carelon Rx

Drug and biologic pipeline update Q2 2026

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CarelonRx's quarterly

Drug and biologic pipeline update

CarelonRx closely monitors the drug and biologic pipeline as part of our mission to improve health, lower the total cost of care across pharmacy and medical, and deliver an exceptional experience for our clients and members. Pipeline monitoring supports evidence-based, clinically appropriate use of drugs and therapies at the time of launch. In addition, future cost impact estimates provide valuable insights to guide health plan and client planning.

Our Q2 2026 update highlights three agents in late-stage development:

- Atacicept for immunoglobulin A nephropathy (IgAN)
- Isaralgagene civaparvovec for Fabry disease
- Hepcludex for hepatitis D virus (HDV) treatment

You will also find an overview of other products that are expected to reach the market in the next 12 months and an update on gene therapies and biosimilars.

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Emerging new therapies

Atacicept

Condition:

Immunoglobulin A nephropathy (IgAN), also known as Berger's disease, is an autoimmune condition caused by the buildup of immunoglobulin A and other antibodies in the blood vessels of the kidneys, known as glomeruli. It is a chronic, slowly progressive disease with about 50% of individuals developing end stage renal disease over 20 years. The incidence of IgAN in the United States is approximately 2 to 3 individuals per 100,000 per year with an average age at diagnosis of approximately 35 years old. The disease more commonly affects Asian and White individuals, and White males are twice as likely to develop IgAN than females.

Role in treatment:

The goal of therapy is to prevent disease progression to end-stage kidney disease, accomplished with simultaneous use of both immunosuppressive and nonimmunosuppressive strategies. Standard nonimmunosuppressive treatment recommended by Kidney Disease: Improving Global Outcomes (KDIGO) involves blood pressure management with either angiotensin-converting enzyme inhibitors (ACEi), angiotensin II receptor blockers (ARBs), or Filspari® (sparsentan), in addition to lifestyle modifications. Vanrafia® (atrasentan) is an agent currently under accelerated approval (based on surrogate endpoint versus clinical outcomes) for IgAN that can be used in addition to ACEi/ARBs. KDIGO recommends Tarpeyo® (budesonide delayed release) or systemic glucocorticoids as immunosuppressive therapies for IgAN. Other immunosuppressive therapies include Fabhalta® (iptacopan) and Voyxact® (sibeprenlimab), both currently under accelerated approval.

If approved, atacicept will be another immunosuppressive therapy for IgAN offering a dual mechanism of action. Like Voyxact, it will be available as a self-administered subcutaneous (SC) injection but will be dosed once weekly whereas Voyxact is dosed once every four weeks.

Other injectable immunosuppressive therapies are being studied for IgAN. Povetacicept, a BAFF/APRIL inhibitor like atacicept, was recently granted Breakthrough Therapy Designation, with complete submission to the Food and Drug Administration (FDA) for accelerated approval expected in the first half of 2026. Agents in phase 3 development include sefaxersen, a complement factor B inhibitor, zigakibart, an APRIL inhibitor like Voyxact, Ultomiris® (ravulizumab), a complement inhibitor already FDA-approved for other indications, and two monoclonal antibodies, mezagitamab, and felzartamab.

Efficacy:

The Biologics License Application (BLA) submission for atacicept is supported by data from a prespecified interim analysis of the phase 3 ORIGIN 3 trial. Percentage reduction from baseline in the urinary protein-to-creatinine ratio (a measure of protein in the urine to monitor kidney damage) at week 36 was 42% lower with atacicept compared to placebo. The trial is still ongoing to evaluate the change in kidney function over two years in 431 adults and is expected to complete in 2027.

Safety:

Based on data from the interim analysis, atacicept was well-tolerated. The incidence of adverse events (AEs) was generally balanced between atacicept and placebo groups, with most being mild in severity. The most common AEs with atacicept were injection site reactions and upper respiratory tract infection.

Product:
Atacicept

Indication:
Treatment of adults with immunoglobulin A nephropathy (IgAN)

Estimated FDA approval:
July 2026

Therapeutic class:
B-cell activating factor (BAFF) and A proliferation-inducing ligand (APRIL) inhibitor

Route of administration:
Subcutaneous (SC) injection

FDA designations:
Breakthrough Therapy; Orphan Drug

Manufacturer:
Vera Therapeutics

Financial impact:

The price of atacicept is unknown. However, it could be priced similarly to other targeted immunosuppressive IgAN treatments which cost $30,000 to $48,000 per month.

CarelonRx view:

The IgAN treatment landscape is becoming increasingly competitive, particularly among targeted immunosuppressive agents with overlapping mechanisms of action. The significance of the dual BAFF/APRIL inhibition of atacicept compared to other available immunosuppressive therapies remains unknown. However, the once weekly self-administered injection provides an alternative dosing option over daily oral regimens and appears to be well-tolerated.

