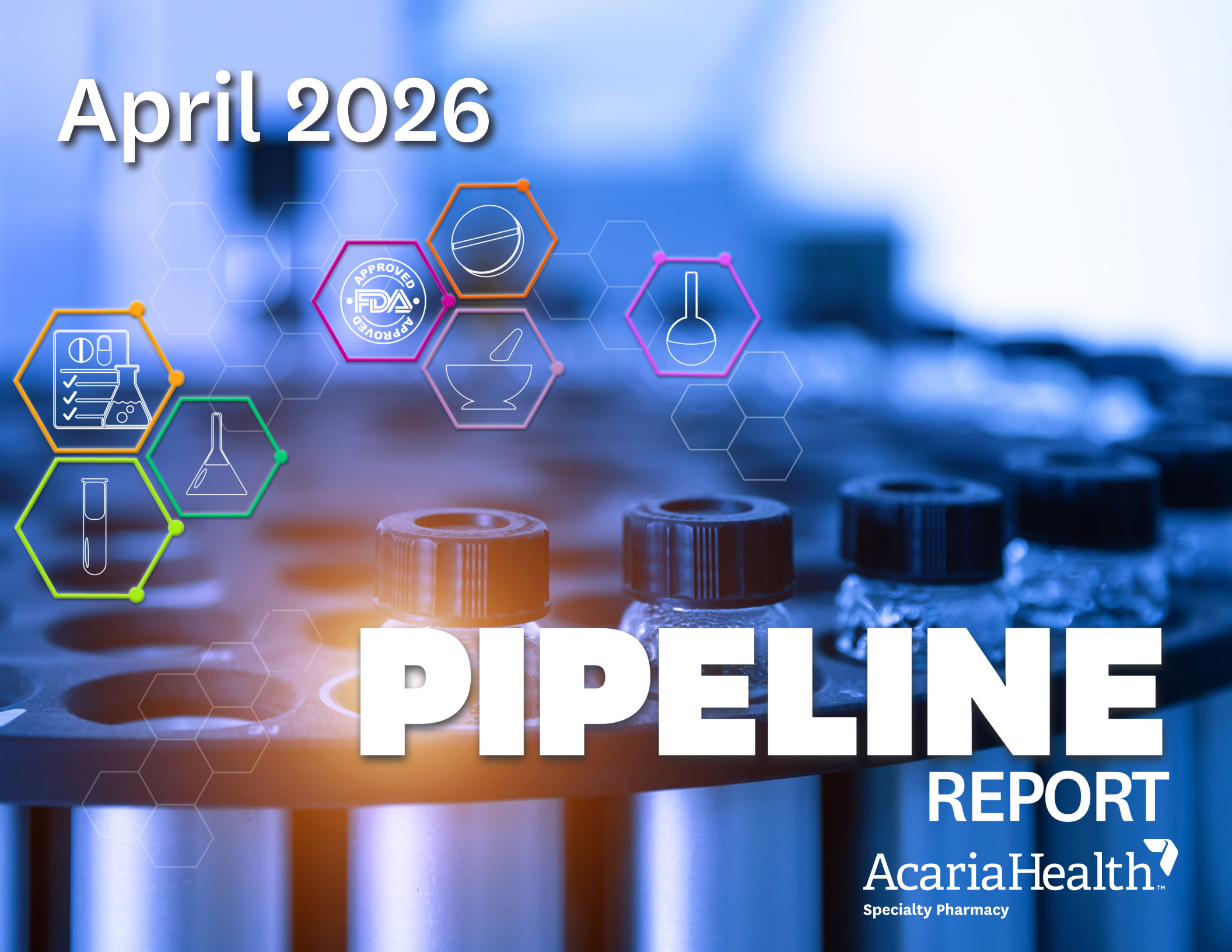

April 2026
APPROVED
FDA
APPROVED
PIPELINE
REPORT
AcariaHealth
Specialty Pharmacy

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.

