peripheral artery disease

Term	Definition
PBC	primary biliary cholangitis
Phe	phenylalanine
pJIA	polyarticular juvenile idiopathic arthritis
PKU	phenylketonuria
PPF	progressive pulmonary fibrosis
PsA	psoriatic arthritis
PsO	plaque psoriasis
PSVT	paroxysmal supraventricular tachycardia
RA	rheumatoid arthritis
RRP	recurrent respiratory papillomatosis
SC	subcutaneous
SCD	sickle cell disease
SERD	selective estrogen receptor degrader
siRNA	small interfering ribonucelic acid
sJIA	systemic juvenile idiopathic arthritis
SMA	spinal muscular atrophy
SOT	solid organ transplant
T2DM	type 2 diabetes mellitus
TA-TMA	transplant-associated thrombotic microangiopathy
TGCT	tenosynovial giant cell tumor
TK2d	thymidine kinase 2 deficiency
TKD	tyrosine kinase domain
TKI	tyrosine kinase inhibitor
UC	ulcerative colitis
VOC	vaso-occlusive crisis
VMS	vasomotor symptoms
WAC	Wholesale Acquisition Cost
WAS	Wiskott Aldrich syndrome

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