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Emerging new therapies

Atacicept

(*continued from page 3*)

Comparison of agents for IgAN

Brand (generic)	Filspari (sparsentan)	Vanrafia (atrasentan)	Tarpeyo (budesonide)	Fabhalta (iptacopan)	Voyxact (sibeprenlimab)	Atacicept (exact label pending approval)
FDA-approval for IgAN	Full approval	Accelerated approval	March 2026	Accelerated approval	Accelerated approval	Accelerated approval to be determined
IgAN indication	Slow kidney function decline in adults with IgAN	Reduce proteinuria in adults with IgAN	Reduce loss of kidney function in adults with IgAN	Reduce proteinuria in adults with IgAN	Reduce proteinuria in adults with IgAN	Adults with IgAN
	Nonimmunosuppressive		Immunosuppressive			
Mechanism	Dual endothelin receptor antagonist (ERA) + ARB	ERA	Corticosteroid	Complement B factor inhibitor	APRIL inhibitor	BAFF/ APRIL inhibitor
Route (frequency)	Oral (once daily)	Oral (once daily)	Oral (once daily for 9 months)	Oral (twice daily)	SC (every 4 weeks)	SC (every week)
Key safety	Boxed warnings: hepatotoxicity, embryo-fetal toxicity	Boxed warning: embryo-fetal toxicity	High cortisol levels and adrenal suppression with chronic use	Boxed warning: serious infections by encapsulated bacteria	Increased risk of infection	Increased risk of infection
Manufacturer	Travere Therapeutics	Novartis	Calliditas Therapeutics	Novartis	Otsuka	Vera

Emerging new therapies

Isaralgagene civaparvovec

Condition:

Fabry disease, also called Anderson-Fabry disease, is a rare X-linked genetic condition that results in accumulation of fatty molecules in blood vessels and tissues due to decreased function or complete absence of an enzyme called alpha-galactosidase A (alpha-GAL A). Because Fabry disease is X-linked, males are typically more severely affected, with females having a variable disease course ranging from no symptoms to severe disease.

The classic form of Fabry disease is the most severe, affecting approximately 1 in 22,000 to 1 in 40,000 males. Symptoms appear during childhood or adolescence and include severe nerve pain, gastrointestinal issues, kidney damage, and skin lesions, progressing to heart problems, kidney failure, and strokes in adulthood. Late-onset Fabry disease usually presents at age 30 or older, with symptoms most commonly involving the heart. Late-onset Fabry disease affects approximately 1 in 1,000 to 1 in 3,000 males, and 1 in 6,000 to 1 in 40,000 females.

Role in treatment:

Current management strategies for Fabry disease include enzyme replacement therapy (ERT), pharmacologic chaperone therapy to stabilize the alpha-GAL A enzyme, and supportive care. Elfabrio® (pegunigalsidase alfa-iwxj) and Fabrazyme® (agalsidase beta) are intravenous ERTs administered every two weeks. Infusion-associated and hypersensitivity reactions may occur, so pretreatment with antihistamines, antipyretics, and/or corticosteroids may be necessary. Galafold® (migalastat) is an oral pharmacologic chaperone administered every other day but is only effective in individuals with specific genetic variants.

While these therapies can slow disease progression, they are not curative and require chronic administration. Isaralgagene civaparvovec is an investigational gene therapy designed to deliver a functional GLA gene to the liver, enabling production of alpha-GAL A enzyme. By increasing enzyme production, isaralgagene civaparvovec may eliminate the need for ongoing ERT and, if FDA-approved, would provide a potential one-time treatment option for individuals with Fabry disease.

Lucerastat and venglustat are oral substrate reduction therapies with a novel mechanism of action currently in phase 3 development for Fabry disease. These agents decrease synthesis of the fatty molecules that accumulate due to deficient alpha-GAL A enzyme regardless of the genetic variant, unlike Galafold.

Efficacy:

The BLA for isaralgagene civaparvovec is supported by data from the phase 1/2 STAAR trial that enrolled 33 adults with Fabry disease, regardless of their baseline ERT status. Efficacy endpoints were measured after 12 months, with a median duration of follow-up of 24 months. Cardiac structure and function remained stable with renal function improving across all subgroups. Quality of life measures were significantly improved compared to baseline, and all participants on ERT discontinued and remained off ERT as of the data cutoff date. The longest treated participant had durable alpha-GAL A activity at 4.5 years post-treatment.

Product:
Isaralgagene civaparvovec (ST-920)

Indication:
Fabry disease treatment

Estimated FDA approval:
Second half of 2026

Therapeutic class:
Gene therapy

Route of administration:
Intravenous (IV) infusion

FDA designations:
Fast Track; Orphan Drug; Regenerative Medicine Advanced Therapy (RMAT)

Manufacturer:
Sangamo Therapeutics

Safety:

Isaralgagene civaparvovec was generally well-tolerated. The majority of AEs were considered mild to moderate in severity, with the most common AEs (>20%) being fever, COVID-19 infection, nasopharyngitis, headache, fatigue, and nausea. Four participants experienced treatment-emergent serious AEs, including left arm pain, noncardiac chest pain, sepsis, stroke, and a single treatment-related event of shoulder enthesopathy (any issues at site where tendons, ligaments, or other soft tissues attach to bones), all resolved. No AEs led to study discontinuation, and there were no deaths.

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Emerging new therapies

Isaralgagene civaparvovec

(*continued from page 5*)

Financial impact:

Although isaralgagene civaparvovec is expected to carry a high upfront cost typical of gene therapies, the overall impact may be limited due to the rarity of Fabry disease. Potential offsets may include avoidance of lifelong ERT and associated medical costs. However, real-world durability and long-term economic impact remain uncertain.

CarelonRx view:

Isaralgagene civaparvovec may offer a one-time therapeutic option for individuals with Fabry disease and the potential to discontinue chronic ERT, with associated improvements in quality of life. However, given the limited number of participants in the clinical trial and duration of follow-up, additional long-term efficacy and safety data will be important to fully characterize durability of response and long-term risk.

