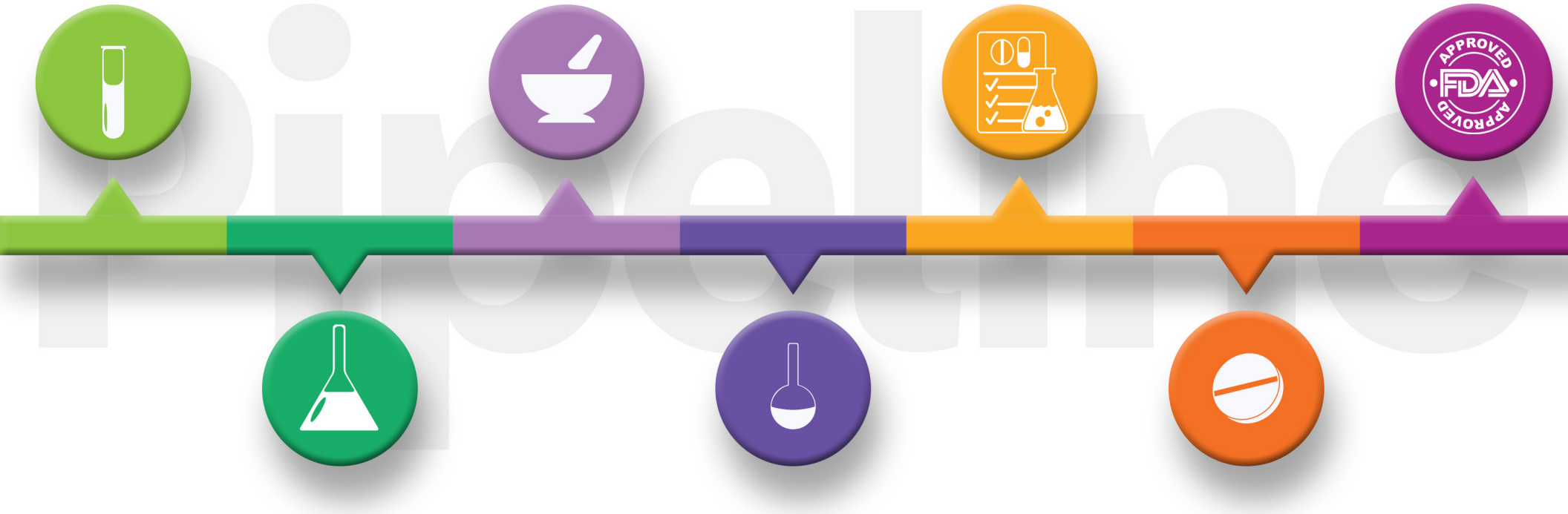

PIPELINE REPORT: APRIL 2025

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.

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PIPELINE REPORT: **APRIL 2025**

Highlights

APPROVED: ENCELTO ™ *(revakinagene taroretcel-lwey)* is the first therapy approved by the FDA to treat macular telangiectasia type 2 (MacTel)

APPROVED: QFITLIA ™ *(fitusiran)* is approved to treat all scenarios of hemophilia- both A and B, with or without inhibitors

APPROVED: VYKAT™ XR *(diazoxide choline)* is the first FDA-approved therapy to address hyperphagia associated with Prader-Willi syndrome (PWS)

APPROVED: ZEVASKYN ™ *(prademagene zamikeracel)* is the second gene therapy FDA-approved for the treatment of recessive dystrophic epidermolysis bullosa (RDEB)

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Recent Specialty Drug Approvals

