



Aetna Institutes® Gene-Based, Cellular and Other Innovative Therapies (GCIT®) Designated Providers

New FDA approved gene therapies have the potential to cure previously untreatable, often fatal conditions. Gene therapy involves modification of cells to treat disease or produce a therapeutic effect by replacing or repairing defective genetic material. The cost of these new therapies can be very high.

The GCIT® Designated Network program is Aetna's participating network for certain gene therapy services. The program helps patients who have been diagnosed with certain genetic conditions that may be treated with the use of innovative FDA-approved GCIT products.

GCIT® Designated Networks Providers and Program Criteria

To learn about our program requirements, and obtain a listing of GCIT Designated Providers, visit the [Aetna Institutes®](#) page on Aetna.com, scroll to the GCIT Designated Networks section and select the applicable item, or call Aetna Provider services at [1-888-632-3862](tel:1-888-632-3862).
TTY: 711

Providers that offer GCIT services and have met our credentialing and cost-efficiency criteria have been selected to participate in the GCIT Designated Provider network. These providers have been designated on a GCIT specific basis and are considered participating only for the GCIT service listed in the directory. To be considered in-network for coverage for GCIT related services, including home, office or hospital-based infusions or injections, you must utilize an Aetna Institutes GCIT Designated participating provider that has been specifically designated by us for your GCIT service type.

All GCIT services must be preauthorized for coverage to be effective. Any provider that is not specified as an Aetna Institutes Designated GCIT Provider is considered non-participating or non-preferred for GCIT related services, even if they are considered participating for other types of services.

Note: Some GCIT Designated Providers may not be part of your plan's network. Please confirm the provider is participating in your plan before obtaining services.



Amtagvi®

On February 16, 2024, the FDA approved AMTAGVI (lifileucel), a tumor-derived autologous T cell immunotherapy indicated for the treatment of adult patients with unresectable or metastatic melanoma previously treated with a PD-1 blocking antibody, and if BRAF V600 mutation positive, a BRAF inhibitor with or without a MEK inhibitor.

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-cellular-therapy-treat-patients-unresectable-or-metastatic-melanoma>

Casgevy®

On December 8, 2023, the FDA approved Casgevy (exagamglogene autotemcel), an autologous genome edited hematopoietic stem cell-based gene therapy drug used to treat sickle cell disease CASGEVY (SCD) in patients 12 years and older with recurrent vaso-occlusive crises (VOCs).

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapies-treat-patients-sickle-cell-disease>

Elevidys

On June 22, 2023, the FDA approved Elevidys (delandistrogene moxeparvovec-roki), a gene therapy drug used to treat certain patients with duchene muscular dystrophy.

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-treatment-certain-patients-duchenne-muscular-dystrophy>

Encelto™

On March 6, 2025, the FDA has approved Encelto, the first-ever treatment for Macular Telangiectasia Type 2, a rare eye disease that leads to vision loss [pharmaphorum.com](https://www.pharmaphorum.com)+2.

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/vaccines-blood-biologics/center-biologics-evaluation-and-research-cber-product-approval-information/encelto>

Fayuvi™

On September 17, 2026, the FDA has approved Fayuvi, the first treatment for pediatric patients with mucopolysaccharidosis type IIIA (MPS IIIA), also known as Sanfilippo syndrome type A., MPS IIIA is a rare inherited disease that progressively damages the brain and nervous system, causing children to lose cognitive, language and other developmental abilities over time.

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-pediatric-patients-sanfilippo-syndrome-type>



Genglycos™

On August 19, 2026, The FDA issued an accelerated approval for Genglycos (pariglasgene breccaparovvec-opnr) to reduce daily cornstarch intake as an adjunct to nutritional management in adults and pediatric patients 8 years of age and older with glycogen storage disease type Ia (GSDIa), a rare, inherited genetic disorder caused by a deficiency of the enzyme glucose-6-phosphatase, which prevents the body from properly breaking down stored glycogen into glucose. Genglycos is the first approved treatment for this condition.

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-therapy-patients-aged-8-years-and-older-glycogen-storage-disease-type-ia>

Hemgenix®

On November 22, 2022, the FDA approved Hemgenix (etranacogene dezaparvovec), a gene therapy drug used to treat adults with Hemophilia B.

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/vaccines-blood-biologics/vaccines/hemgenix>

Itvisma®

On November 24, 2025, the FDA approved Itvisma, for the treatment of children two years and older, teens and adults living with spinal muscular atrophy (SMA) with a confirmed mutation in the survival motor neuron 1 (SMN1) gene, making it the first and only gene replacement therapy available for this broad population.

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/itvisma>

Kebilidi™

On November 13, 2024, the FDA approved Kebilidi (eladocogene exuparovvec-tneq) for the treatment of adult and pediatric patients with aromatic L-amino acid decarboxylase (AADC) deficiency.