TABLE OF CONTENTS

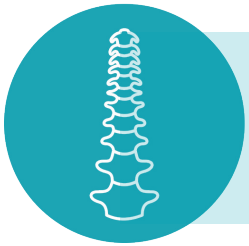
SPECIALTY

HIGHLIGHTS

PIPELINE REPORT: **APRIL 2026**

APPROVED: ZYCUBO *(copper histidinate)* first approved therapy for Menkes disease

APPROVED: LOARGYS *(pegzilarginase-nbln)* first approved therapy for arginase-1 deficiency



APPROVED: SPINRAZA *(nusinersen)* high-dose regimen for spinal muscular atrophy

APPROVED: FOUNDAYO *(orforglipron)*, the second oral GLP-1 receptor agonist and **WEGOVY HD** *(semaglutide 7.2 mg)*, both for weight management

 | Data is current as of 4/27/2026

Recent Specialty Drug Approvals

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC) /Utilizer
DERMATOLOGY					
ICOTYDE™ *icotrokinra* oral tablet Available through **AcariaHealth**	Johnson & Johnson	Plaque psoriasis (PsO)	3/17/2026	· Approved for the treatment of moderate-to-severe PsO in adults and pediatric patients ≥ 12 years of age who weigh ≥ 40 kg who are candidates for systemic therapy or phototherapy · Once daily oral dosing · Enters a crowded market of biologic agents available for the treatment of PsO including oral SOTYKTU and multiple injectable agents · Projected impact: cost replacement of existing therapies	$100,800/year
ENDOCRINOLOGY					
ZYCUBO® *copper histidinate* SC injection	Zydus Pharmaceuticals/ Sentynl Therapeutics	Menkes disease	1/12/2026	· Approved for the treatment of Menkes disease (a rare, X-linked pediatric disease caused by gene mutations of copper transporter ATP7A) in pediatric patients · Low survival rate past age 3 in untreated Menkes patients · First FDA-approved treatment for Menkes disease (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	Age ≤ 12 months: $1,362,910/ year Age > 12 months: $681,455/year
LOARGYS® *pegzilarginase-nbln* SC and IV injections	Immedica	Arginase 1 deficiency (ARG1-D)	2/23/2026	· Accelerated FDA approval for the treatment of hyperargininemia in adult and pediatric patients ≥ 2 years of age with ARG1-D, in conjunction with dietary protein restriction · Once weekly enzyme replacement therapy · First FDA-approved therapy for ARG1-D which has a global prevalence of ~1 in every 1,000,000 people · Projected impact: new cost in a very small population	Weight-dependent dosing: $596,404 -$2,087,414/ year
YUVIWEL® *navepegritide* SC injection	Ascendis Pharmaceuticals	Achondroplasia	2/27/2026	· Accelerated FDA approval to increase linear growth in pediatric patients ≥ 2 years of age with achondroplasia with open epiphyses · Dosed SC once weekly · Competes with VOXZOGO (dosed SC once daily for the same indication) · Projected impact: cost replacement of existing therapy	$498,225/year

 | Data is current as of 4/27/2026

CONTINUED

Recent Specialty Drug Approvals

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC) /Utilizer
AVLAYAH™ *tividenofusp alfa-eknm* IV infusion	Denali Therapeutics	Mucopolysaccharidosis type II (MPS II)	3/24/2026	• Accelerated FDA approval for the treatment of neurological manifestations of MPS II (Hunter syndrome) when initiated in presymptomatic or symptomatic pediatric patients weighing ≥ 5 kg prior to advanced neurologic impairment • Brain-penetrant therapy that may better address MPS II neurological manifestations/cognitive impairment symptoms than current intravenous enzyme replacement therapy (ELAPRASE) • MPS II prevalence estimate: 1 in 100,000 to 1 in 170,000 births • Projected impact: cost replacement of existing therapy	Weight-based dosing: $270,400 - $1,081,600/ year
HEMATOLOGY					
KRESLADI™ *marnetegragene autotemcel* IV infusion	Rocket Pharmaceuticals, Inc.	Leukocyte adhesion deficiency-I (LAD-I)	3/26/2026	**GENE THERAPY** • FDA approved for the treatment of pediatric patients with severe LAD-I (rare genetic condition that results in recurrent life-threatening bacterial and fungal infections that respond poorly to antibiotics and require frequent hospitalizations) • Accelerated approval for patients with biallelic variants in ITGB2 without an available human leukocyte antigen (HLA)-matched sibling donor for allogeneic hematopoietic stem cell transplant • LAD-I prevalence estimate: ~1 in every 1 million people worldwide • Bone marrow transplant is the only available curative therapy • 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 • Projected impact: new cost in a very small population	Pending launch