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC) /Utilizer
COAGULATION DISORDERS					
QFITLIA™ *fitusiran* SC injection	Sanofi	Hemophilia A or hemophilia B	3/28/2025	· Approved for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients ≥ 12 years of age with hemophilia A or B with or without factor VIII or IX inhibitors. · Administered as a SC injection once every two months. · Will enter a crowded market of available alternatives for both hemophilia A and hemophilia B, including recently FDA-approved products ALHEMO and HYMPAVZI, as well as HEMLIBRA. · Projected impact: cost replacement of existing therapy.	$968,400/ year
DERMATOLOGY					
ZEVASKYN ™ *prademagene zamikeracel* epidermal sheet	Abeona Therapeutics	Recessive dystrophic epidermolysis bullosa (RDEB)	4/29/2025	**GENE THERAPY** · Approved for the treatment of wounds in adult and pediatric patients with RDEB. · ZEVASKYN is produced as autologous, COL7A1 gene-corrected epidermal sheets which are surgically applied over RDEB wounds to promote wound healing and pain reduction. · VYJUVEK is another gene therapy that is also FDA-approved for RDEB, but which is applied topically weekly until wound closure. · Projected impact: new cost for a small population.	$3.1 million/ one-time treatment *The development of new RDEB lesions in different areas of the body would require additional courses of therapy.*

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Recent Specialty Drug Approvals

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC) /Utilizer
ENDOCRINOLOGY					
VYKAT™ XR *diazoxide choline* extended-release oral tablet	Soleno Therapeutics	Prader-Willi syndrome (PWS)	3/26/2025	· Approved for the treatment of hyperphagia in adults and pediatric patients ≥ 4 years of age with PWS. · The hallmark symptom of PWS is hyperphagia, a chronic feeling of insatiable hunger that severely diminishes the quality of life for PWS patients and their families. Hyperphagia can lead to significant morbidities (e.g., stomach rupture, obesity, diabetes, cardiovascular disease) and mortality (e.g., choking, accidental death due to food-seeking behavior). · There are currently no FDA-approved therapies for hyperphagia associated with PWS. · Projected impact: new cost for a small population.	$466,200/year for the average-weight patient; $1,134,420/ year for the maximum recommended dose (for body weight ≥ ~200 lbs)
GASTROINTESTINAL DISEASES					
CTEXLI™ *chenodiol* oral tablet	Mirum Pharmaceuticals	Cerebrotendinous xanthomatosis (CTX)	2/21/2025	· Approved for the treatment of CTX in adults. · Chenodiol is also currently FDA-approved as brand CHENODAL for the treatment of gallbladder stones but is already being used off-label as standard first-line therapy for CTX. · Projected impact: cost replacement of existing therapy.	$653,354/year
ONCOLOGY					
DATROWAY® *datopotamab deruxtecan-dlnk* IV infusion	AstraZeneca	Breast cancer	1/17/2025	· Approved for the treatment of adult patients with unresectable or metastatic, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative (IHC 0, IHC 1+ or IHC 2+/ISH-) breast cancer who have received prior endocrine-based therapy and chemotherapy for unresectable or metastatic disease. · Projected impact: cost replacement of existing therapy.	$440,000/ year

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GRAFAPEX™ *treosulfan* IV infusion	Medexus Pharmaceuticals	Allogeneic hematopoietic stem cell transplantation (allo-HSCT)	1/22/2025	• Approved for use in combination with fludarabine as a preparative regimen for allo-HSCT in adult and pediatric patients ≥1 year of age with acute myeloid leukemia (AML) or myelodysplastic syndromes (MDS). • Will compete with busulfan for the same indication. • The GRAFAPEX Prescribing Information includes a Boxed Warning re: severe and prolonged myelosuppression. • Projected impact: cost replacement of existing therapy.	$36,600/ course of therapy
GOMEKLI™ *mirdametinib* oral capsules and tablets	SpringWorks Therapeutics	Neurofibromatosis type 1 (NF1)-associated plexiform neurofibromas (PN)	2/11/2025	• Approved for the treatment of adult and pediatric patients ≥ 2 years of age with NF1 who have symptomatic PN not amenable to complete resection. • KOSELUGO is FDA-approved for the same indication for pediatric patients and has also been used off-label for adults with NF1-associated PN. • Projected impact: cost replacement of existing therapy.	$415,800/year
ROMVIMZA™ *vimseltinib* oral capsule	Ono Pharmaceuticals	Tenosynovial giant cell tumor (TGCT)	2/14/2025	• Approved for treatment of adult patients with symptomatic TGCT for which surgical resection will potentially cause worsening functional limitation or severe morbidity. • Will compete with TURALIO for the same indication. • Projected impact: cost replacement of existing therapy.	$339,664/year
OPDIVO® *nivolumab* IV infusion	Bristol Myers Squibb	Hepatocellular carcinoma (HCC)	4/11/2025	• **New indication for an existing agent.** • Approved for combination use with YERVOY (ipilimumab) for the treatment of adult patients with unresectable or metastatic HCC, as a first-line treatment. • OPDIVO was previously approved in combination with YERVOY for the treatment of HCC in patients previously treated with sorafenib.	$190,793/year

