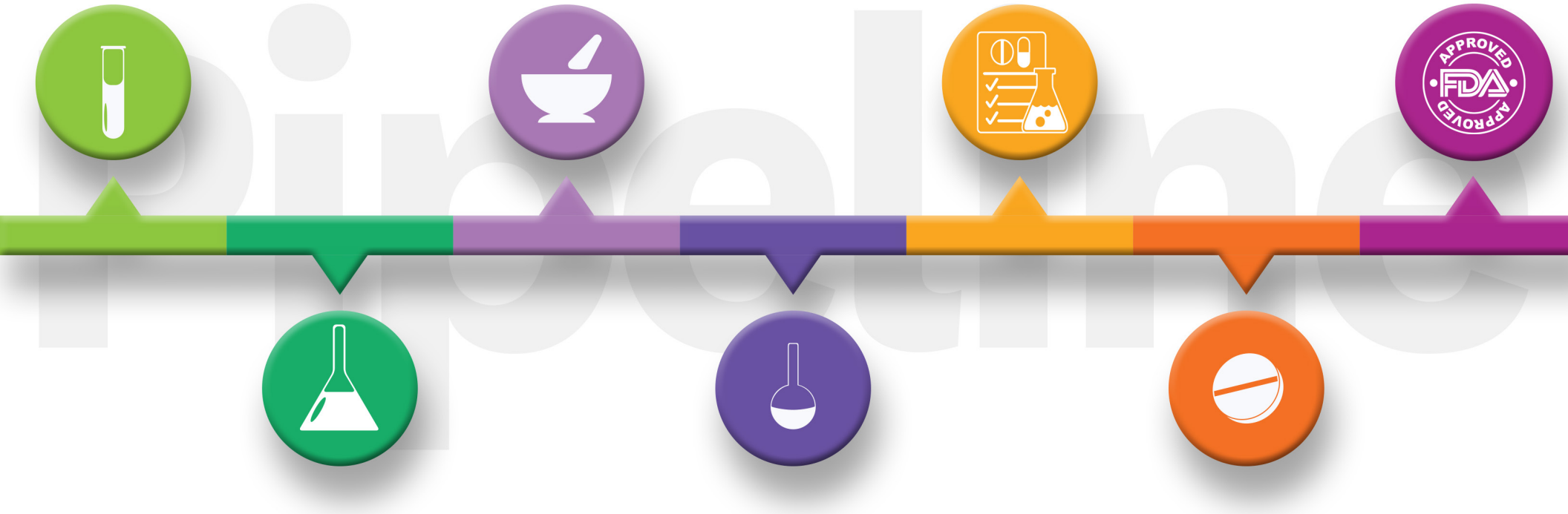

PIPELINE REPORT: OCTOBER 2025

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

PIPELINE REPORT: **OCTOBER 2025**

Highlights

APPROVED: FORZINITY *(elamipretide)* for the treatment of ultra-rare disease Barth syndrome

APPROVED: PAPZIMEOS *(zopapogene imadenovec-drba)* for the treatment of recurrent respiratory papillomatosis

 | Data is current as of 10/22/2025

Recent Specialty Drug Approvals

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC) /Utilizer
DERMATOLOGY					
ANZUPGO® *delgocitinib* topical cream	Leo Pharma	Chronic hand eczema (CHE)	7/23/2025	· Approved for the topical treatment of moderate to severe CHE in adults who have had an inadequate response to, or for whom topical corticosteroids are not advisable. · Current treatment options for CHE include steroids, calcineurin inhibitors, vitamin D derivatives, and emollients. · Projected impact: cost replacement of existing therapies.	$1,986/30 gm tube
RHAPSIDO® *remibrutinib* oral tablet	Novartis	Chronic spontaneous urticaria (CSU)	9/30/2025	· Approved for the treatment of CSU in adult patients who remain symptomatic despite H1 antihistamine treatment. · Competes with DUPIXENT and XOLAIR, two injectable biologic agents which are also FDA-approved for CSU. · Projected impact: cost replacement of existing therapies.	$54,252/year
ENDOCRINOLOGY					
SEPHIENCE® *sepiapterin* oral powder packets	PTC Therapeutics	Phenylketonuria (PKU)	7/28/2025	· Approved for the treatment of hyperphenylalaninemia (HPA) in adult and pediatric patients ≥ 1 month of age with sepiapterin-responsive phenylketonuria (PKU). Sephience is to be used in conjunction with a phenylalanine (Phe)-restricted diet. · Competes with KUVAN (available generically as sapropterin) for the same indication. · Projected impact: cost replacement of existing therapies.	$501,875/year for a 45 kg patient

