AMWINS
GROUP BENEFITS

Gene Therapy Solutions (GTS): Frequently Asked Questions

What is the difference between gene and cell therapy?

Gene therapy is used to treat diseases by introducing healthy genes into patients via a vector, or engineered virus. The virus then enters your cells and manipulates your DNA, creating copies of the virus. There are three ways to administer gene therapy:

- Ex Vivo – Genetic material is modified outside of the body
- In Vivo – Genetic material is directly inserted into the body
- CRISPR – Gene editing

Cell therapy is a method used to treat disease by transferring modified cells into the patient. There are two types of cell therapy:

- Autologus – the use of patient cells
- Allogenic – the use of donor cells

What therapies are covered and what is the cost?

Effective January 1, 2026, we offer coverage for 18 gene and cell therapies under Amwins GTS-18.

Treated Disease(s)	Covered Pharmaceutical(s)	Maximum Reimbursement	Cost of Program
Leber Congenital Amaurosis (LCA)	Luxturna	$913,750	Please reach out to your sales representative.
Spinal Muscular Atrophy (SMA) Types 1 & 2 (Children ages 2 and under)	Zolgensma	$2,511,291	
	Spinraza*		
Transfusion DependentBeta Thalassemia	Zynteglo	$2,800,000	
	Casgevy	$2,200,000	
Cerebral Adrenoleukodystrophy (CALD)	Skysona	$3,000,000	
Hemophilia A	Roctavian	$3,031,840	
Hemophilia B	Hemgenix	$3,500,000	
Duchenne Muscular Dystrophy (DMD)	Elevidys	$3,200,000	
Sickle Cell Disease	Casgevy	$2,200,000	
	Lyfgenia	$3,100,000	
Metachromatic Leukodystrophy (MLD)	Lenmeldy	$4,250,000	

Treated Disease(s)	Covered Pharmaceutical(s)	Maximum Reimbursement	Cost of Program
Multiple Myeloma	Abecma**	$528,312	Please reach out to your sales representative.
	Carvykti**	$555,310	
Congenital Athymia	Rethymic**	$2,811,385	
Metastatic Synovial Sarcoma	Tecelra**	$727,000	
Idiopathic Macular Telangiectasia Type 2 (MacTel)	Encelto	$400,000	
L Amino Acid Decarboxylase (AADC) Deficiency	Kebilidi	$3,950,000	
Recessive Dystrophic Epidermolysis Bullosa	Zevaskyn	$3,100,000	

**Maintenance drug; Cost in year 1 is ~ $750K and $~375K in subsequent years.*
***Cell Therapies.*

How often can each therapy be administered and what is the maximum reimbursement value for each therapy?

Covered Pharmaceuticals	Administration Schedule
Luxturna	In Vivo; One injection in each eye administered six days apart
Zolgensma	In Vivo; One-time injection
Spinraza*	Annual maintenance drug administered as a series of four injections in year one and a series of three injections each subsequent year
Zynteglo	Ex Vivo; One-time treatment
Skysona	Ex Vivo; One-time treatment
Hemgenix	In Vivo; One-time
Roctavian	Ex Vivo; One-time
Lyfgenia	Ex Vivo; One-time
Casgevy	CRISPR – Gene editing; one-time
Elevidys	In Vivo; One-time
Lenmeldy	Ex Vivo; One-time
Carvykti	Autologous; One-time
Abecma	Autologous; One-time
Rethymic	Allogeneic; one-time
Kebilidi	In-vivo; One-time
Encelto	In-vivo; One-time surgical implantation
Zevaskyn	Ex-vivo; one-time surgical application
Tecelra	Ex-vivo; One-time

**Amwins Gene Therapy Solutions addresses Spinal Muscular Atrophy as a disease state. While Spinraza is not classified as a gene therapy treatment, it is a Chronic Specialty Therapy for patients with SMA. Spinraza is costly, with the initial treatment expense of ~$750,000 and an additional ~$375,000 expected annually. We include Spinraza in our program to help reduce this financial burden.*

What new features have been added to the program effective January 1, 2026?