Product:
Isaralgagene civaparvovec (ST-920)

Indication:
Fabry disease treatment

Estimated FDA approval:
Second half of 2026

Therapeutic class:
Gene therapy

Route of administration:
Intravenous (IV) infusion

FDA designations:
Fast Track; Orphan Drug; Regenerative Medicine Advanced Therapy (RMAT)

Manufacturer:
Sangamo Therapeutics

Emerging new therapies

Hepcludex (bulevirtide)

Condition:

Hepatitis D is a liver infection caused by the hepatitis D virus (HDV). It only occurs in people already infected with the hepatitis B virus (HBV). When hepatitis B and hepatitis D viruses invade an individual at the same time, it is called coinfection. When HDV exposure occurs after first being infected with HBV, it is called superinfection. HDV can be acute and short term, or become a chronic, long-term infection. In immunocompetent adults, more than 95% clear both viruses when they are acquired at the same time. HDV becomes a chronic disease in more than 80% of people with superinfection. HDV can cause severe symptoms including fever, vomiting, abdominal pain, dark urine, and jaundice, which may lead to liver damage or death.

HDV is the most severe form of viral hepatitis and can have mortality rates as high as 50% within five years in individuals with cirrhosis. At least 12 million people worldwide are coinfected with HDV and HBV. Coinfection leads to more serious liver disease than HBV alone with a faster progression of liver damage, an increased risk of liver cancer, and death. There are approximately over 230,000 people in the U.S. with HDV.

Role in treatment:

There is no vaccine to prevent HDV infection. Prevention of HBV with hepatitis B vaccine may protect against HDV. Hepcludex would be the first FDA-approved treatment for adults with HDV. Its use would be in chronic infection with compensated (asymptomatic) liver disease. It is a novel antiviral that inhibits the penetration of the HDV into liver cells. Off-label use of pegylated interferon alfa is the only current option for treatment. Treatment of the HBV infection would continue during Hepcludex administration.

Three additional treatments are in late-stage development for individuals with chronic HDV and, if approved, could compete with Hepcludex. Vir Biotechnology is developing a combination treatment containing a monoclonal antibody, tobevibart, and elebsiran, a small interfering ribonucleic acid (siRNA). Sentynl Therapeutics is developing an oral prenylation inhibitor, lonagarnib. Lastly, Mirum Pharmaceuticals is developing a monoclonal antibody, brelovitug, which is currently being compared directly to Hepcludex in an ongoing phase 3 trial.

Efficacy:

In October 2022, the FDA denied approval of Hepcludex citing concerns with manufacturing and delivery. No new studies were requested. Hepcludex was resubmitted in 2025, supported by final data from the pivotal phase 3 MYR301 trial. The primary end point in MYR301 was a combined response at week 48 of an undetectable HDV RNA level, or a level that decreased by at least two $\log_{10}$ international unit (IU) per milliliter from baseline, and normalization of the alanine aminotransferase (ALT) level. Both doses of Hepcludex met the primary endpoint with statistical significance compared to placebo, with 45% of participants in the 2-mg group, 48% in the 10-mg group, versus 2% in the placebo group. It remains unclear whether Hepcludex will be marketed as a finite or ongoing therapy.

Safety:

Based on results from the phase 3 MYR301 trial, the safety profile of Hepcludex did not show any serious adverse events. The most common ones included raised levels of bile salts in the blood and injection site reactions.

Product:
Hepcludex® (bulevirtide)

Indication:
Hepatitis D virus (HDV) treatment

Estimated FDA approval:
First half of 2026

Therapeutic class:
Antiviral; entry inhibitor

Route of administration:
Subcutaneous (SC) injection

FDA designations:
Breakthrough Therapy; Orphan Drug

Manufacturer:
Gilead Sciences

Financial impact:

Although the product may be costly, it is unlikely to have a major impact on overall drug spend due to the rarity of the condition. Numbers for HDV infection have declined in the past due to HBV vaccination programs. However, it is unknown what effect the December 2025 Centers for Disease Control and Prevention (CDC) change in HBV vaccination recommendations will have on future HDV infection rates. The CDC now recommends shared decision making versus universal HBV immunizations at birth for infants born to mothers who test negative for HBV.

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Emerging new therapies

Hepcludex (bulevirtide)

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CarelonRx view:
Although prevalence is likely low, HDV infection may be serious because having both HBV and HDV infection increases the risk of liver disease, liver cancer, and death. Current off-label treatment with pegylated interferon alpha products is not very effective. Hepcludex may provide a significant benefit in people with chronic HDV and compensated liver disease. There are some remaining questions regarding long-term outcomes and optimal treatment duration.