 | Data is current as of 4/27/2026

CONTINUED

Recent Specialty Drug Approvals

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC) /Utilizer
HEPATOLOGY					
LYNAVOY™ *linerixibat* oral tablet	GSK/Alfasigma	Primary biliary cholangitis (PBC)	3/17/2026	· Approved for the treatment of cholestatic pruritus (a serious, sometimes debilitating condition) associated with PBC in adult patients · 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. · Projected impact: cost replacement of existing therapies	Pending launch
INFECTIOUS DISEASES					
IDVYNSO™ *islatravir/doravirine* oral tablet	Merck	Human immunodeficiency virus-1 (HIV-1) infection	4/20/2026	· Approved 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 < 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 · This combination is the first FDA-approved two-drug regimen without an integrase inhibitor · Projected impact: cost replacement of existing therapies	$53,460/year
NEUROMUSCULAR DISEASES					
SPINRAZA HD® *nusinersen* intrathecal injection	Biogen	Spinal muscular atrophy (SMA)	3/27/2026	· New high-dose formulation approved for the treatment of SMA in pediatric and adult patients · Higher-dose 28 mg and 50 mg vials with a differentiated loading dose regimen that reduces the number of loading doses at treatment initiation from four to two · Projected impact: cost replacement of existing therapy	Year 1: $846,000 Year 2 and beyond: $456,000/year

 | Data is current as of 4/27/2026

CONTINUED

Recent Specialty Drug Approvals

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC) /Utilizer
ONCOLOGY					
YESCARTA® *axicabtagene ciloleucel* IV infusion	Gilead	Primary central nervous system lymphoma (PCNSL)	2/5/2026	**NEW INDICATION FOR AN EXISTING CAR T-CELL THERAPY** • Approved for the treatment of relapsed or refractory (R/R) PCNSL • First CAR T-cell therapy to gain this indication • Previously PCNSL was called out as a Limitation of Use in the YESCARTA Prescribing Information • PCNSL incidence estimate: 1,500 cases annually in the U.S., most commonly in the elderly and in people with a compromised immune system • Projected impact: new cost in a small population	$503,580/one-time treatment
LIFYORLI™ *relacorilant* oral capsule	Corcept Therapeutics	Ovarian cancer	3/25/2026	• Approved for use in combination with nab-paclitaxel for the treatment of adults with platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer who have received 1 to 3 prior systemic treatment regimens, at least 1 of which included bevacizumab • Will compete with standard of care antineoplastic agents for ovarian cancer • Projected impact: cost replacement of existing therapies	$37,900/28-day treatment cycle
OTOLOGY					
OTARMENI™ *lunsotogene parvec-cwha* intracochlear injection	Regeneron	Congenital deafness	4/23/2026	**GENE THERAPY** • Accelerated approval for the 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 • Otoferlin-related hearing loss is ultra-rare, affecting ~50 newborns per year in the U.S. • First gene therapy to be FDA-approved under the FDA Commissioner's National Priority Voucher program	$0 for clinically eligible patients (admini-stration costs may still apply)