GTS-18 participants can elect to integrate Emerging Therapy Solutions (ETS) Center of Excellence into their benefit structure at no additional program cost.

What is ETS and what value does this solution add to Amwins GTS-18?

ETS offers a Center of Excellence, which is a national cell and gene therapy network. This provides clients with access to pre-negotiated rates for all FDA-approved gene and cell therapies which applies to both the administration and the therapy cost.

What is required to implement the ETS component of the solution?

Participating clients will need to implement Summary Plan Document (SPD) language changes to support the implementation of the program. This type of change requires Third Party Administrator (TPA) approval. Our partners at ETS are integrated with a significant number of TPAs in the market. If they aren't integrated yet, they are happy to support conversations with the TPA to establish a partnership for the client.

What components of the claim are reimbursable?

Amwins GTS-18 provides reimbursement for the cost of the therapy only. The implementation of ETS provides pre-negotiated rates for the cost of administration, in addition to the cost of the therapy.

How does the reimbursement process work?

Claims are adjudicated through the group medical benefit plan. Once the claim is funded through the group medical benefit plan, Amwins GTS-18 will reimburse qualified claims up to the maximum payable amount. The group will receive the first dollar up to the group's specific deductible and the balance of the reimbursement will be sent to the group's stop loss carrier.

How is the reimbursement amount calculated for Amwins GTS-18?

Amwins GTS-18 will reimburse up to the Wholesale Acquisition Cost (WAC). This amount is the maximum payable per covered person per benefit period. If a client implements the ETS Centers of Excellence, the maximum reimbursement for the therapy is based on the negotiated rate ETS was able to achieve through their network discounts.

Claims adjudication

Claim funded by medical plan

GTS reimbursement for qualified claims

How does ETS partner with the TPA to ensure that claims are paid at ETS pre-negotiated contracted rates?

Implementation of SPD language is critical. The TPA will pay claims based on the SPD language, which involves leveraging ETS rates. ETS partners directly with the TPA to ensure a smooth client experience when an opportunity is identified.

What are the eligibility requirements?

The claim must be approved and paid by the group's medical health plan.