 | Data is current as of 10/22/2025

CONTINUED

Recent Specialty Drug Approvals

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC) /Utilizer
FORZINITY™ *elamipretide* SC injection	Stealth BioTherapeutics	Barth syndrome	9/19/2025	• FDA granted accelerated approval to improve muscle strength in adult and pediatric patients with Barth syndrome weighing ≥ 30 kg. • Barth syndrome is an ultra-rare metabolic disorder characterized by skeletal muscle weakness, delayed growth, fatigue, varying degrees of physical disability, cardiomyopathy, neutropenia and methylglutaconic aciduria. The estimated incidence of Barth syndrome is between one in 300,000 to 400,000 births. • FORZINITY is the first FDA-approved therapy for Barth syndrome; previously used off-label treatments for Barth syndrome have been focused on reducing symptoms and preventing complications. • Projected impact: significant new cost in a very small population.	$795,750/year
PALSONIFY™ *paltusotine* oral tablet	Crinetics Pharmaceuticals	Acromegaly	9/25/2025	• For the treatment of adults with acromegaly who had an inadequate response to surgery and/or for whom surgery is not an option. • Once-daily oral therapy. • Would compete with injectable somatostatin analogs (e.g., SOMATULINE DEPOT, SANDOSTATIN, SIGNIFOR) and twice-daily oral MYCAPSSA. • Projected impact: cost replacement of existing therapies.	$290,000/ year
HEMATOLOGY					
EKTERLY® *sebetralstat* oral tablet	KalVista Pharmaceuticals	Hereditary angioedema (HAE)	7/3/2025	• Approved for the treatment of acute attacks of HAE in adult and pediatric patients ≥ 12 years of age. • EKTERLY is the first oral, on-demand therapy for people living with HAE. • Competes with other HAE therapies used for on-demand treatment such as FIRAZYR (now generic) and BERINERT, KALBITOR, and RUCONEST. • Projected impact: cost replacement of existing therapies.	$200,640/year (for 12 acute attacks per year)

 | Data is current as of 10/22/2025

CONTINUED

Recent Specialty Drug Approvals

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC) /Utilizer
DAWNZERA™ *donidalorsen* SC injection	Ionis Pharmaceuticals	HAE	8/21/2025	• Approved for prophylaxis to prevent attacks of HAE in adult and pediatric patients ≥ 12 years of age. • DAWNZERA is dosed once every 4 weeks with the option to extend dosing to once every 8 weeks depending on clinical response. • Competes with existing HAE prophylactic agents including, CINRYZE, ORLADEYO, and TAKHZYRO. • Projected impact: cost replacement of existing therapies.	Every 4-week dosing: $747,006/year Every 8-week dosing: $344,772/year
WAYRILZ™ *rilzabrutinib* oral tablet	Sanofi	Immune thrombocytopenia (ITP)	8/29/2025	• Approved for the treatment of adult patients with persistent or chronic ITP who have had an insufficient response to a previous treatment. • Prednisone, immunoglobulins, RITUXAN, PROMACTA, NPLATE, TAVALISSE are existing treatment alternatives. • Projected impact: cost replacement of existing therapies.	$212,917/year
ONCOLOGY					
ZEGFROVY™ *sunvozertinib* oral tablets	Dizal	Non-small cell lung cancer (NSCLC)	7/2/2025	• Approved for the treatment of adult patients with locally advanced or metastatic NSCLC with epidermal growth factor receptor (EGFR) exon 20 insertion mutations, as detected by an FDA-approved test, whose disease has progressed on or after platinum-based chemotherapy. • RYBREVANT intravenous infusion is FDA-approved for use as a single agent for the same indication. • Projected impact: cost replacement of existing therapies.	Pending launch