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Recent Specialty Drug Approvals

Drug Name & Administration Method	Manufacturer(s)	Indication(s)	FDA Approval Date	Comments	Cost (WAC) /Utilizer
OPHTHALMOLOGY					
ENCELTO™ *revakinagene taroretcel-lwey* intraocular implant	Neurotech	Macular telangiectasia type 2 (MacTel)	3/5/2025	• Approved for the treatment of adults with idiopathic MacTel. • MacTel is a neurodegenerative disease resulting in photoreceptor atrophy and loss of vision. • Treatment with ENCELTO significantly reduced anatomical disease progression through 24 months in two phase 3 studies. • Projected impact: new cost for a small population.	$250,000/ one-time treatment/eye (both eyes are usually affected)
RENAL DISEASES					
VANRAFIA® *atrasentan* oral tablet	Novartis	Immunoglobulin A nephropathy (IgAN)	4/2/2025	• Approved to reduce proteinuria in adults with primary IgAN at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g. • FABHALTA, FILSPARI, and TARPEYO are also FDA-approved for the treatment of patients with IgAN. • Projected impact: cost replacement of existing therapy.	$162,500/year

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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
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	9/26/2025
DERMATOLOGY						
delgocitinib topical cream	Leo Pharma	Chronic hand eczema (CHE)	Pan-Janus kinase (JAK) inhibitor	· Proposed for the treatment of adults with moderate to severe chronic hand eczema. · Current treatment options for CHE include steroids, calcineurin inhibitors, vitamin D derivatives, and emollients.	$15,000/year	7/23/2025
ENDOCRINOLOGY						
MTP131 Ⓢ *elamipretide* SC injection	Stealth BioTherapeutics	Barth syndrome	Mitochondrial cardiolipin stabilizer	· 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. · There are currently no FDA-approved therapies for Barth syndrome; treatment is focused on reducing symptoms and preventing complications. · On 10/10/2024, the FDA's Cardiovascular and Renal Drugs Advisory Committee voted 10-6 that elamipretide is effective for Barth syndrome and cited the urgent unmet need.	$850,000/ year	2Q 2025

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

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AEB1102 Ⓢ *pegzilarginase* IV infusion	Immedica	Arginase I deficiency	Enzyme replacement therapy	• Proposed for the treatment of arginase I deficiency, which is one of the eight urea cycle disorder subtypes. • Arginase I deficiency has a global prevalence of ~1 in every 1,000,000 people and is identifiable via newborn screening. • Pegzilarginase would be the first FDA-approved treatment for this condition.	$500,000/ year	5/5/2025
SL1009 Ⓢ *sodium dichloroacetate* oral solution	Saol Therapeutics	Pyruvate dehydrogenase complex deficiency (PDCD)	Pyruvate dehydrogenase kinase inhibitor	• PDCD is an ultra-rare mitochondrial disorder of carbohydrate oxidation that mostly affects the nervous system and skeletal muscle and leads to decreased ATP production and energy failure. • The U.S. prevalence of PDCD is estimated to be up to 2,000 people.	$750,000/ year	5/27/2025
CUTX-101 Ⓢ *copper histidinate* SC injection	Fortress Biotech, Sentynl Therapeutics	Menkes disease	Copper replacement therapy	• Menkes disease is a rare X-linked pediatric disease caused by gene mutations of copper transporter ATP7A. • There is currently no FDA-approved treatment specifically for Menkes disease and its variants; however, daily injections of copper supplements are currently used as an off-label therapy, along with supportive therapies. • Most Menkes disease patients do not survive past age three without treatment.	$750,000/ year	6/30/2025
PTC923 *sepiapterin* oral therapy	PTC Therapeutics	Phenylketonuria (PKU)	Tetra-hydrobiopterin precursor	• Proposed for the treatment of pediatric and adult patients with PKU. • Would compete with KUVAN® (available generically as sapropterin) for the same indication.	$200,000/ year	7/30/2025