Product:
Hepcludex® (bulevirtide)

Indication:
Hepatitis D virus (HDV) treatment

Estimated FDA approval:
First half of 2026

Therapeutic class:
Antiviral; entry inhibitor

Route of administration:
Subcutaneous (SC) injection

FDA designations:
Breakthrough Therapy; Orphan Drug

Manufacturer:
Gilead Sciences

Other significant product approvals

Additional product approvals expected to reach the market in the next 12 months*

Drug or biologic manufacturer	Indication/route	Place in therapy	Estimated approval date	Impact on overall drug or medical spend
Baxdrostat AstraZeneca	Resistant hypertension/oral	**First in class:** will compete most directly with Tryvio™	Second quarter 2026	
Camizestrant AstraZeneca	Hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer/oral	**Addition to class:** for individuals previously treated with endocrine therapy; same class as Orserdu®	Second quarter 2026	
Vepdegestrant Arvinas	HR+/HER2- locally advanced or metastatic breast cancer/oral	**Addition to class:** for individuals previously treated with endocrine therapy; same class as Orserdu	06/05/2026	
Xocova (ensitrelvir fumaric acid) Shionogi	COVID-19 prevention following exposure to infected individual/oral	**Addition to class:** first antiviral for prevention following exposure to COVID-19 virus	06/16/2026	
Tabex® (cytisinicline) Achieve Life Sciences	Smoking cessation/oral	**First in class:** naturally occurring plant alkaloid with binding affinity to the nicotinic acetylcholine receptor	06/26/2026	
SEL-212, Rapamycin/ Pegsiticase Swedish Orphan Biovitrum AB	Gout/intravenous (IV) infusion	**First in class:** every 4 weeks novel therapy for uncontrolled gout	06/27/2026	
Veligrotug Viridian Therapeutics	Thyroid eye disease/IV	**Addition to class:** would compete with Tepezza®; lower rate of hearing related adverse events	06/30/2026	

In addition to treatments listed previously, these important drugs and biologics listed in the table at left are scheduled to receive Food and Drug Administration (FDA) approval within the next 12 months.*

Table glossary:

Orphan drug/rare disease; expected to be high cost, but with minimal impact to overall drug/medical spend due to low utilization

Potential to significantly increase overall drug/ medical spend

New entrant into current or future high-spend/ trending category

No significant impact to incremental spend due to replacement of existing competitors based on initial analysis

* As of March 2, 2026

Other product approvals expected to reach the market in the next 12 months* (*continued*)

Drug or biologic manufacturer	Indication/route	Place in therapy	Estimated approval date	Impact on overall drug or medical spend
Molgramostim Savara	Autoimmune pulmonary alveolar proteinosis/ inhalation	**Addition to class:** would be first FDA-approved treatment for this indication	Third quarter 2026	
Oveporexton Takeda	Narcolepsy type 1/oral	**Addition to class:** novel mechanism of action in narcolepsy (other approval in insomnia)	Third quarter 2026	
Emcitate® (tiratricol) Egetis Therapeutics	Monocarboxylate transporter 8 deficiency/ oral	**Addition to class:** would be first FDA-approved treatment for this indication	Third quarter 2026	
Rebisufligene etisparvovec; UX111 Ultragenyx Pharmaceutical	Mucopolysaccharidosis IIIA/IV	**First in class:** gene therapy; would be first FDA-approved agent for this indication	Third quarter 2026	
DTX 401; pariglasgene brecaparvovec Ultragenyx Pharmaceutical	Glycogen storage disease, type 1a/IV	**First in class:** would be first FDA-approved treatment for this indication; gene therapy	Third quarter 2026	
Pimicotinib Abbisklo Therapeutics	Pigmented villonodular synovitis (PVNS)/oral	**Addition to class:** will compete with Turalio® and Romvimza™	Third quarter 2026	
Icotrokinra Johnson & Johnson	Plaque psoriasis, moderate-to-severe, ages 12 and older/oral	**First in class:** selective interleukin-23 receptor blocker	(July 2026) Approved 03/18/2026	
Atacicept Vera Therapeutics	Immunoglobulin A (IgA) nephropathy/ subcutaneous (SC) injection	**Addition to class:** same mechanism of action as Voyxact® with more frequent administration	07/07/2026	

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Other product approvals expected to reach the market in the next 12 months* (*continued*)

Drug or biologic manufacturer	Indication/route	Place in therapy	Estimated approval date	Impact on overall drug or medical spend
Relacorilant Corcept	Ovarian cancer/oral	**Addition to class:** for individuals with platinum-resistant disease	07/11/2026	
Gedatolisib Celcuity	HR+/HER2- advanced breast cancer/IV	**Addition to class:** targeted therapy inhibits more enzymes than competitors	07/17/2026	
Camrelizumab Elevar Therapeutics	Liver cancer, first-line/IV	**Addition to class:** programmed cell death protein 1 (PD-1) inhibitor for use in combination with rivoceranib, also under FDA review	07/23/2026	
Rivoceranib Elevar Therapeutics	Liver cancer, first-line/IV	**Addition to class:** tyrosine kinase inhibitor for use in combination with camrelizumab, also under FDA review	07/23/2026	
Centanafadine Otsuka Pharmaceutical	Attention deficit hyperactivity disorder in children, adolescents, and adults/oral	**First in class:** novel norepinephrine, dopamine, and serotonin reuptake inhibitor (NDSRI)	07/24/2026	
Brepocitinib Priovant Therapeutics	Dermatomyositis/oral	**Addition to class:** would be the first targeted therapy for this indication	08/06/2026	
Zidesamtinib Nuvalent	Non-small cell lung cancer (NSCLC), ROS1-positive/oral	**Addition to class:** for individuals who have received at least one prior ROS1 tyrosine kinase inhibitor	09/18/2026	
Tavapadon Cerevel	Parkinson's disease/oral	**First in class:** submission based on data in early disease and as adjunctive to levodopa in individuals experiencing motor fluctuations	09/26/2026	
Mim8; Denecimig Novo Nordisk	Hemophilia A/SC	**Addition to class:** for individuals with or without inhibitors; potential for once monthly dosing	09/29/2026	