 | Data is current as of 4/27/2026

Specialty Products on Our Radar

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
DERMATOLOGY						
ANB019 *imsidolimab* IV infusion	Vanda Pharmaceuticals	Generalized pustular psoriasis (GPP)	Anti-IL-36 receptor antibody	· Other agents available for the treatment of GPP: SPEVIGO, methotrexate, cyclosporin, and acitretin	$100,000/ year	12/12/2026
ENDOCRINOLOGY						
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
VTS-270 Ⓢ *adrabetadex* intrathecal injection	Beren Therapeutics	Niemann-Pick disease Type C (NPC)	NPC1 protein mimetic	· Proposed for the treatment of infantile-onset NPC · Would be the third FDA-approved therapy for NPC after AQNEURSA and MIPLYFFA, but the first to focus on infantile-onset disease (most severe NPC subtype) · Administered as an intrathecal injection while AQNEURSA and MIPLYFFA are both oral therapies	$750,000/ year	8/17/2026
DTX401 Ⓢ *pariglasgene brecaparvovec* IV infusion	Ultragenyx	Glycogen storage disease Type 1a (GSD1a)	Gene therapy	**GENE THERAPY** · GSDIa is a rare, genetic metabolic disorder leading to inability to maintain normal glucose levels, estimated to affect ~600 people in the U.S. · Currently no FDA-approved therapies for GSD1a	$3 million/ one-time treatment	8/23/2026
UX111 Ⓢ *rebisufligene etisparvovec* IV infusion	Ultragenyx	Mucopolysaccharidosis type IIIA (MPS IIIA)	*SGSH* gene-directed gene therapy	**GENE THERAPY** · Proposed for the treatment of Sanfilippo syndrome type A (aka MPS IIIA), a rare, fatal lysosomal storage disease that primarily affects the central nervous system, characterized by rapid neurodegeneration, with onset in early childhood · Currently no approved treatment for MPS IIIA	$3 million/ one-time treatment	9/19/2026

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

 | Data is current as of 4/27/2026

CONTINUED

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
EMCITATE Ⓢ *tiratricol* oral therapy	Egetis Therapeutics	Monocarboxylate transporter 8 (MCT8) deficiency	Thyroid hormone analog	• Proposed for the treatment of MCT8 deficiency (aka Allan-Herndon-Dudley syndrome), an ultra-rare genetic disease with no cure and high unmet medical need • Once daily oral therapy • Treatment focuses on supportive care (physical, occupational, and speech therapy) and managing thyroid hormone imbalance	$500,000/ year	9/28/2026
HEMATOLOGY						
BBM-H901 Ⓢ *dalnacogene ponparvovec* IV infusion	Belief BioMed	Hemophilia B	Gene therapy	**GENE THERAPY** • Proposed for the treatment of adults with severe or moderately severe hemophilia B • Would be the third FDA-approved gene therapy for hemophilia B (after HEMGENIX and BEQVEZ), second available on the U.S. market after removal of BEQVEZ	$3.5 million/ one-time treatment	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 SCD and recurrent vaso-occlusive crises (VOCs) or with TDT • Currently FDA-approved for the treatment of patients ≥ 12 years of age with SCD and TDT • Expanded age range will compete with ZYNTEGLO (approved for TDT in adult and pediatric patients with data supporting use in patients as young as 4 years of age) • Expanded indications selected by FDA to receive the Commissioner's National Priority Voucher (allows for potential FDA approval within 1-2 months of a completed regulatory filing submission); Vertex indicated intent to complete filing during 1H 2026	$2.2 million/ one-time treatment	1H 2026

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

 | Data is current as of 4/27/2026

CONTINUED

Specialty Products on Our Radar

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
MIM8 *denecimig* SC injection	Novo Nordisk	Hemophilia A	Factor VIIIa mimetic bispecific antibody	• Proposed for the treatment of people aged ≥ 12 years with hemophilia A with or without inhibitors • Would compete with HEMLIBRA, HYMPAVZI, ALHEMO, and FVIII replacement therapies	$750,000/ year	9/1/2026
HEPATOLOGY						
HEPCLUDEX® *bulevirtide* SC injection	Gilead	Hepatitis delta virus (HDV) infection	Viral entry inhibitor	• Would be the first FDA-approved agent for this indication • 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
IMMUNOLOGY						
brepocitinib oral therapy	Priovant Therapeutics	Dermatomyositis	TYK2/JAK1 inhibitor	• Would be the first targeted therapy FDA-approved for dermatomyositis	$400,000/ year	3Q 2026
IdeS *imlifidase* IV injection	Hansa Medical	Transplant desensitization	IgG degrader	• Proposed for the desensitization of highly sensitized adult patients undergoing deceased donor kidney transplantation • Particularly underserved group in kidney transplantation, highly sensitized patients represent an estimated 10–15% of individuals on transplant waiting lists • Existing institution-specific desensitization protocols can include any combination of plasma exchange, immunoglobulin, anti-CD20 antibody, and SOLIRIS where appropriate OR remain on wait list for a more compatible organ offer	$450,000/ one-time treatment	12/19/2026