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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). • MPS IIIA is a rare, fatal lysosomal storage disease with no approved treatment that primarily affects the central nervous system and is characterized by rapid neurodegeneration, with onset in early childhood.	$3 million/ one-time treatment	8/18/2025
PTC743 Ⓢ *vatiquinone* oral therapy	PTC Therapeutics	Friedreich's ataxia (FA)	Glutathione biosynthesis enhancing agent	• Proposed for the treatment of children and adults living with FA. • If approved, vatiquinone would be the first FDA-approved therapy for children with FA; SKYCLARYS is FDA-approved for FA in patients aged ≥ 16 years of age.	$500,000/ year	8/19/2025
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	August 2025
CRN00808 *paltusotine* oral capsule	Crinetics Pharmaceuticals	Acromegaly	Somatostatin type 2 receptor agonist	• Proposed for the treatment and long-term maintenance therapy of acromegaly in adults. • Once-daily oral therapy. • Would compete with injectable somatostatin analogs (e.g., SOMATULINE® DEPOT, SANDOSTATIN®, SIGNIFOR) and twice-daily oral MYCAPSSA®.	$175,000/ year	9/25/2025

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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. • Will compete with TRYNGOLZA for the same indication.	$595,000/ year	11/18/2025
relacorilant oral therapy	Corcept Therapeutics	Hypercortisolism	Glucocorticoid II (GR-II) receptor antagonist	• Proposed for the treatment of patients with endogenous hypercortisolism (Cushing's syndrome). • 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.	$600,000/ year	12/30/2025
HEMATOLOGY						
PRN1008 *rilzabrutinib* oral therapy	Principia Biopharma	Immune thrombocytopenic purpura (ITP)	Bruton's tyrosine kinase inhibitor	• Prednisone, immunoglobulins, RITUXAN, PROMACTA, NPLATE, TAVALISSE are existing treatment alternatives.	$200,000/ year	8/29/2025
IMMUNOLOGY						
KVD900 *sebetralstat* oral therapy	KalVista Pharmaceuticals	Hereditary angioedema (HAE)	Kallikrein inhibitor	• Proposed for the on-demand treatment of HAE attacks in adults and pediatric patients ≥ 12 years of age. • Would compete with other HAE therapies used for on-demand treatment such as FIRAZYR (now generic) and RUCONEST. • If approved, sebetralstat would be the first oral, on-demand therapy for people living with HAE.	$350,000/ year	6/17/2025

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IONIS-PKK-LRx Ⓢ *donidalorsen* SC injection	Ionis Pharmaceuticals	Hereditary angioedema (HAE)	Prekallikrein-targeting antisense oligonucleotide	• Proposed for the prophylaxis of acute attacks of HAE in adult and pediatric patients ≥ 12 years of age. • Would compete with existing HAE prophylactic agents including, CINRYZE, ORLADEYO and TAKHZYRO.	$650,000/ year	8/21/2025
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	9/28/2025
NEUROMUSCULAR CONDITIONS						
M281 *nipocalimab* IV infusion	Johnson & Johnson	Generalized myasthenia gravis (gMG)	Anti-FcRn monoclonal antibody	• Proposed for the treatment of antibody positive (anti-AChR, anti-MuSK, anti-LRP4) patients with gMG. • Would compete with VYVGART, VYVGART HYTRULO, and ZILBRYSQ in AChR antibody-positive patients, and with RYSTIGGO in AChR- or MuSK antibody-positive patients. • Antibodies specific for LRP4 occur in up to 5% of patients with MG.	$300,000/ year	2Q 2025
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.	$750,000/ year	2Q 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 US. Standard of care treatment is supportive and there are currently no FDA-approved therapies.	$500,000/ year	8/11/2025