<table>
<tr><th>Covered Pharmaceutical</th><th>Disease State</th><th>Run-in Period</th><th>Coverage Criteria</th><th>Treatment Period</th><th>Claims Period</th></tr>
<tr><td>Luxturna</td><td>Leber Congenital Amaurosis (LCA)</td><td rowspan="15">N/A</td><td rowspan="3">Covered Person must meet the FDA label guidelines as an eligible recipient of the Covered Pharmaceutical.</td><td rowspan="16">Covered Pharmaceutical must be initially administered to Covered Person meeting Coverage Criteria between the first day of the Agreement Period and the 12 months immediately following the last day of the Agreement Period.</td><td rowspan="16">Claims for Covered Pharmaceuticals must be filed, approved, and paid by the Named Insured and the Covered Stop Loss Plan within 24 months immediately following the last day of the Agreement Period and are valid for Covered Pharmaceuticals administered during the Treatment Period.</td></tr>
<tr><td>Zynteglo</td><td rowspan="2">Beta Thalassemia</td></tr>
<tr><td>Casgevy</td></tr>
<tr><td>Skysona</td><td>Cerebral Adrenoleukodystrophy (CALD)</td></tr>
<tr><td>Abecma</td><td rowspan="2">Multiple Myeloma</td><td rowspan="5">Covered Person must meet the FDA label guidelines in effect August 1, 2025 as an eligible recipient of the Covered Pharmaceutical.</td></tr>
<tr><td>Carvykti</td></tr>
<tr><td>Casgevy</td><td rowspan="2">Sickle Cell</td></tr>
<tr><td>Lyfgenia</td></tr>
<tr><td>Roctavian</td><td>Hemophilia A</td></tr>
<tr><td>Hemgenix</td><td>Hemophilia B</td></tr>
<tr><td>Tecelra</td><td>Metastatic Synovial Sarcoma</td></tr>
<tr><td>Zevaskyn</td><td>Recessive Dystrophic Epidermolysis Bullosa</td><td>Covered Person must be diagnosed with a Covered Disease during the Agreement Period; or Covered Person with an existing diagnosis must join the Covered Stop Loss Plan during the Agreement Period and must not have been a Covered Person at any time during the 12 months preceding the inception of the Agreement Period.</td></tr>
<tr><td>Elevidys</td><td>Duchenne Muscular Dystrophy (DMD)</td><td>Covered Person must be between the ages of four and eight years and diagnosed with a Covered Disease during the Agreement Period; and meet all other FDA label guidelines as an eligible recipient of the Covered Pharmaceutical.</td></tr>
<tr><td>Lenmeldy</td><td>Metachromatic Leukodystrophy (MLD)</td><td rowspan="4">Covered Person must be diagnosed with a Covered Disease during the Agreement Period.</td></tr>
<tr><td>Rethymic</td><td>Congenital Athymia</td></tr>
<tr><td>Kebilidi</td><td>L Amino Acid Decarboxylase (AADC)</td></tr>
<tr><td>Encelto</td><td>Macular Telangiectasia Type 2 (MacTel)</td></tr>
<tr><td>Zolgensma</td><td rowspan="2">Spinal Muscular Atrophy (SMA) Types 1 & 2 (Children up to age 2)</td><td rowspan="2">Covered Person must be born within:
– the Agreement Period
– 90 days immediately preceding the first day of the Agreement Period or the enrollment start date of Covered Person into the Names Insured's self-funded health care benefits plan within the Agreement Period (the "Run-in Period"), provided in both cases the Covered Person did not receive a diagnosis for the Covered Disease during such 90-day period.</td><td>Covered Person must be diagnosed with a Covered Disease between the first day of the Agreement Period and 12 months immediately following the last day of the Agreement Period.</td></tr>
<tr><td>Spinraza</td><td>Covered Person must be diagnosed with a Covered Disease between the first day of the Agreement Period and 24 months immediately following the last day of the Agreement Period.</td><td>Covered Pharmaceutical must be initially administered to Covered Person meeting Coverage Criteria between the first day of the Agreement Period and the 24 months immediately following the last day of the Agreement Period.</td></tr>
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Will I need to update my plan's SPD?

Amwins GTS-18 does not interfere with the medical benefit plan and no additional language is required. To be eligible for a reimbursement, the medical plan must provide coverage for gene therapy treatments and process the claim. Once the claim is adjudicated, Amwins GTS-18 will process a reimbursement for qualifying claims.

SPD changes are required for implementation of the ETS Centers of Excellence. Please contact your Amwins representative for sample language.

What happens if our Group Health Plan does not include gene and cell therapy coverage after the Amwins Gene Therapy Solutions policy begins?

Participation in the GTS-18 program is contingent upon the inclusion of gene and cell therapy coverage within the Group Health Plan. In the event it is determined that such coverage is not provided following the commencement of the GTS-18 policy, any premiums paid shall be deemed non-refundable, and no reimbursement shall be issued under any circumstances.

What specific gene therapies are covered under Amwins Gene Therapy Solutions?

Amwins Gene Therapy Solutions currently covers 11 of the 13 approved gene therapies. Reasons for not including coverage for the remaining two therapies include criteria and multi-use treatment considerations.

Will the cost and/or covered therapies change during my agreement year?

The drug list and PEPM charge will remain the same for the duration of your agreement year. The agreement year corresponds with your stop loss policy's effective date.

What gene therapy treatments are FDA approved?

All FDA approved gene and cell therapy treatments can be found here: **Approved Cellular and Gene Therapy Products**

Are there plans to include additional FDA approved therapies?

We continuously monitor FDA approvals and evaluate the possibility of adding new FDA-approved therapies to GTS. When advantageous, we will make additions every twelve months.

Contact your Amwins Sales Representative today to explore all program offerings!
For our renewing clients, we've enhanced your coverage to GTS-18 in your latest renewal proposal.