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-treatment-aromatic-l-amino-acid-decarboxylase-deficiency>

Kresladi™

On March 26, 2026, the FDA approved Kresladi, as the first gene therapy for the treatment of severe Leukocyte Adhesion Deficiency Type I (LAD-I). Kresladi is indicated for the treatment of pediatric patients with severe leukocyte adhesion deficiency I (LAD-I) due to biallelic variants in *ITGB2* without an available human leukocyte antigen (HLA)-matched sibling donor for allogeneic hematopoietic stem cell transplant.

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-severe-leukocyte-adhesion-deficiency-type-i>



Lenmeldy™

On March 18, 2024, the FDA approved Lenmeldy (atidarsagene autotemcel), an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of children with pre-symptomatic late infantile (PSLI), pre-symptomatic early juvenile (PSEJ) or early symptomatic early juvenile (ESEJ) metachromatic leukodystrophy (MLD).

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-children-metachromatic-leukodystrophy>

Luxturna®

On December 18, 2017, the FDA approved Luxturna (voretigene neparvovec-rzyl), a gene therapy drug used to treat children and adult patients with an inherited form of vision loss that may result in blindness.

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/luxturna>

Lyfgenia™

On December 8, 2023, the FDA approved Lyfgenia (lovotibeglogene autotemcel), an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of patients 12 years of age or older with sickle cell disease and a history of vaso-occlusive events.

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapies-treat-patients-sickle-cell-disease>

Otarmeni™

On April 23, 2026, the FDA approved Otarmeni, as the first-ever dual adeno-associated virus (AAV) vector-based gene therapy. Otarmeni is indicated for the treatment of pediatric and adult patients with severe-to-profound and profound sensorineural hearing loss (any frequency >90 dB HL) associated with molecularly confirmed biallelic variants in the *OTOF* gene.

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-ever-gene-therapy-treatment-genetic-hearing-loss-under-national-priority-voucher>

Qalsody®

On April 25, 2023, the FDA approved Qalsody (tofersen), an innovative drug used for the treatment of amyotrophic lateral sclerosis associated with a mutation in the SOD1 gene.

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-treatment-amyotrophic-lateral-sclerosis-associated-mutation-sod1-gene>



Skysona™

On September 16, 2022, the FDA approved Skysona (elivaldogene autotemcel), a gene therapy drug used to slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy (CALD).

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/vaccines-blood-biologics/skysona>

Spinraza®

On December 23, 2016, the FDA approved Spinraza (nusinersen), an innovative drug used for the treatment of spinal muscular atrophy (SMA) in children and adults. SMA is a rare genetic disease and is often fatal.

U.S. Food and Drug Administration announcement:

<https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.proceedings&ApplNo=209531>

Tecelra®

On August 2, 2024, the FDA approved Tecelra (afamitresgene autoleucel) for the treatment of adults with unresectable or metastatic synovial sarcoma who have received prior chemotherapy, are HLA antigen(s) A*02:01P, -A*02:02P, -A*02:03P, or -A*02:06P positive and whose tumor expresses the MAGE-A4 antigen as determined by FDA-approved or cleared companion diagnostic devices.

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-treat-adults-metastatic-synovial-sarcoma>

Waskyra™

On December 9, 2025, the FDA approved Waskyra, as the first gene therapy for the treatment of pediatric patients aged 6 months and older and adults with Wiskott-Aldrich Syndrome (WAS), a rare genetic disease associated with bleeding problems, eczema and increased susceptibility to infections and auto immune disorders.

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapy-treatment-wiskott-aldrich-syndrome>

Zanvastro™

On September 3, 2026, the FDA has approved Zanvastro, the first FDA-approved treatment for Alexander disease and the first therapy to directly target the protein buildup that drives the disease.

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/news-events/press-announcements/fda-approves-first-drug-treat-alexander-disease>



Zevaskyn™

On April 29, 2025, the FDA has approved Zevaskyn, the first autologous cell-based gene therapy for treating wounds in adults and children with recessive dystrophic (RDEB), a rare, debilitating genetic skin disease.

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/vaccines-blood-biologics/zevaskyn>

Zolgensma®

On May 24, 2019, the FDA approved AVXS-101/Zolgensma (onasemnogene abeparvovec-xioi), a gene therapy drug used for the treatment of spinal muscular atrophy (SMA) in infants under two years of age. SMA is a leading genetic cause of infant mortality.

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/news-events/press-announcements/fda-approves-innovative-gene-therapy-treat-pediatric-patients-spinal-muscular-atrophy-rare-disease>

Zynteglo™

On August 17, 2022, the FDA approved Zynteglo (betibeglogene autotemcel), stem cell-based gene therapy drug used to treat adult and pediatric patients with Bthalassemia who require regular red blood cell (RBC) transfusions.

U.S. Food and Drug Administration announcement:

<https://www.fda.gov/vaccines-blood-biologics/zynteglo>