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Other product approvals expected to reach the market in the next 12 months* (*continued*)

Drug or biologic manufacturer	Indication/route	Place in therapy	Estimated approval date	Impact on overall drug or medical spend
Pivekimab AbbVie	Blastic plasmacytoid dendritic cell neoplasm (BPDCN)/IV	**Addition to class:** would compete with Elzonris®	09/30/2026	
Daznelimgene lisbac OS Therapie	Osteosarcoma/IV	**First in class:** for prevention or delay of recurrent, fully resected, pulmonary metastatic osteosarcoma	09/30/2026	
CagriSema (cagrilintide/ semaglutide) Novo Nordisk	Chronic weight management in adults with obesity or overweight/SC	**First in class:** combines a novel amylin analogue with an existing glucagon-like peptide-1 (GLP-1) receptor agonist	Fourth quarter 2026	
Efsitora alfa Eli Lilly	Type 2 diabetes mellitus/SC	**Addition to class:** long-acting basal insulin analog for once-weekly dosing	10/30/2026	
INO-3107 Inovio Pharmaceuticals	Recurrent respiratory papillomatosis/ intramuscular (IM) injection	**First in class:** will compete with Papzimeos™; more convenient administration	10/30/2026	
Gefurulimab AstraZeneca	Myasthenia gravis/SC	**Addition to class**: once weekly, self-administered injection	Between November and December 2026	
Ivonescimab Akeso	Non-small cell lung cancer (NSCLC)/IV	**First in class:** novel agent for second-line or later treatment of individuals with epidermal growth factor receptor (EGFR)-mutated locally advanced or metastatic non-squamous NSCLC	11/14/2026	

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Imsidolimab Vanda Pharmaceuticals	Generalized pustular psoriasis (GPP)/IV, SC	**Addition to class:** for both treatment of flares and maintenance therapy	12/12/2026	
VTS-270; adrabetadex Mandos	Niemann-Pick disease type C/intrathecal	**First in class:** would be first disease-modifying treatment for this condition	12/18/2026	
Imlifidase Sarepta Therapeutics	Desensitization of highly sensitized adults undergoing deceased donor kidney transplantation/IV	**First in class:** would be first FDA-approved treatment for this indication; one-time treatment	12/19/2026	
Anitocabtagene autoleucel Arcellx	Multiple myeloma/IV	**First in class:** next-generation chimeric antigen receptor (CAR) T-cell therapy	12/23/2026	
Bezuclastinib Cogent Biosciences	Mastocytosis/oral	**Addition to class:** for individuals with non-advanced systemic disease	12/30/2026	
Lirafugratinib Elevar Therapeutics	Biliary tract cancer/oral	**First in class:** second-line treatment option for individuals with fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement	01/28/2027	

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The FDA requires all approved biologic products, including reference, biosimilar, and interchangeable products, be evaluated for safety and efficacy to determine whether the benefits outweigh any known potential risks.

Reference biologics undergo several phases of clinical studies to establish safety and effectiveness before they are FDA approved. Clinical trials begin with early, small-scale, phase 1 studies and move toward late-stage, large scale, phase 3 studies. After the biologic has entered the market, post-marketing monitoring continues to assess the safety, efficacy, and clinical benefit in a larger population.

Biosimilar products are highly similar to their reference product in terms of structure and function and lack clinically meaningful differences in terms of safety and efficacy. Biosimilar products may be approved for all or some of the reference product indications due to patent exclusivity.

Prescriptions for biosimilar products need to be written for the biosimilar by name. Biosimilar products that are granted interchangeability are allowed to be substituted for their reference biologic without the intervention of the prescriber. This is similar to how generic drugs may be substituted for brand name drugs. Unlike reference biologics, biosimilar products are not required to submit evidence to establish safety and efficacy. However, a biosimilar manufacturer must submit clinical trial data that establishes biosimilarity with the reference product.