Expected to cost ≥ $500,000 per member

 | Data is current as of 4/27/2026

CONTINUED

Specialty Products on Our Radar

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
MUSCULOSKELETAL DISEASE						
REGN2477 Ⓢ *garetosmab* IV infusion	Regeneron	Fibrodysplasia ossificans progressiva (FOP)	Activin A neutralizer	• Proposed for the treatment of adults with FOP • Garetosmab would be the second FDA-approved agent for FOP after Sohonos, which is also approved for pediatric patients with FOP • Estimated disease prevalence of ~1.36-1.43 per million individuals	$650,000/ year	8/1/2026
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
SIBNAYAL® *potassium citrate and potassium bicarbonate* oral granules	Advicenne	Distal renal tubular acidosis (dRTA)	pH modifier	• Proposed for the treatment of dRTA (rare disease of the distal tubule caused by impaired urinary acid secretion that may result in failure to thrive, rickets/ osteomalacia, lithiasis, and nephrocalcinosis that can lead to renal failure) • Estimated 20,000 patients in the U.S. suffer from primary and secondary dRTA • Twice a day oral treatment (current standard of care: various unapproved potassium products administered every four to six hours to attempt to re-balance the body's pH)	$250,000/ year	9/3/2026

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

 | Data is current as of 4/27/2026

CONTINUED

Specialty Products on Our Radar

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
NEUROMUSCULAR DISEASES						
CAP-1002 Ⓢ *deramiocel* IV infusion	Capricor Therapeutics	Duchenne muscular dystrophy (DMD)-associated cardiomyopathy	Anti-fibrotic, anti-inflammatory, angiogenic	**CELL THERAPY** · CAP-1002 is an allogeneic stromal cell therapy manufactured from donor heart tissue · Initial target treatment population: patients in advanced stages of DMD (late ambulatory or non-ambulatory) · Administered as an IV infusion once every 3 months	$600,000/ year	8/22/2026
ALXN1720 *gefurulimab* SC injection	AstraZeneca	Generalised myasthenia gravis (gMG)	Complement C5 binder	· Proposed for the treatment of adults with anti-acetylcholine receptor (AChR) antibody-positive (Ab+) gMG · Would compete with multiple existing agents for the treatment of AChR-positive gMG including SOLIRIS, ULTOMIRIS, and ZILBRYSQ, in addition to non-complement-mediated agents such as VYVGART, RYSTIGGO, and IMAAVY · Once weekly SC injection	$475,000/ year	2H 2026
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 · Would increase the total cost of care over the existing cost for SMN-targeted treatments when used as intended as adjunctive therapy · Scholar Rock resubmitted the BLA to the FDA in March 2026	$400,000/ year	Pending FDA's acceptance of the BLA re-submission

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

 | Data is current as of 4/27/2026

CONTINUED

Specialty Products on Our Radar

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NEUROLOGY						
ION373 Ⓢ *zilganersen* intrathecal injection	Ionis	Alexander disease (AxD)	Antisense oligonucleotide	· Proposed for the treatment of AxD (severe, progressive and debilitating ultra-rare neurodegenerative disease estimated to occur in approximately one in one million to one in three million people worldwide) · AxD usually leads to death within 14 - 25 years after symptom onset · Currently no FDA-approved therapies for AxD · Intrathecal injection every 12 weeks	$850,000/ year	9/22/2026
relutrigine Ⓢ oral therapy	Praxis Precision Medicines	Developmental and epileptic encephalopathies (DEEs)	Sodium current inhibitor	· Proposed for the treatment of SCN2A and SCN8A DEEs (rare developmental and epileptic encephalopathies that cause recurrent, typically drug-resistant seizures) · Seizures can start as early as the first day of life, be of multiple different types, up to dozens per day, with poor response to current treatment options	$500,000/ year	9/27/2026
ONCOLOGY						
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 (a rare subtype of aggressive B-cell non-Hodgkin lymphoma) who have received prior treatment with a BTK inhibitor · MCL accounts for approximately 5% of all non-Hodgkin lymphoma cases	$250,000/ year	5/26/2026
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