 | Data is current as of 10/22/2025

CONTINUED

Recent Specialty Drug Approvals

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC) /Utilizer
LYNOZYFIC™ *linvoseltamab-gcpt* IV infusion	Regeneron	Multiple myeloma (MM)	7/2/2025	• Approved for the treatment of adult patients with relapsed or refractory MM who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. • The LYNOZYFIC Prescribing Information includes a Boxed Warning re: cytokine release syndrome and neurologic toxicity, including immune effector cell-associated neurotoxicity syndrome. • Multiple other agents, including CAR T-cell therapies such as ABECMA and CARVYKTI, are also FDA-approved for use as 5th-line or later therapy in relapsed or refractory MM. • Projected impact: cost replacement of existing therapies.	Year 1: $472,820 - $604,420 Year 2 and thereafter: $244,400 - $488,800/year *Annual cost varies based on response to therapy by Week 24 of treatment.*
MODEYSO™ *dordaviprone* oral capsule	Jazz Pharmaceuticals	Glioma	8/6/2025	• FDA granted accelerated approval for the treatment of adult and pediatric patients ≥ 1 year of age with diffuse midline glioma harboring an *H3 K27M* mutation with progressive disease following prior therapy. • MODEYSO is the first FDA-approved treatment for this ultra-rare and aggressive brain tumor that affects an estimated 2,000 people in the U.S. each year and which is most commonly diagnosed in children and young adults. This type of glioma is associated with an extremely poor prognosis, with limited therapeutic options and very low survival rates following recurrence. Median survival is approximately one year from diagnosis and < 6 months after progressing following frontline therapy. • Projected impact: new cost in a small population.	Range of weight-based dosing: $166,400 - $832,000/year

 | Data is current as of 10/22/2025

CONTINUED

Recent Specialty Drug Approvals

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC) /Utilizer
HERNEXEOS® *zongertinib* oral tablet	Boehringer Ingelheim	NSCLC	8/8/2025	· FDA granted accelerated approval for the treatment of adult patients with unresectable or metastatic non-squamous NSCLC whose tumors have HER2 (ERBB2) tyrosine kinase domain activating mutations, as detected by an FDA-approved test, and who have received prior systemic therapy. · HERNEXEOS is the first oral agent to be FDA-approved for this indication; ENHERTU is an IV-administered agent approved for the same indication. · Projected impact: cost replacement of existing therapy.	$263,615/year
PAPZIMEOS™ *zopapogene imadenovec-drba* SC injection	Precigen, Inc.	Recurrent respiratory papillomatosis (RRP)	8/14/2025	· Approved for the treatment of adults with RRP. · PAPZIMEOS is designed to elicit immune responses directed against cells infected with human papillomavirus (HPV) 6 or HPV 11. · The prevalence of RRP is estimated to be ~27,000 adults in the U.S. · Papillomas are benign, but in extremely rare cases can undergo cancerous transformation; additionally, although benign, papillomas can cause severe, life-threatening airway obstruction and respiratory complications. · Recurrence of papilloma after surgical removal is very common and repeated procedures are required to debulk and monitor the disease, which exposes patients to anesthetic and surgical risks, and emotional distress. · Projected impact: new cost with the potential for some medical cost offset by avoidance of recurrent debulking surgeries.	$460,000/ one-time treatment course
INLEXZO™ *gemcitabine* intravesical instillation	Janssen	Non-muscle invasive bladder cancer (NMIBC)	9/9/2025	· Approved for the treatment of adult patients with Bacillus Calmette-Guérin (BCG)-unresponsive NMIBC with carcinoma in situ (CIS) with or without papillary tumors. · Radical cystectomy is currently recommended for NMIBC patients who are unresponsive to BCG therapy, with > 90% cancer-specific survival if performed before muscle-invasive progression. · The INLEXZO Prescribing Information supports a total duration of therapy of two years. · Projected impact: cost replacement of existing therapy.	Year 1: $552,000 Year 2: $276,000