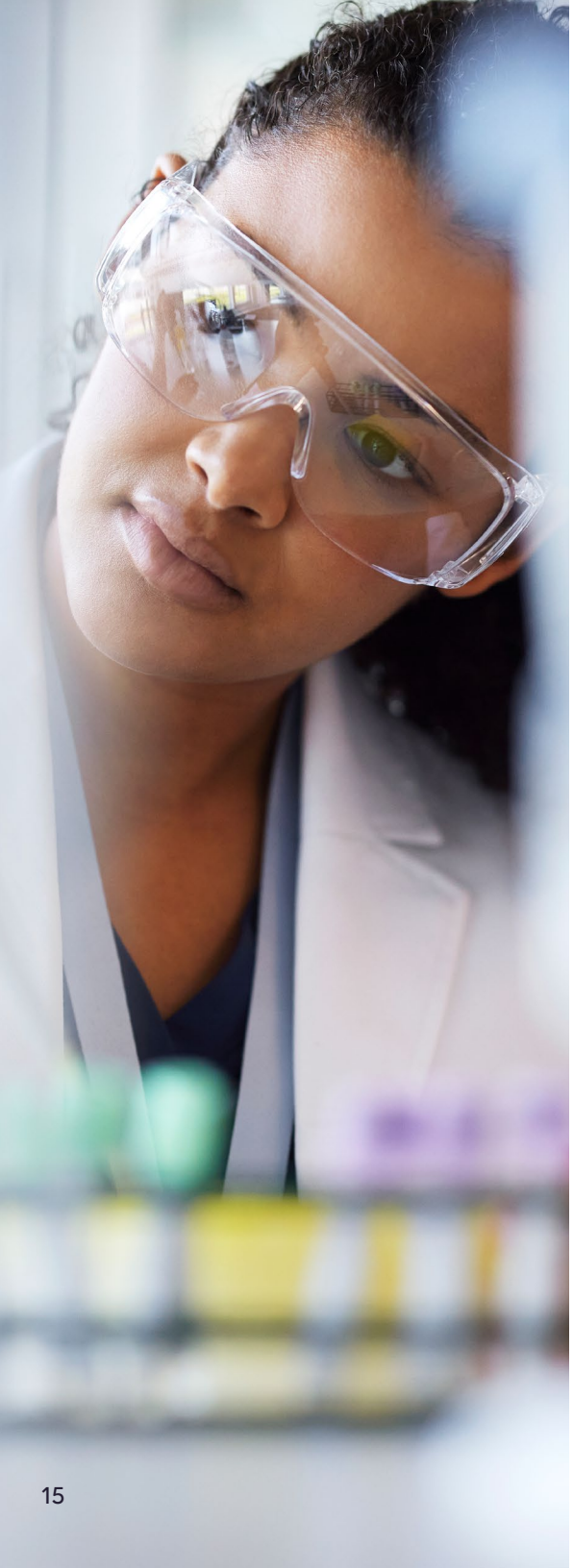
Biosimilar pipeline update

Currently 82 biosimilar products are FDA approved in the United States which represent 20 unique reference biologic products. Recent approvals include Nufymco® (ranibizumab-leyk), Boncresa™, and Oziltus™ (denosumab-mobz) in December 2025 and Filkri® (filgrastim-laha) in January 2026. Sixty-five of the approved products have been launched.

Biosimilar products awaiting launch and/or approval*

Brand name	Brand manufacturer	Biosimilar name	Biosimilar manufacturer	FDA approval*
Actemra®	Roche; Chugai; Genentech	Avtozma®	Celltrion	01/24/2025
Avastin®	Genentech; Roche	Avzivi®	Bio-Thera Solutions; Sandoz	12/06/2023
		FKB238	Centus Biotherapeutics; AstraZeneca; Fujifilm Kyowa Kirin	Pending
		HLX04	Henlius	Pending
Enbrel®	Amgen; Immunex	Erelzi™	Sandoz	08/30/2016
		Eticovo™	Samsung Bioepis	04/25/2019
Eylea®	Regeneron	Ahzantive®	Formycon; Santo Holding; Bioeq; Klinge Pharma	06/28/2024
		Enzeevu™	Sandoz; Hexal	08/09/2024
		Eydenzelt®	Celltrion	10/02/2025
		Opuviz™	Samsung Bioepis; Biogen	05/20/2024
		Yesafili™	Momenta; Mylan; Johnson & Johnson; Biocon; Viatris	05/20/2024
		SCD411	Sam Chun Dang Pharm; Fresenius Kabi	Pending
Herceptin®	Roche; Genentech	TX05	Tanvex	Pending
Humalog®	Eli Lilly	GL-LIS	Gan & Lee; Sandoz	Pending
Humalog Pen				Pending
Humalog U-100 KwikPen				Pending
Lantus SoloStar®	Sanofi	GL-GLA	Gan & Lee; Sandoz	Pending

* As of March 2, 2026. Excludes biosimilars that are FDA approved and have launched.



Biosimilar products awaiting launch and/or approval* (*continued*)

Brand name	Brand manufacturer	Biosimilar name	Biosimilar manufacturer	FDA approval*
Lucentis®	Roche; Genentech	Nufymco	Formycon; Bioeq; Zydus; Polpharma	12/18/2025
		LUBT010	Lupin	Pending
Neulasta®	Amgen	Armlupeg™	Lupin	11/28/2025
		Lapelga	Apotex; Accord; Intas	Pending
Neupogen®	Amgen	Filkri	Apotex; Accord; Intas	01/15/2026
Novolog® (10 mL vial)	Novo Nordisk	AMP-004	Amphastar	Pending
Novolog FlexPen				
Novolog FlexTouch				
Novolog PenFill				
Novolog (10 mL vial)	Novo Nordisk	GL-ASP	Gan & Lee; Sandoz	Pending
Novolog FlexPen				
Novolog FlexTouch				
Novolog PenFill				
Orencia®	Bristol-Myers Squibb	DRL_AB IV	Dr. Reddy's Laboratories	Pending
Perjeta®	Genentech; Roche	Poherdy®	Henlius; Organon	11/13/2025
		PERT-IJS	Biocon	Pending
Prolia®/Xgeva®	Amgen	Boncresa/Oziltus	mAbxience; Insud Pharma; Fresenius Kabi; Amneal	12/19/2025
		Bosaya™/Aukelso™	Biocon	09/16/2025
		Xbryk™	Samsung Bioepis; Samsung Biologics	02/13/2025
		Osvyrti®/Jubereq®	Intas; Accord	10/29/2025
		ENZ215	Enzene; Alkem Labs	Pending
Simponi®/Simponi Aria	Johnson & Johnson	BAT2506	Bio-Thera Solutions; Accord; Intas	Pending
Xolair®	Roche; Genentech; Novartis	Omlyclo®	Celltrion	03/07/2025
		ADL-018	Kashiv Biosciences; Amneal	Pending

* As of March 2, 2026. Excludes biosimilars that are FDA approved and have launched.

