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?

We offer two options to meet budgetary considerations for all of our clients. We offer **GTS-5** which provides reimbursement for five therapies and **GTS-15** which provides reimbursement for fifteen therapies.

Program Options	Covered Pharmaceuticals	Treated Diseases	Maximum Payable Per Covered Person Per Benefit Period	Cost of Program
GTS-5	Luxturna	Leber Congenital Amaurosis (LCA)	$913,750	Contact an Amwins representative for additional information.
	Zolgensma	Spinal Muscular Atrophy (SMA) Types 1 & 2 (Children ages 2 and under)	$2,322,044	
	Spinraza*			
	Zynteglo	Beta Thalassemia	$2,800,000	
	Skysona	Cerebral Adrenoleukodystrophy (CALD)	$3,000,000	
GTS-15	Roctavian	Hemophilia A	$2,900,000	Contact an Amwins representative for additional information.
	Hemgenix	Hemophilia B	$3,500,000	
	Beqvez			
	Elevidys	Duchenne Muscular Dystrophy (DMD)	$3,200,000	
	Casgevy	Sickle Cell	$2,200,000	
		Transfusion Dependent Beta Thalassemia		
	Lyfgenia	Sickle Cell	$3,100,000	
	Lenmeldy	Metachromatic Leukodystrphy (MLD)	$4,250,000	
	Abecma**	Multiple Myeloma	$498,408	
	Carvykti**		$522,055	
	Rethymic**	Congenital Athymia	$2,729,500	

**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
Beqvez	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

**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 components of the claim are reimbursable?

The program provides reimbursement for the cost of the therapy only.

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, GTS 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.

Claims adjudication

Claim funded by medical plan

GTS reimbursement for qualified claims

What are the eligibility requirements?

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

<table>
<tr><th>Covered Pharma-ceutical</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="13">Not applicable.</td><td rowspan="3">Covered Person must meet the FDA label guidelines as an eligible recipient of the Covered Pharmaceutical.</td><td rowspan="15">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 May 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>
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<tr><td>Hemgenix</td><td rowspan="2">Hemophilia B</td></tr>
<tr><td>Beqvez</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>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>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 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></tr>
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Will I need to update my plan's SPD?

GTS 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, GTS will process a reimbursement for qualifying claims.

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.