 | Data is current as of 10/22/2025

CONTINUED

Recent Specialty Drug Approvals

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC) /Utilizer
KEYTRUDA QLEX™ *pembrolizumab + berahyaluronidase-pmph* SC infusion	Merck	Multiple solid tumor types	9/19/2025	• **New SC formulation of an existing IV agent.** • Approved for the treatment of adults across most solid tumor indications for IV KEYTRUDA and for pediatric patients ≥ 12 years of age with melanoma, microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR) solid tumors, and Merkel cell carcinoma. • Competes with IV KEYTRUDA and with SC/IV versions of other checkpoint inhibitors (e.g., OPDIVO QVANTIG, TECENTRIQ HYBREZA). • KEYTRUDA QLEX can be given in one minute every three weeks or in two minutes every six weeks vs. a 30-minute IV infusion of KEYTRUDA. • Projected impact: cost replacement of existing therapies.	$204,533/year
INLURIYO™ *imlunestrant* oral tablet	Eli Lilly	Breast cancer	9/25/2025	• Approved for the treatment of adults with estrogen receptor (ER)-positive, human epidermal growth factor 2 (HER2)-negative, estrogen receptor-1 (ESR1)-mutated advanced or metastatic breast cancer with disease progression following at least one line of endocrine therapy. • An ESR1 mutation is one of the key resistance mechanisms that can develop in later treatment lines of metastatic breast cancer. • ORSERDU (elacestrant) is similarly indicated as INLURIYO, but for postmenopausal women and adult men. • Projected impact: cost replacement of existing therapies.	$292,500/year

 | Data is current as of 10/22/2025

Recent Specialty Drug Approvals

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC) /Utilizer
RESPIRATORY DISEASES					
BRINSUPRI™ *brensocatib* oral tablet	Insmed Inc.	Non-cystic fibrosis bronchiectasis (NCFB)	8/12/2025	• Approved for the treatment of NCFB in adult and pediatric patients ≥ 12 years of age. • NCFB is a chronic inflammatory lung disease that has a marked impact on quality of life and predominantly affects females and older adults. • Approximately half of patients with bronchiectasis experience ≥ 2 exacerbations per year. Treatment has previously been focused on preventing exacerbations and reducing symptoms, and typically consists of airway clearance techniques, antibiotics, inhaled bronchodilators, or anti-inflammatory medications. • Projected impact: incremental cost increase primarily in the older adult population that experiences recurrent exacerbations.	$89,222/year
JASCAYD® *nerandomilast* oral tablet	Boehringer Ingelheim	Idiopathic pulmonary fibrosis (IPF)	10/7/2025	• Approved for the treatment of IPF in adult patients. • An sNDA for this agent for the treatment of progressive pulmonary fibrosis (PPF) has also been submitted to the FDA. • Current therapies approved for the treatment of IPF include oral ESBRIET (available as a generic) and OFEV. • Projected impact: cost replacement of existing therapies.	$197,340/year

 | Data is current as of 10/22/2025

Specialty Products on Our Radar

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
CARDIOVASCULAR DISEASE						
CK-3773274 *aficamten* oral therapy	Cytokinetics, Inc.	Obstructive hypertrophic cardiomyopathy (oHCM)	Cardiac myosin inhibitor	· Proposed for the treatment of symptomatic oHCM. · Would compete with CAMZYOS, which is FDA-approved for the same indication.	$100,000/ year	12/26/2025
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 new Commissioner's National Priority Voucher which allows for potential FDA approval within 1-2 months of a completed regulatory filing submission.	$350,000/ year	4Q 2025
ENDOCRINOLOGY						
MT1621 Ⓢ *doxecitine/doxribtimine* oral therapy	UCB Biosciences Inc.	Thymidine kinase 2 deficiency (TK2d)	Deoxynucleoside substrate enhancement therapy	· 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. · There are currently no FDA-approved therapies for TK2d.	$500,000/ year	4Q 2025
ARO-APOC3 Ⓢ *plozasiran* SC injection	Arrowhead Pharmaceuticals	Familial chylomicronemia syndrome (FCS)	Apolipoprotein C-III (apoC-III)-targeting RNAi therapeutic	· Proposed as an adjunct to diet for reducing triglycerides in adult patients with FCS. · Would compete with TRYNGOLZA for the same indication.	$595,000/ year	11/18/2025

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

 | Data is current as of 10/22/2025

CONTINUED

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	11/30/2025
CORT125134 Ⓢ *relacorilant* oral therapy	Corcept Therapeutics	Hypercortisolism and ovarian cancer	Glucocorticoid II (GR-II) receptor antagonist	· Proposed for the treatment of patients with endogenous hypercortisolism (Cushing's syndrome) and for the treatment of platinum-resistant ovarian cancer in combination with nab-paclitaxel. · Would compete with other agents which are FDA-approved or considered standard therapy for Cushing's disease or Cushing's syndrome such as KORLYM, ISTURISA, RECORLEV, ketoconazole, and SIGNIFOR. · Would also compete with standard of care antineoplastic agents for ovarian cancer.	$600,000/ year	Cushing's syndrome: 12/30/2025 Ovarian cancer: 7/11/2026
DNL310 Ⓢ *tividenofusp alfa* IV infusion	Denali Therapeutics	Mucopolysaccharidosis type II (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

