

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 two 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

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

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

What therapies are covered?

Amwins offers two programs:

GTS-3: This program covers two gene therapies as well as a maintenance medication for a total of three therapies.

Covered Pharmaceuticals	Treated Diseases
Luxturna	Leber Congenital Amaurosis (LCA)
Zolgensma	Spinal Muscular Atrophy (SMA) Type I and Type II
Spinraza*	

GTS-5: This program covers all three therapies included in GTS-3 plus two additional gene therapies for a total of five therapies.

Covered Pharmaceuticals	Treated Diseases
Luxturna	Leber Congenital Amaurosis (LCA)
Zolgensma	Spinal Muscular Atrophy (SMA) Type I and Type II
Spinraza*	
Zynteglo	Transfusion Dependent Beta Thalassemia (TDT)
Skysona	Cerebral Adrenoleukodystrophy (CALD)

*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.



How often can each therapy be administered?

Covered Pharmaceuticals	Luxturna	Zolgensma	Spinraza*	Zynteglo	Skysona
Administration Schedule	In Vivo; One injection in each eye administered six days apart	In Vivo; One-time injection	Annual maintenance drug administered as a series of four injections in year one and a series of three injections each subsequent year	Ex Vivo; One-time treatment	Ex Vivo; One-time treatment

What is the maximum reimbursement value for each therapy?

Covered Pharmaceuticals	Maximum Payable Per Covered Person Per Benefit Period
Luxturna	\$850,000
Zolgensma	\$2,200,000
Spinraza*	\$2,800,000
Zynteglo	\$2,800,000
Skysona	\$3,000,000

What components of the claim are reimbursable?

The program provides reimbursement for the cost of the therapy only. This program does not include the cost of administering 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, 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.



What are the eligibility requirements?

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

Eligibility is determined based on the covered person's diagnosis date. The diagnosis date must occur during the Agreement Year.

Additionally, Zolgensma and Spinraza claimants must have a date of birth 90 days or less prior to the effective date of the Agreement Year or a date of birth during the Agreement Year AND the diagnosis date must occur during the Agreement Year. Additional eligibility requirements can be found [here](#).

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.

What is the cost of each program?

GTS-3

Covered Pharmaceuticals	Cost of Program
Luxturna	– Please contact your broker for pricing information.
Zolgensma	
Spinraza*	

GTS-5

Covered Pharmaceuticals	Cost of Program
Luxturna	– Please contact your broker for pricing information.
Zolgensma	
Spinraza*	
Zynteglo	
Skysona	

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 are continuously monitoring FDA approvals and evaluating the possibility of adding new FDA-approved therapies to GTS. When advantageous, we will make additions every six to twelve months.