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

 | Data is current as of 4/27/2026

CONTINUED

Specialty Products on Our Radar

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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
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** • Would compete with conventional allogeneic hematopoietic stem cell transplants, with the potential for lower rates of graft vs. host disease	$450,000/ one-time treatment	7/6/2026
gedatolisib IV infusion	Celcuity	Breast cancer	Dual PI3K and mTOR inhibitor	• Proposed for the treatment of patients with HR+/ HER2-, *PIK3CA* wild-type advanced or metastatic breast cancer after progression on CDK4/6 therapy	$400,000/ year	7/17/2026
rivoceranib* + *camrelizumab oral therapy and IV infusion	Elevar Therapeutics	Hepatocellular carcinoma (HCC)	Tyrosine kinase inhibitor + PD-1 inhibitor	• Proposed for use as first-line treatment for unresectable or metastatic HCC • Would compete with regimens such as TECENTRIQ plus bevacizumab as first-line therapy for unresectable HCC	$400,000/ year	7/23/2026
iberdomide oral therapy	Bristol Myers Squibb	Relapsed or refractory multiple myeloma (RRMM)	Cereblon E3 ligase modulator	• Proposed in combination with standard treatment (daratumumab + dexamethasone) for the treatment of patients with RRMM	$350,000/ year	8/17/2026

 | Data is current as of 4/27/2026

CONTINUED

Specialty Products on Our Radar

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ITM-11 *^{177}Lu-edotreotide* IV infusion	ITM Isotope Technologies Munich	Gastroenteropan-creatic neuroendocrine tumors (GEP-NETs)	Radiopharmaceu-tical	• Proposed for the treatment of GEP-NETs (rare types of tumors originating in the pancreas or other parts of the gastrointestinal tract) • Early diagnosis of GEP-NETs 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
PTG-300 *rusfertide* SC injection	Protagonist Therapeutics	Polycythemia vera (PV)	Synthetic hepcidin analog	• Proposed for the treatment of adults with PV • Current treatments include phlebotomy to reduce the volume of red blood cells in the body and pharmacologic agents such as hydroxyurea and JAKAFI	$200,000/ year	3Q 2026
RLY-4008 *lirafugratinib* oral therapy	Elevar Therapeutics	Cholangiocarci-noma	FGFR2 inhibitor	• Proposed as second-line therapy for cholangiocarcinoma patients with FGFR2 fusion or rearrangement	$350,000/ year	9/27/2026
ASBSK021 *pimicotinib* oral therapy	Abbisko Therapeutics	Tenosynovial giant cell tumor (TGCT)	CSF-1R inhibitor	• Proposed for the treatment of patients with TGCT who are not amenable to surgery • Would compete with ROMVIMZA and TURALIO which are also FDA-approved for TGCT	$350,000/ year	October 2026
SMT112 *ivonescimab* IV infusion	Summit Therapeutics	NSCLC	Anti-PD-1 and VEGF bispecific antibody	• Proposed in combination with chemotherapy in patients with EGFR-mutated locally advanced or metastatic non-squamous NSCLC post-tyrosine kinase inhibitor therapy	$250,000/ year	11/14/2026
XL092 *zanzalintinib* oral tablet	Exelixis	Colorectal cancer (CRC)	Kinase inhibitor	• Proposed in combination with atezolizumab for the treatment of adult patients with metastatic CRC who have been previously treated with fluoropyrimidine-, oxaliplatin- and irinotecan-based chemotherapy, and, if RAS wild-type, an anti-EGFR therapy	$350,000/ year	12/3/2026