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

 | Data is current as of 10/22/2025

CONTINUED

Specialty Products on Our Radar

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
RGX-121 Ⓢ *clemidsogene lanparvovec* intracerebral injection	RegenXBio, Inc.	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. DNL310 is a brain-penetrant therapy that may better address the neurological manifestations of MPS II.	$3 million/ one-time treatment	2/8/2026
NASP Ⓢ *pegadricase/sirolimus* IV infusion	Sobi/Cartesian Therapeutics	Gout	pegadriase: pegylated uricase enzyme sirolimus: immunosuppressant	· Proposed for the treatment of chronic refractory gout. · Would compete with KRYSTEXXA for the same indication.	$750,000/ year	6/27/2026
HEMATOLOGY						
OMS721 Ⓢ *narsoplimab* IV infusion	Omeros Corporation	Hematopoietic stem cell transplant-associated thrombotic microangiopathy (HSCT-TMA)	Anti-MASP-2 monoclonal antibody	· Proposed for the treatment of high-risk HSCT-TMA in those who have persistent TMA despite modification of immunosuppressive therapy. · Administered once weekly for up to 8 weeks. · Persistent TMA is a life-threatening complication of HSCT with a reported mortality rate in high-risk patients of > 90%. There are no FDA-approved therapies, though some off-label usage occurs with agents such as SOLIRIS.	$500,000/ one-time course of therapy	12/26/2025

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

 | Data is current as of 10/22/2025

CONTINUED

Specialty Products on Our Radar

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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
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

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

 | Data is current as of 10/22/2025

CONTINUED

Specialty Products on Our Radar

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IMMUNOLOGY						
etuvetidigene autotemcel (S) IV infusion	Fondazione Telethon	Wiskott Aldrich syndrome (WAS)	*WAS* gene-directed gene therapy	**GENE THERAPY** • 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.	$4.5 million/ one-time treatment	4Q 2025

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

 | Data is current as of 10/22/2025

CONTINUED

Specialty Products on Our Radar

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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
NEUROLOGY						
SAR442168 *tolebrutinib* oral therapy	Sanofi	Multiple sclerosis	Bruton's tyrosine kinase inhibitor	• Proposed for the treatment of adults with non-relapsing secondary progressive multiple sclerosis (nrSPMS).	$200,000/ year	12/28/2025
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

 | Data is current as of 10/22/2025

CONTINUED

Specialty Products on Our Radar

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
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 4/30/25 has passed, with uncertainty around an ultimate FDA approval.	$750,000/ year	4Q 2025
BHV-4157 $ *troriluzole* oral therapy	Biohaven	Spinocerebellar ataxia (SCA)	Glutamate modulator	· Troriluzole is a prodrug of riluzole which has been used off-label for the treatment of SCA. · SCA is a rare, debilitating neurodegenerative disorder that is estimated to affect approximately 22,000 people in the U.S. Standard of care treatment is supportive and there are currently no FDA-approved therapies.	$500,000/ year	4Q 2025
ZOLGENSMA® $ *onasemnogene abeparvovec-xioi* intrathecal injection	Novartis	SMA	*SMA* gene-directed gene therapy	**GENE THERAPY** · Proposed for the treatment of patients with SMA Type 2, up to 18 years of age. · This is an intrathecally delivered alternative formulation of the existing IV ZOLGENSMA product which is currently only FDA-approved for patients < 2 years of age. · The proposed indication represents an expansion of the potential market of ZOLGENSMA utilizers.	$2 million/ one-time treatment	Late 2025

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

 | Data is current as of 10/22/2025

CONTINUED

Specialty Products on Our Radar

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ONCOLOGY						
BLENREP® *belantamab mafodotin-blmf* IV infusion	GSK	Multiple myeloma (MM)	Anti-B-cell maturation antigen (BCMA) antibody-drug conjugate (ADC)	• Proposed market re-entry for use in combinations with bortezomib plus dexamethasone or with pomalidomide plus dexamethasone for the treatment of patients with MM who have received at least one prior line of therapy. • 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. • Regulatory re-submission 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.	$350,000/ year	10/23/2025
BAY 2927088 *sevabertinib* oral therapy	Bayer	Non-small cell lung cancer (NSCLC)	Tyrosine kinase inhibitor	• Proposed for the treatment of adult patients with advanced NSCLC whose tumors have activating human epidermal growth factor receptors 2 (HER2) (ERBB2) mutations and who have received a prior systemic therapy. • Activating HER2 mutations are found in 2% to 4% of advanced NSCLC cases.	$300,000/ year	11/28/2025
ziftomenib oral therapy	Kura Oncology	Acute myeloid leukemia (AML)	Menin protein binder	• Proposed for the treatment of adult patients with relapsed/refractory AML with a nucleophosmin 1 (NP1) mutation. • 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.	$300,000/ year	11/30/2025

