

EXECUTIVE SUMMARY

Financial protection for high-cost gene therapies: Gene Therapy Stop-Loss

Gene therapies have the potential to relieve or even cure genetic disorders. Many of these were previously untreatable, significantly affecting patients' quality of life. Now payors are looking for innovative ways to manage costs associated with these novel therapies, which can cost millions.

Lenmeldy	Hemgenix	Lyfgenia
Approved to treat metachromatic leukodystrophy	Approved to treat hemophilia B	Approved to treat sickle cell disease
Reported to cost as much as \$4.2M per patient ¹	Reported to cost as much as \$3.5M per patient ²	Reported to cost as much as \$3.1M per patient ³

How it works

When a gene therapy claim is incurred, the client is reimbursed for the cost above the individual stop-loss attachment point up to 100% of the wholesale acquisition cost (WAC).*

Key features

- Coverage is provided without laserling members, a practice in which certain individuals are covered at a higher specific deductible than the rest of the group, including those who have a high potential for receiving gene therapy.**
- Works with existing medical coverage.



Gene Therapy Stop-Loss coverage helps provide peace of mind for employers looking for financial risk protection from high-cost gene therapy claims.

Options

Individual stop-loss levels

- \$30,000
- \$250,000
- \$400,000

Your choice to cover

- U.S. Food and Drug Administration (FDA)-approved and pipeline gene therapies (\$2.50 PMPM or less[†]), or
- FDA-approved gene therapies only (\$2.20 PMPM or less[†])

Scope of gene therapies

FDA-approved

- Single-administration therapies including Luxturna (voretigene neparvovec-rzyl), Zolgensma (onasemnogen abeparvovec-xioi), Zynteglo (betibeglogene autotemcel), Skysona (elivaldogene autotemcel), Hemgenix (etranacogene dezaparvovec-drlb), Elevidys (delandistrogene moxeparvovec-rokl), Roctavian valoctocogene roxaparvovec-rvox), Casgevy (exagamglogene autotemcel), Lyfgenia (lovotibeglogene autotemcel), Lenmeldy (atidarsagene autotemcel), Kebilidi (eladocagene exuparvovec-tneq)⁴

Pipeline

- Single-administration gene therapies that are anticipated to be approved by the FDA⁵

CVS Health — and Aetna as a health insurer — help employers manage health care costs while ensuring appropriate utilization of cutting-edge therapies. Gene Therapy Stop-Loss coverage is an innovative solution that helps reduce the impact of unexpected, high-cost gene therapies.



Contact your CVS Health account team today to get started, or **visit our website** to learn more about our cost management solutions.

* This policy's ISL coverage is for the gene therapy products themselves (the current FDA-approved as well as pipeline gene therapies listed in each quote). They must be approved by the U.S. Food and Drug Administration for the specific gene therapy usage (e.g. based on diagnosis, age and/or condition of patient, gene expression) and considered eligible claim expenses under the Stop-Loss policy. There is no coverage for any other medical costs associated with the gene therapy treatment, the underlying medical condition, or any other claims paid by the plan.

** For new business: A gene therapy drug is excluded from this feature if a member is known to have received or be actively progressing through gene therapy treatment at the time a final, firm Stop-Loss proposal is delivered. Actively progressing through gene therapy treatment starts with initiating the prior authorization process through receiving an FDA-approved gene therapy drug.

† Per member per month. For the majority of quotes at \$30,000 ISL. Pricing is client-specific.

1. <https://www.pharmaceutical-technology.com/analyst-comment/lenmeldy-becomes-worlds-most-expensive-drug>.

2. <https://www.medscape.com/viewarticle/fda-approves-second-gene-therapy-hemophilia-b-2024a100086v>.

3. <https://www.fiercepharma.com/pharma/gene-therapy-war-bluebird-trails-vertex-patient-starts-leads-treatment-centers>.

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

5. <https://business.caremark.com/insights/2024/minimizing-financial-impact-breakthrough-therapies.html>.

As of June 1, 2024, includes 20+ pipeline gene therapies anticipated to be approved by the FDA in the near term. A complete list is provided at the time of quote.

Stop-Loss coverage is provided by Aetna Life Insurance Company and its affiliates (Aetna). Aetna is a member of the CVS Health family of companies.

This document contains references to brand-name prescription drugs that are trademarks or registered trademarks of pharmaceutical manufacturers not affiliated with CVS Health.