Gene therapies in the pipeline

Gene therapy introduces or edits genetic material to treat disease. We group these drugs into 1) single-use gene therapies that aim to cure inherited conditions and 2) gene-based therapeutics that require repeat dosing. Because prices are disclosed only after FDA approval, forecasting remains difficult, but most forthcoming gene therapies are likely to launch in the $2 million to $4 million range — consistent with recent approvals.

The following gene therapies and gene-based therapeutics are scheduled to receive an FDA decision in the next 12 months, or we expect they could file a biologics license application (BLA) with the FDA before the end of 2027.

Gene and gene-based therapies with submitted applications for potential FDA approval*

Gene therapy/ gene-based therapy	Indication/route and frequency	Place in therapy	Estimated approval date
Cretostimogene grenadenorepvec Novartis	Bacillus Calmette-Guérin (BCG) unresponsive, non-muscle invasive bladder cancer (NMIBC)/multiple intravesical doses	Second gene-based therapeutic; will compete with Adstiladrin®. Uses viral vector (adeno-associated virus).	Second half 2026–2027 (initiated rolling BLA)
Isaralgagene civaparvovec Sangamo	Fabry disease/single intravenous (IV) infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	Second half 2026–2027 (initiated rolling BLA)
Marnetegragene autotemcel (marne-cel) Rocket	Leukocyte adhesion deficiency-I/ single IV infusion	First gene therapy for this indication. Uses viral vector (lentivirus).	03/28/2026 (refiled)
Vusolimogene oderparepvec Replimune	Advanced melanoma/multiple intratumoral injections	Addition to class; gene-based oncolytic immunotherapy; used in combination with nivolumab. Uses viral vector (herpes simplex virus).	04/10/2026 (refiled)
Dalnacogene ponparvovec Belief BioMed	Hemophilia B/single IV infusion	Third gene therapy for this indication; will compete with Hemgenix®. Uses viral vector (adeno-associated virus).	04/12/2026
DB-OTO Regeneron	Congenital hearing loss/single intracochlear infusion	First gene therapy for hearing loss due to OTOF mutations. Uses viral vector (adeno-associated virus).	First half 2026 (filed)
Pariglasgene brecaparvovec Ultragenyx	Glycogen storage disease type Ia/single IV infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	Third quarter 2026
Rebisufligene etisparvovec Abeona	Mucopolysaccharidosis IIIA (Sanfilippo type A)/single IV infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	Third quarter 2026 (refiled)
Sonpiretigene isteparvovec Nanoscope	Retinitis pigmentosa (RP)/single intravitreal injection	First mutation-agnostic gene therapy for RP. Uses viral vector (adeno-associated virus).	Second half 2026 (initiated rolling BLA)

* As of March 2, 2026.

Gene and gene-based therapies of significant interest with potential FDA submissions in 2026/2027*

Gene therapy/ gene-based therapy	Indication/route	Place in therapy	Estimated approval date
AAV-AIPL1 MieraGTx	Leber Congenital Amaurosis 4 (LCA4)/single subretinal injection	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2026
Bidridistrogene xeboparvovec Sarepta	Limb-girdle muscular dystrophy (LGMD) Subtype 2E/R4/single IV infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2026 (trials on hold)
Botaretigene sparoparvovec Johnson & Johnson	X-linked retinitis pigmentosa (XLRP)/single subretinal injection	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2026
Casgevy (exagamglogene autotemcel; exa-cel) Vertex and CRISPR	Sickle cell disease/single IV infusion	Potential to expand approval to include children ages 5 to 11; will compete with HCT and chronic RBC transfusions. Uses gene editing.	2026
Giroctocogene fitelparvovec Sangamo	Hemophilia A/single IV infusion	Gene therapy for hemophilia A; will compete with FVIII products and Hemlibra®. Uses viral vector (adeno-associated virus).	2026
SGT-003 Solid Biosciences	Duchenne muscular dystrophy (DMD)/single IV infusion	Competing to be second gene therapy for DMD; will compete with Elevidys. Uses viral vector (adeno-associated virus).	2026
Avalotcagene ontaparvovec Ultragenyx	Ornithine transcarbamylase (OTC) deficiency/single IV infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2026–2027
OCU400 Ocugen	Retinitis pigmentosa (RP)/single subretinal injection	Potential to be first gene therapy for RP associated with RHO mutations; may also get approval for people with any other RP associated mutation with a clinical phenotype of RP. Uses viral vector (adeno-associated virus).	2026–2027
RGX-202 Regenxbio	Duchenne muscular dystrophy (DMD)/single IV infusion	Second gene therapy for DMD; will compete with Elevidys. Uses viral vector (adeno-associated virus).	2026–2027
RP-A501 Rocket	Danon disease/single IV infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2026–2027
AAV-AQP1 MeiraGTx Holdings	Radiation-induced xerostomia/ single intraparotid injection	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2027
AAV-GAD MeiraGTx	Parkinson's disease/single surgical infusion into the brain	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2027

* As of March 2, 2026.