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CONTINUED

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giredestrant oral therapy	Genentech	Breast cancer	SERD	• Proposed in combination with everolimus for the treatment of adult patients with ER+/HER2-, ESR1-mutated locally advanced or metastatic breast cancer following recurrence or progression on a prior endocrine-based regimen • Would compete with INLURIYO and ORSERDU which are FDA-approved for the same tumor type	$300,000/ year	12/18/2026
tirabrutinib oral capsule	Deciphera Pharmaceuticals	Primary central nervous system lymphoma (PCNSL)	Bruton tyrosine kinase inhibitor	• Proposed for the treatment of relapsed or refractory PCNSL • PCNSL incidence estimate: 1,500 cases in U.S., mostly seen in elderly and people with compromised immune system	$350,000/ year	12/18/2026
bezuclastinib oral tablet	Cogent Biosciences	Non-advanced systemic mastocytosis (nonAdvSM)	KIT tyrosine kinase inhibitor	• Proposed for the treatment of patients with nonAdvSM previously treated with avapritinib as well as patients with smoldering systemic mastocytosis	$350,000/ year	12/30/2026
OPHTHALMOLOGY						
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
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	1H 2026

 | Data is current as of 4/27/2026

CONTINUED

Specialty Products on Our Radar

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
MOLBREEVI® Ⓢ *molgramostim* inhalation therapy	Savara Pharmaceuticals	Autoimmune pulmonary alveolar proteinosis (aPAP)	Granulocyte-macrophage colony-stimulating factor	• aPAP is characterized by the abnormal build-up of surfactant in the lungs leading to impaired gas exchange, resulting in shortness of breath, often with cough and frequent fatigue • Potential serious complications to long-term include lung fibrosis and need for lung transplant • PAP estimated prevalence: 7 people per million • Currently no FDA-approved therapies; current standard of care is whole lung lavage	$500,000/ year	11/22/2026
INO-3107 *doruxapapogene ralaplasmid* 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 4/27/2026

Drug Name & Administration Method	Manufacturer(s)	Biosimilar Reference Drug	Indication(s)	Status/Estimated Approval	Biosimilar Currently Launched?	Comments
ENDOCRINOLOGY						
PONLIMSI® *denosumab-adet* SC injection	Teva	PROLIA	osteoporosis and prevention of fractures related to cancer therapy	FDA approval: 3/27/2026	Yes - BILDYOS, BOSAYA, CONEXXENCE, ENOBY, JUBBONTI, STOBOCLO, OSPOMYV	• 10th PROLIA biosimilar after CONEXXENCE, STOBOCLO, JUBBONTI, OSPOMYV, BILDYOS, BOSAYA, ENOBY, OSVYRTI, BONCRESA
HEMATOLOGY						
FILKRI™ *filgrastim-laha* SC and IV injections	Accord Biopharma	NEUPOGEN	neutropenia, hematopoietic syndrome of acute radiation syndrome	FDA approval: 1/15/2026	Yes - NIVESTYM, NYPOZI, RELEUKO, ZARXIO	• 5th NEUPOGEN biosimilar after NIVESTYM, NYPOZI, RELEUKO, ZARXIO
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 • 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
DRL_AB *abatacept* IV infusion	Dr. Reddy's Laboratories	ORENCIA	RA, PsA, pJIA	BLA is under FDA review (BsUFA date: December 2026)	No	• Would be the first FDA-approved biosimilar to ORENCIA

 | Data is current as of 4/27/2026

CONTINUED

Drug Name & Administration Method	Manufacturer(s)	Biosimilar Reference Drug	Indication(s)	Status/Estimated Approval	Biosimilar Currently Launched?	Comments
omalizumab SC injection	Teva	XOLAIR	persistent asthma; chronic rhinosinusitis with nasal polyps (CRSwNP), chronic spontaneous urticaria	BLA is under FDA review (BsUFA date: 1Q 2027)	No	· Would be a subsequent XOLAIR biosimilar, after OMLYCLO
ONCOLOGY						
HLX04 *bevacizumab* IV infusion	Shanghai Henlius Biotech	AVASTIN	colorectal cancer, non-small cell lung cancer, glioblastoma, renal cell carcinoma, cervical cancer, ovarian cancer	BLA is under FDA review (BsUFA date: October 2026)	Yes - ALYMSYS, JOBEVNE, MVASI, VEGZELMA, ZIRABEV	· Would be the 7th biosimilar to AVASTIN after ALYMSYS, AVZIVI, JOBEVNE, MVASI, VEGZELMA, ZIRABEV
OPHTHALMOLOGY						
AVT06 *aflibercept* intraocular injection	Alvotech	EYLEA	Wet AMD	BLA is under FDA review (BsUFA date: 2Q 2026)	Yes - PAVBLU	· Would be a subsequent EYLEA biosimilar, after AHZANTIVE, ENVEEZU, OPUVIZ, PAVBLU, and YESAFILI