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CAP-1002 Ⓢ *deramiocel* IV infusion	Capricor Therapeutics/NS Pharma	DMD-associated cardiomyopathy	Anti-fibrotic, anti-inflammatory, angiogenic	**CELL THERAPY** · CAP-1002 is an allogeneic stromal cell therapy manufactured from donor heart tissue. · The initial target treatment population is those who are in the advanced stages of DMD (late ambulatory or non-ambulatory). · Administered as an IV infusion once every 3 months.	$600,000/ year	8/31/2025
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.	$400,000/ year	9/22/2025
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	2H 2025

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

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ONCOLOGY						
KEYTRUDA® pembrolizumab IV infusion	Merck	Locally advanced head and neck squamous cell carcinoma (LA-HNSCC)	PD-1 inhibitor	• **New indication for an existing agent.** • Proposed for the treatment of patients with resectable LA-HNSCC as neoadjuvant treatment, then continued as adjuvant treatment in combination with standard of care radiotherapy with or without cisplatin and then as a single agent. • KEYTRUDA is currently approved as monotherapy and in combination regimens for appropriate patients with metastatic or with unresectable, recurrent HNSCC.	$212,318/year	6/23/2025
taletrectinib oral therapy	Nuvation Bio	Non-small cell lung cancer (NSCLC)	ROS1 inhibitor	• Proposed for the treatment of adult patients with advanced or metastatic ROS1-positive NSCLC who are ROS1 tyrosine kinase inhibitor (TKI) treatment naïve or previously treated with crizotinib.	$300,000/ year	6/23/2025
avutometinib + defactinib oral therapy	Verastem Oncology	Ovarian cancer	avutometinib: MEK 1/2 inhibitor defactinib: focal adhesion kinase (FAK) inhibitor	• Proposed for combination use for the treatment of patients with KRAS mutant recurrent low-grade serous ovarian cancer who received at least one prior systemic therapy.	$350,000/ year	6/30/2025
DZD9008 *sunvozertinib* oral therapy	Dizal	Non-small cell lung cancer (NSCLC)	EGFR inhibitor	• Proposed for the treatment of patients with locally advanced or metastatic NSCLC with epidermal growth factor receptor (EGFR) exon 20 insertion mutations (exon20ins), 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.	$350,000/ year	7/7/2025

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REGN5458 *linvoseltamab* IV infusion	Regeneron	Multiple myeloma (MM)	BCMAxCD3 bispecific antibody	• Proposed for the treatment of adult patients with relapsed/refractory (R/R) MM who have received at least four prior lines of therapy or those who have received three prior lines of therapy and are refractory to the last line of therapy.	$400,000/ year	7/10/2025
RP1 *vusolimogene oderparepvec* intratumoral injection	Replimune	Melanoma	Viral 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.	$400,000/ year	7/22/2025
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	7/23/2025

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REGN1979 *odronextamab* IV infusion	Regeneron	Follicular lymphoma (FL); diffuse large B-cell lymphoma (DLBCL)	CD20xCD3 bispecific antibody	· Proposed for the treatment of adult patients with relapsed/refractory (R/R) FL or R/R DLBCL, who have progressed after at least two prior systemic therapies.	$400,000/ year	7/30/2025
ONC201 *dordaviprone* oral therapy	Chimerix	Diffuse glioma	Mitochondrial caseinolytic protease P (ClpP)-targeting agent	· Proposed for the treatment of adult recurrent H3 K27M-mutant diffuse glioma.	$350,000/ year	8/18/2025
BI 1810631 *zongertinib* oral therapy	Boehringer Ingelheim	NSCLC	Tyrosine kinase inhibitor (TKI)	· Proposed for the treatment of adult patients with unresectable or metastatic NSCLC whose tumors have HER2 (ERBB2) mutations and who have received prior systemic therapy.	$300,000/ year	8/19/2025
PRGN-2012 Ⓢ *zopapogene imadenovec* SC injection	Precigen, Inc.	Recurrent respiratory papillomatosis (RRP)	Therapeutic vaccine	· PRGN-2012 is designed to elicit immune responses directed against cells infected with human papillomavirus (HPV) 6 or HPV 11. · 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. · The prevalence of RRP is estimated to be ~27,000 adults in the U.S.	$750,000/ treatment course	8/27/2025
KEYTRUDA® SC *pembrolizumab + berahyaluronidase* SC infusion	Merck	NSCLC	PD-1 inhibitor	• **New SC formulation of an existing IV agent.** · Would compete with IV Keytruda and SC/IV Opdivo and other SC/IV checkpoint inhibitors (e.g., Tecentriq Hybreza). · Administered every six weeks with a median injection time of two minutes.	$215,000/ year	9/23/2025