Gene and gene-based therapies of significant interest with potential FDA submissions in 2026/2027* (*continued*)

Gene therapy/ gene-based therapy	Indication/route	Place in therapy	Estimated approval date
Aglatimagene besadenovec Candel	Intermediate-to-high-risk localized prostate cancer/ multiple intratumoral injections	First localized gene-based viral immunotherapy for this indication; used in combination with an oral anti-herpes drug, such as valacyclovir, to destroy cancer cells. Uses viral vector (adeno-associated virus).	2027
BBP-812 Aspa	Canavan disease/single IV infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2027
Dabocemagene autoficel Castle Creek Biosciences	Dystrophic epidermolysis bullosa (DEB)/multiple intradermal injections	Third localized gene-based wound therapeutic for this indication; will compete with Vyjuvek® and Zevaskyn™. Uses viral vector (lentivirus).	2027
Detalimogene voraplasmid enGene	BCG unresponsive, NMIBC/ multiple intravesical instillations	Third gene-based therapeutic for NMIBC; will compete with Adstiladrin® and cretostimogene grenadenorepvec, if approved. Uses viral vector (adeno-associated virus).	2027
Elevidys (delandistrogene moxeparvovec-rokl) Sarepta	Duchenne muscular dystrophy (DMD)/single IV infusion	Potential to expand approval to include nonambulatory individuals and children age 4 and younger with DMD. Uses viral vector (adeno-associated virus).	2027
IMNN-001 Imunon	Newly diagnosed advanced ovarian, fallopian tube, or peritoneal cancers/multiple intraperitoneal infusions	First gene-based oncolytic immunotherapy for these indications; used in combination with chemotherapy. Uses a DNA plasmid vector enclosed in a nanoparticle delivery system.	2027
KB801 Krystal	Neurotrophic keratitis (NK) (ophthalmic)	First gene-based therapeutic for NK. Uses viral vector (herpes simplex virus type 1).	2027
KB803 (beremagene geperpavec) Krystal Biotech	Dystrophic epidermolysis bullosa (DEB)/multiple ophthalmic doses	First ophthalmic formulation of Vyjuvek™ to treat ocular complications secondary to DEB. Uses viral vector (herpes simplex virus).	2027
Laruparetigene zovaparvovec Beacon	X-linked retinitis pigmentosa (XLRP)/single subretinal injection	Second gene therapy for this indication; potential to compete with botaretigene sparoparvovec, if it's approved. Uses non-viral vector (Dually Derivatized Oligochitosan® (DDX) platform).	2027
Lonvoguran ziclumeran (lonvo-z) Intellia	Hereditary angioedema (HAE)/ single IV infusion	First gene therapy for this indication. Uses gene editing, delivered by lipid nanoparticles.	2027
LX2006 Lexeo	Friedreich's Ataxia Cardiomyopathy/single IV infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2027

* As of March 2, 2026.

Gene and gene-based therapies of significant interest with potential FDA submissions in 2026/2027* (*continued*)

Gene therapy/ gene-based therapy	Indication/route	Place in therapy	Estimated approval date
Ristoglogene autogetemcel (risto-cel) Beam Therapeutics	Sickle cell disease (SCD)/single IV infusion	Third gene therapy for this indication; will compete with Casgevy and Lyfgenia. Uses gene editing.	2027
Rivunatpagene miziparvovec Ultragenyx	Wilson disease/single IV infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2027
Surabgene lomparvovec Regenxbio	Neovascular age-related macular degeneration (wet AMD)/single subretinal and/or suprachoroidal injection	First gene therapy for this indication; will compete with treatments requiring multiple intravitreal injections such as Eylea® and Vabysmo®. Uses viral vector (adeno-associated virus).	2027
Tavokinogene telseplasmid (TAVO) OncoSec Medical	Metastatic melanoma/multiple intratumoral injections	Addition to class; gene-based oncolytic immunotherapy; used in combination with Keytruda®; uses non-viral vector (plasmid DNA).	2027
TG-C Kolon TissueGene	Osteoarthritis of the knee/ multiple intraarticular injections	First gene-based therapeutic for this indication; potential to compete with intraarticular steroid injections and knee replacement surgery. Uses viral vector (retrovirus).	2027
TSHA-102 Taysha Gene Therapies	Rett syndrome/single intrathecal infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2027
Avigbagene parvec (FLT201) Spur Therapeutics	Gaucher disease/single IV infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2027–2028
BEAM-302 Beacon Therapeutics	Alpha-1 antitrypsin deficiency (AATD)/single IV infusion	First gene therapy for this indication. Uses gene editing.	2027–2028
KB407 Krystal	Cystic fibrosis (CF)/inhaled via nebulization	First gene-based, mutation-agnostic therapeutic for CF. Uses viral vector (HSV-1).	2027–2028
NGN-401 Neurogene	Rett syndrome/single intracerebroventricular infusion	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2027–2028
OCU410ST Ocugen	Stargardt disease/single subretinal injection	First gene therapy for this indication. Uses viral vector (adeno-associated virus).	2027–2028
OTL-203 Orchard	Mucopolysaccharidosis I (MPS I; Hurler Syndrome)/ single IV infusion	First gene therapy for this indication. Uses viral vector (lentivirus).	2027–2028
4D-150 4D Molecular Therapeutics	Neovascular age-related macular degeneration (wet AMD)/single intravitreal injection	Second gene therapy for this indication; could compete with surabgene lomparvovec. Uses viral vector (adeno-associated virus).	2028

* As of March 2, 2026.

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