 | Data is current as of 4/27/2026

Recent Approvals			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**MARKET LAUNCH DATE**
rilpivirine hydrochloride	EDURANT®	Somerset Therapeutics	2/10/2026
pomalidomide	POMALYST®	Breckenridge	2/28/2026
nintedanib esylate	OFEV®	Apotex; Cipla; Dexcel; Dr. Reddy's Laboratories; Sandoz	4/2/2026

Pipeline Agents*			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**ANTICIPATED LAUNCH DATE**
melphalan hydrochloride	EVOMELA®	Actavis/Teva	6/1/2026
macitentan	OPSUMIT®	Alembic; Amneal; Apotex; Aurobindo; Laurus Labs; MSN Laboratories; Mylan/Viatris; Seasons Biotechnology; Sun; Zydus	2Q 2026
sugammadex sodium	BRIDION®	Aspiro Pharma; B. Braun; Dr. Reddy's Laboratories; Eugia Pharma/Aurobindo; Fresenius Kabi; Gland Pharma; Hikma; Mankind Pharma; MSN Laboratories; Mylan/Viatris; Qilu Pharmaceutical (Hainan); Sandoz; Shandong DaGuan Medicine; Sun; Tamarang; Teva; USV; Zenara/Biophore; Zydus	7/28/2026
riociguat	ADEMPAS®	Alembic; MSN Laboratories; Teva	4Q 2026
treprostinil	TYVASO®	Actavis/Teva	2026
naltrexone	VIVITROL®	Teva	1/15/2027
buprenorphine hydrochloride	BELBUCA®	Teva	1/23/2027
selexipag (tablet and intravenous)	UPTRAVI®	Alembic; MSN Laboratories; Vgyaan; Zydus	April 2027

***Includes generic agents with > 50% launch probability**

 | Data is current as of 4/27/2026

Glossary

Term	Definition
Ab+	antibody-positive
AChR	acetylcholine receptor
ADC	antibody-drug conjugate
ADHD	attention-deficit hyperactivity disorder
ALL	acute lymphoblastic leukemia
allo-HSCT	allogeneic hematopoietic stem cell transplantation
AMD	age-related macular degeneration
AML	acute myeloid leukemia
aPAP	autoimmune pulmonary alveolar proteinosis
apoC-III	apolipoprotein C-III
ARG1-D	arginase 1 deficiency
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
CRC	colorectal cancer
CRSwNP	chronic rhinosinusitis with nasal polyps
CSU	chronic spontaneous urticaria
DED	dry eye disease
DEE	developmental and epileptic encephalopathy
DLBCL	diffuse large B-cell lymphoma
DMD	Duchenne muscular dystrophy
DPP1	dipeptidyl peptidase 1
dRTA	distal renal tubular acidosis
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
FOP	fibrodysplasia ossificans progressiva
GEP-NET	Gastroenteropancreatic neuroendocrine tumor
GIP	glucose-dependent insulinotropic polypeptide
GLP-1	glucagon-like peptide-1
gMG	generalized myasthenia gravis
GR-II	glucocorticoid II
GSD1a	glycogen storage disease Type 1a
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
MCT8	monocarboxylate transporter 8
MM	multiple myeloma
MPS II	mucopolysaccharidosis type II
MPS IIIA	mucopolysaccharidosis type IIIA
MZL	marginal zone lymphoma
NCFB	non-cystic fibrosis bronchiectasis
nmDMD	nonsense mutation Duchenne muscular dystrophy
NMIBC	non-muscle invasive bladder cancer
nonAdvSM	non-advanced systemic mastocytosis
NPC	Niemann-Pick disease Type C
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
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
PV	polycythemia vera
RA	rheumatoid arthritis
RRMM	relapsed or refractory multiple myeloma
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

CONTINUED

 | Data is current as of 4/27/2026

Glossary

Term	Definition
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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