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

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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 aged 12 years and older with type 2 inflammation characterised by an eosinophilic phenotype on medium- to high-dose inhaled corticosteroids (ICS) plus another asthma controller. · Will 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
INS1007 *brensocatib* oral tablet	Insmed Inc.	Non-cystic fibrosis bronchiectasis (NCFB)	Dipeptidyl peptidase 1 (DPP1) inhibitor	· NCFB is a rare, chronic, inflammatory lung disease that has a marked impact on quality of life and predominantly affects females and older adults. · The current standard of care includes airway clearance, mucolytics, and antibiotics as needed.	$90,000/ year	8/12/2025

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Biosimilars

Drug Name & Administration Method	Manufacturer(s)	Biosimilar Reference Drug	Indication(s)	Status/Estimated Approval	Biosimilar Currently Launched?	Comments
DERMATOLOGY						
BAT2206 *ustekinumab* SC injection	Bio-Thera Solutions	STELARA®	PsO	BLA is under FDA review (BsUFA date: 2Q 2025)	No	• Would be the eighth STELARA biosimilar, after IMULDOSA, OTULFI, PYZCHIVA, SELARSDI, STEQEYMA, WEZLANA, and YESINTEK.
ENDOCRINOLOGY						
XBRYK™ *denosumab-dssb* SC injection	Samsung Bioepis	XGEVA®	Skeletal-related complications of multiple myeloma and of bone metastases; giant cell tumor of the bone; hypercalcemia of malignancy	FDA approval: 2/13/2025 Anticipated launch: TBD	No	• Is the 2nd biosimilar to XGEVA, after WYOST. • FDA granted interchangeable status.
OSPOMYV™ *denosumab-dssb* SC injection	Samsung Bioepis	PROLIA®	Osteoporosis; increasing bone mass when receiving aromatase inhibitor therapy for breast cancer; increasing bone mass when receiving androgen deprivation therapy for prostate cancer	FDA approval: 2/13/2025 Anticipated launch: TBD	No	• Is the 2nd biosimilar to PROLIA, after JUBBONTI. • FDA granted interchangeable status.
OSENVELT® *denosumab-bmwo* SC injection	Celltrion	XGEVA®	Skeletal-related complications of multiple myeloma and of bone metastases; giant cell tumor of the bone; hypercalcemia of malignancy	FDA approval: 2/28/2025	No	• Is the 3rd biosimilar to XGEVA, after WYOST and XBRYK. • Anticipated launch: June 2025.

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Biosimilars

Drug Name & Administration Method	Manufacturer(s)	Biosimilar Reference Drug	Indication(s)	Status/Estimated Approval	Biosimilar Currently Launched?	Comments
STOBOCLO® *denosumab-bmwo* SC injection	Celltrion	PROLIA®	Osteoporosis; increasing bone mass when receiving aromatase inhibitor therapy for breast cancer; increasing bone mass when receiving androgen deprivation therapy for prostate cancer	FDA approval: 2/28/2025	No	· Is the 3rd biosimilar to PROLIA, after JUBBONTI and OSPOMYV. · Anticipated launch: June 2025.
BOMYNTRA® *denosumab-bnht* SC injection	Fresenius Kabi	XGEVA®	Skeletal-related complications of multiple myeloma and of bone metastases; giant cell tumor of the bone; hypercalcemia of malignancy	FDA approval: 3/25/2025	No	· Is the 4th biosimilar to XGEVA, after WYOST, XBRYK, and OSENVELT. · Anticipated launch: mid-2025.
CONEXXENCE® *denosumab-bnht* SC injection	Fresenius Kabi	PROLIA®	Osteoporosis; increasing bone mass when receiving aromatase inhibitor therapy for breast cancer; increasing bone mass when receiving androgen deprivation therapy for prostate cancer	FDA approval: 3/25/2025	No	· Is the 4th biosimilar to PROLIA, after JUBBONTI, OSPOMYV, AND STOBOCLO. · Anticipated launch: mid-2025.
HLX14 *denosumab* SC injection	Shanghai Henlius Biotech, Inc.	PROLIA®	Postmenopausal osteoporosis	BLA is under FDA review (BsUFA date: 8/30/2025)	No	· Would be a subsequent denosumab biosimilar, after multiple others.