 | Data is current as of 10/22/2025

CONTINUED

Specialty Products on Our Radar

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BREYANZI® Ⓢ *lisocabtagene maraleucel* IV infusion	Bristol Myers Squibb	Marginal zone lymphoma (MZL)	CAR T-cell therapy	**NEW INDICATION FOR AN EXISTING CAR T-CELL THERAPY** · Proposed for the treatment of adult patients with relapsed or refractory MZL who have received at least two prior lines of systemic therapy. · Would be the first CAR T-cell therapy to be FDA-approved for MZL.	$531,350/ one-time treatment	12/5/2025
TAB-CEL *tabelecleucel* IV infusion	Atara Biotherapeutics	Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD)	Allogeneic, EBV-specific T-cell immunotherapy	· Proposed as monotherapy for treatment of adult and pediatric patients ≥ 2 years of age with EBV+ PTLD who have received at least one prior therapy. · EBV+ PTLD can impact patients who have undergone solid organ transplant (SOT) or an allogeneic hematopoietic stem cell transplantation (allo-HSCT). Poor median survival of 0.7 months and 4.1 months for HSCT and SOT, respectively, is reported in EBV+ PTLD patients for whom rituximab ± chemotherapy failed. · Patients received a median of two treatment cycles in the pivotal trial for Tab-cel.	$300,000/ 35-day treatment cycle	1/10/2026
ORCA-T *hematopoietic stem cells and T cells* IV infusion	Orca Bio	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
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 10/22/2025

CONTINUED

Specialty Products on Our Radar

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
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
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
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

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

 | Data is current as of 10/22/2025

CONTINUED

Specialty Products on Our Radar

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	Mechanism(s) of Action	Comments	Anticipated Cost	Anticipated Approval Date
RENAL DISEASES						
VIS649 *sibeprenlimab* SC injection	Otsuka	Immunoglobulin A nephropathy (IgAN)	Humanized IgG2 monoclonal antibody	· TARPEYO, FILSPARI, and VANRAFIA are also FDA-approved for IgAN. · Dosed as a self-administered SC injection every 4 weeks.	$200,000/ year	11/28/2025
RESPIRATORY DISEASES						
GSK3511294 *depemokimab* SC injection	GSK	Chronic rhinosinusitis with nasal polyps (CRSwNP); Asthma	IL-5 inhibitor	· Under FDA review for two proposed indications: for use as add-on maintenance treatment in adults with inadequately controlled CRSwNP and for use as add-on maintenance treatment of asthma in adult and pediatric patients ≥12 years of age with type 2 inflammation characterised by an eosinophilic phenotype on medium- to high-dose inhaled corticosteroids (ICS) plus another asthma controller. · Would compete with existing biologics already FDA-approved for CRSwNP and/or eosinophilic asthma such as CINQAIR, DUPIXENT, FASENRA, and NUCALA. · Ultra-long acting product with one dose administered every 6 months.	$50,000/ year	12/16/2025
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 and OFEV.	$150,000/ year	4Q 2025

 | Data is current as of 10/22/2025

Biosimilars

Drug Name & Administration Method	Manufacturer(s)	Biosimilar Reference Drug	Indication(s)	Status/Estimated Approval	Biosimilar Currently Launched?	Comments
ENDOCRINOLOGY						
KIRSTY™ *insulin aspart-xjhz* IV and SC injections	Biocon Biologics	NOVOLOG®	Diabetes mellitus	FDA approval: 7/15/2025	Yes - MERILOG	• 2nd NOVOLOG biosimilar after MERILOG. • FDA granted interchangeable status. • KIRSTY became commercially available in late August 2025 but a steady market supply is not expected until July 2026.
BILDYOS® *denosumab-nxxp* SC injection	Shanghai Henlius Biotech, Inc.	PROLIA®	Osteoporosis and prevention of fractures related to cancer therapy	FDA approval: 8/29/2025	Yes - BILDYOS, CONEXXENCE, JUBBONTI, STOBOCLO	• 5th PROLIA biosimilar after CONEXXENCE, STOBOCLO, JUBBONTI, OSPOMYV.
BILPREVDA® *denosumab-nxxp* SC injection	Shanghai Henlius Biotech, Inc.	XGEVA®	Skeletal-related bone events in patients with cancer; hypercalcemia of malignancy	FDA approval: 8/29/2025	Yes - BILPREVDA, BOMYNTRA, OSENVELT, WYOST	• 5th XGEVA biosimilar after BOMYNTRA, OSENVELT, WYOST, XBRYK.
BOSAYA™ *denosumab-kyqq* SC injection	Biocon Biologics	PROLIA®	Osteoporosis and prevention of fractures related to cancer therapy	FDA approval: 9/16/2025	Yes - BILDYOS, CONEXXENCE, JUBBONTI, STOBOCLO	• 6th PROLIA biosimilar after CONEXXENCE, STOBOCLO, JUBBONTI, OSPOMYV, BILDYOS. • FDA granted provisional interchangeable status.
AUKELSO™ *denosumab-kyqq* SC injection	Biocon Biologics	XGEVA®	Skeletal-related bone events in patients with cancer; hypercalcemia of malignancy	FDA approval: 9/16/2025	Yes - BILPREVDA, BOMYNTRA, OSENVELT, WYOST	• 6th XGEVA biosimilar after BOMYNTRA, OSENVELT, WYOST, XBRYK, BILPREVDA. • FDA granted provisional interchangeable status.

 | Data is current as of 10/22/2025

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Biosimilars

Drug Name & Administration Method	Manufacturer(s)	Biosimilar Reference Drug	Indication(s)	Status/Estimated Approval	Biosimilar Currently Launched?	Comments
ENOBY™ *denosumab-qbde* SC injection	Hikma	PROLIA®	Osteoporosis and prevention of fractures related to cancer therapy	FDA approval: 9/26/2025	Yes - BILDYOS, CONEXXENCE, JUBBONTI, STOBOCLO	• 7th PROLIA biosimilar after CONEXXENCE, STOBOCLO, JUBBONTI, OSPOMYV, BILDYOS, BOSAYA.
XTRENBO™ *denosumab-qbde* SC injection	Hikma	XGEVA®	Skeletal-related bone events in patients with cancer; hypercalcemia of malignancy	FDA approval: 9/26/2025	Yes - BILPREVDA, BOMYNTRA, OSENVELT, WYOST	• 7th XGEVA biosimilar after BOMYNTRA, OSENVELT, WYOST, XBRYK, BILPREVDA, AUKELSO.
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: 12/15/2025)	Yes - BILDYOS, CONEXXENCE, JUBBONTI, STOBOCLO, BILPREVDA, BOMYNTRA, OSENVELT, WYOST	• Would be a subsequent denosumab biosimilar, after multiple others.
MB09 *denosumab* SC injection	Amneal	PROLIA®, XGEVA®	Osteoporosis and fractures due to bone metastasis; skeletal-related bone events	BLA is under FDA review (BsUFA date: 4Q 2025)	Yes - BILDYOS, CONEXXENCE, JUBBONTI, STOBOCLO, BILPREVDA, BOMYNTRA, OSENVELT, WYOST	• Would be a subsequent denosumab biosimilar, after multiple others.
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: 2H 2025)	Yes - BILDYOS, CONEXXENCE, JUBBONTI, STOBOCLO, BILPREVDA, BOMYNTRA, OSENVELT, WYOST	• Would be a subsequent denosumab biosimilar, after multiple others.

 | Data is current as of 10/22/2025

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Biosimilars

Drug Name & Administration Method	Manufacturer(s)	Biosimilar Reference Drug	Indication(s)	Status/Estimated Approval	Biosimilar Currently Launched?	Comments
IMMUNOLOGY						
AVT05 *golimumab* SC and IV injections	Alvotech	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: 4Q 2025)	No	• Would be the first FDA-approved biosimilar to SIMPONI.
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.
OPHTHALMOLOGY						
EYDENZELT *aflibercept-boav* intraocular injection	Celltrion	EYLEA®	Wet 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.
LUCAMZI *ranibizumab* intraocular injection	Xbrane/Bausch & Lomb	EYLEA®	Wet age-related macular degeneration (AMD)	BLA is under FDA review (BsUFA date: 10/21/2025)	Yes - BYOOVIZ, CIMERLI	• Would be a subsequent LUCENTIS biosimilar, after BYOOVIZ and CIMERLI.
AVT06 *aflibercept* intraocular injection	Alvotech	EYLEA®	Wet AMD	BLA is under FDA review (BsUFA date: 4Q 2025)	No	• Would be a subsequent EYLEA biosimilar, after AHZANTIVE, ENVEEZU, OPUVIZ, PAVBLU, and YESAFILI.