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Biosimilars

Drug Name & Administration Method	Manufacturer(s)	Biosimilar Reference Drug	Indication(s)	Status/Estimated Approval	Biosimilar Currently Launched?	Comments
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)	No	· Would be a subsequent denosumab biosimilar, after multiple others.
denosumab biosimilar 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)	No	· Would be a subsequent denosumab biosimilar, after multiple others.
RGB-14 *denosumab* SC injection	Hikma	XGEVA®	Osteoporosis and fractures due to bone metastasis	BLA is under FDA review (BsUFA date: 4Q 2025)	No	· Would be a subsequent denosumab biosimilar, after multiple others.
TVB-009P *denosumab* SC injection	Teva	PROLIA®	Osteoporosis	BLA is under FDA review (BsUFA date: 2H 2025)	No	· Would be a subsequent denosumab biosimilar, after multiple others.
IMMUNOLOGY						
AVTOZMA® *tocilizumab-anoz* SC and IV injections	Celltrion	ACTEMRA®	Rheumatoid arthritis (RA); giant cell arteritis; active polyarticular juvenile idiopathic arthritis (pJIA); active systemic juvenile idiopathic arthritis (sJIA); hospitalized adults with COVID-19	FDA approval: 1/24/2025	Yes - TOFIDENCE, TYENNE	· Is the 3rd FDA-approved biosimilar to ACTEMRA. · Anticipated launch: IV formulation in August 2025; SC formulation TBD.
OMLYCLO® *omalizumab-igec* SC injection	Celltrion	XOLAIR®	Asthma, chronic rhinosinusitis with nasal polyps, IgE-mediated food allergy, and chronic spontaneous urticaria	FDA approval: 3/7/2025	No	· Is the first FDA-approved biosimilar to XOLAIR. · FDA granted interchangeable status. · Anticipated launch: on or after 9/1/2026.

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Biosimilars

Drug Name & Administration Method	Manufacturer(s)	Biosimilar Reference Drug	Indication(s)	Status/Estimated Approval	Biosimilar Currently Launched?	Comments
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.
ONCOLOGY						
JOBEVNE™ *bevacizumab-nwgd* IV infusion	Biocon Biologics	AVASTIN®	Colorectal cancer, non-small cell lung cancer; glioblastoma; renal cell carcinoma; cervical cancer; ovarian, fallopian tube, or primary peritoneal cancer	FDA approval: 4/10/2025	Yes - ALYMSYS, MVASI, VEGZELMA, ZIRABEV	• Is the 6th biosimilar to AVASTIN, after ALYMSYS, AVZIVI, MVASI, VEGZELMA, and ZIRABEV.
OPHTHALMOLOGY						
CTP42 *aflibercept* intraocular injection	Celltrion	EYLEA®	Wet AMD	BLA is under FDA review (BsUFA date: 2Q 2025)	Yes - PAVBLU	• Would be a subsequent EYLEA® biosimilar, after AHZANTIVE®, ENVEEZU, OPUVIZ™, PAVBLU, and YESAFILI™ .
AVT06 *aflibercept* intraocular injection	Alvotech	EYLEA®	Wet AMD	BLA is under FDA review (BsUFA date: 4Q 2025)	Yes - PAVBLU	• Would be a subsequent EYLEA biosimilar, after AHZANTIVE, ENVEEZU, OPUVIZ, PAVBLU, and YESAFILI.