 | Data is current as of 10/22/2025

Generic Specialty Agents

Recent Approvals			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**MARKET LAUNCH DATE**
leuprolide acetate	ELIGARD®	UroNova	8/5/2025
bosentan dispersible tablet for oral suspension	TRACLEER®	Natco Pharma	8/18/2025
glycerol phenylbutyrate	RAVICTI®	Par/Endo	10/20/2025
Pipeline Agents*			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**ANTICIPATED LAUNCH DATE**
rilpivirine hydrochloride	EDURANT®	Somerset Therapeutics; Strides	4Q 2025
treprostinil	TYVASO®	Actavis/Teva	1/1/2026
pomalidomide	POMALYST®	Breckenridge/Natco Pharma; Eugia Pharma/ Aurobindo; Mylan; Teva	March 2026
nintedanib esylate	OFEV®	Accord; Apotex; Cipla; Eugia Pharma/ Aurobindo; Glenmark; Lotus Pharmaceutical/Sandoz; Teva	4/2/26
melphalan hydrochloride	EVOMELA®	Actavis/Teva	6/1/26
macitentan	OPSUMIT®	Alembic; Amneal; Apotex; Aurobindo; Laurus Labs; MSN Laboratories; Mylan/Viatris; Sun; Zydus	2Q 2026
tofacitinib	XELJANZ®	Prinston Pharma Inc.; SpecGx; Sun; Zydus	2Q 2026
selexipag (tablet and intravenous)	UPTRAVI®	Alembic; MSN Laboratories; Vgyaan; Zydus	October 2026
riociguat	ADEMPAS®	Alembic; MSN Laboratories; Teva	4Q 2026

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

 | Data is current as of 10/22/2025

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
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
GLP-1	glucagon-like peptide-1
GR-II	glucocorticoid II
HAE	hereditary angioedema

Term	Definition
HER	human epidermal growth factor receptor
HFpEF	heart failure with preserved ejection fraction
HIV-1	human immunodeficiency virus-1
HPV	human papillomavirus
HR	hormone receptor
HSCT	hematopoietic stem cell transplantation
HSCT-TMA	HSCT-associated thrombotic microangiopathy
I2S	iduronate-2-sulfatase
ICS	inhaled corticosteroids
IgAN	Immunoglobulin A nephropathy
IPF	idiopathic pulmonary fibrosis
ITP	immune thrombocytopenia
IV	intravenous
LHON	Leber's hereditary optic neuropathy
MASH	metabolic dysfunction–associated steatohepatitis
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
NP1	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

Term	Definition
PsA	psoriatic arthritis
PsO	plaque psoriasis
PSVT	paroxysmal supraventricular tachycardia
RA	rheumatoid arthritis
RRP	recurrent respiratory papillomatosis
SC	subcutaneous
SCA	spinocerebellar ataxia
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
TGCT	tenosynovial giant cell tumor
TK2d	thymidine kinase 2 deficiency
TKI	tyrosine kinase inhibitor
UC	ulcerative colitis
VMS	vasomotor symptoms
WAC	Wholesale Acquisition Cost
WAS	Wiskott Aldrich syndrome
siRNA	small interfering ribonucelic acid
sJIA	systemic juvenile idiopathic arthritis
SMA	spinal muscular atrophy
T2DM	type 2 diabetes mellitus
TGCT	tenosynovial giant cell tumor
TK2d	thymidine kinase 2 deficiency
TKI	tyrosine kinase inhibitor
UC	ulcerative colitis
UPCR	urine protein-to-creatinine ratio
uUTI	uncomplicated urinary tract infection
VMS	vasomotor symptoms
WAC	Wholesale Acquisition Cost
WAS	Wiskott Aldrich syndrome

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Specialty Pharmacy

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