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Generic Specialty Agents

Pipeline Agents*			
GENERIC NAME	**BRAND NAME**	**MANUFACTURER(S)**	**MARKET LAUNCH DATE**
tolvaptan	JYNARQUE®	Lupin	4/23/25
glycerol phenylbutyrate	RAVICTI®	Par/Endo	7/1/2025
rilpivirine hydrochloride	EDURANT®	Strides	10/22/2025
macitentan	OPSUMIT®	Alembic; Amneal; Apotex; Aurobindo; Laurus Labs; MSN Laboratories; Mylan/Viatris; Seasons Biotechnology (Taizhou); Sun; Teva; Zydus	4Q 2025
sugammadex sodium	BRIDION®	Aspiro Pharma; Gland Pharma; Mankind Pharma; Mylan/Viatris; Sandoz; Sun	2025
treprostinil	TYVASO®	Actavis/Teva	1/1/2026
pomalidomide	POMALYST®	Breckenridge/Natco Pharma; Eugia Pharma/ Aurobindo; Mylan; Teva	1Q 2026
nintedanib esylate	OFEV®	Accord; Glenmark	4/2/2026
cladribine	MAVENCLAD®	Accord	1H 2026

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

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Glossary

Term	Definition
ABR	annualized bleeding rate
ADC	antibody-drug conjugate
ALL	acute lymphoblastic leukemia
allo-HSCT	allogeneic hematopoietic stem cell transplantation
AMD	age-related macular degeneration
AML	acute myeloid leukemia
apo-CIII	apolipoprotein C-III
AS	ankylosing spondylitis
BCMA	B-cell maturation antigen
BLA	biologics license application
BsUFA	Biosimilar User Fee Act
BTC	biliary tract cancer
CAR T-cell	chimeric antigen receptor T-cell
CD	Crohn's disease
CDC	Centers for Disease Control and Prevention
CHE	chronic hand eczema
CKD	chronic kidney disease
CMS	Centers for Medicare & Medicaid Services
CNTF	ciliary neurotrophic factor
CRSwNP	chronic rhinosinusitis with nasal polyps
cSCC	cutaneous squamous cell carcinoma
CTX	cerebrotendinous xanthomatosis
DLBCL	diffuse large B-cell lymphoma
DMD	Duchenne muscular dystrophy
DPP1	dipeptidyl peptidase 1
EGFR	epidermal growth factor receptor
ERT	enzyme replacement therapy
FA	Friedreich's ataxia
FAK	focal adhesion kinase
FCS	familial chylomicronemia syndrome
FDA	Food and Drug Administration
FIX	factor IX
FL	follicular lymphoma
FVIII	factor VIII
GEJ	gastroesophageal junction
GLP-1	glucagon-like peptide-1
gMG	generalized myasthenia gravis
GR-II	glucocorticoid II
HAE	hereditary angioedema
HCC	hepatocellular carcinoma
HER	human epidermal growth factor receptor
HR	hormone receptor
HSCT	hematopoietic stem cell transplantation
ITP	immune thrombocytopenic purpura
IV	intravenous
JAK	Janus Kinase
LA-HNSCC	locally advanced head and neck squamous cell carcinoma
LDH	lumbar disc herniation
MacTel	macular telangiectasia type 2
MDS	myelodysplastic syndrome
MEK 1/2	mitogen-activated protein kinase 1 and 2
MM	multiple myeloma
MPS IIIA	mucopolysaccharidosis type IIIA
NCFB	non-cystic fibrosis bronchiectasis
NF1	neurofibromatosis type 1
nmDMD	nonsense mutation Duchenne muscular dystrophy
NSCLC	non-small cell lung cancer
oHCM	obstructive hypertrophic cardiomyopathy
PDCD	pyruvate dehydrogenase complex deficiency
pJIA	polyarticular juvenile idiopathic arthritis

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CONTINUED

Glossary

Term	Definition
PKU	phenylketonuria
PN	plexiform neurofibroma
PsA	psoriatic arthritis
PsO	plaque psoriasis
PWS	Prader Willi syndrome
RA	rheumatoid arthritis
RDEB	recessive dystrophic epidermolysis bullosa
RRP	recurrent respiratory papillomatosis
RSV	respiratory syncytial virus
SC	subcutaneous
SCA	spinocerebellar ataxia
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

Term	Definition
uUTI	uncomplicated urinary tract infection
VMS	vasomotor symptoms
WAC	Wholesale Acquisition Cost

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