Trends

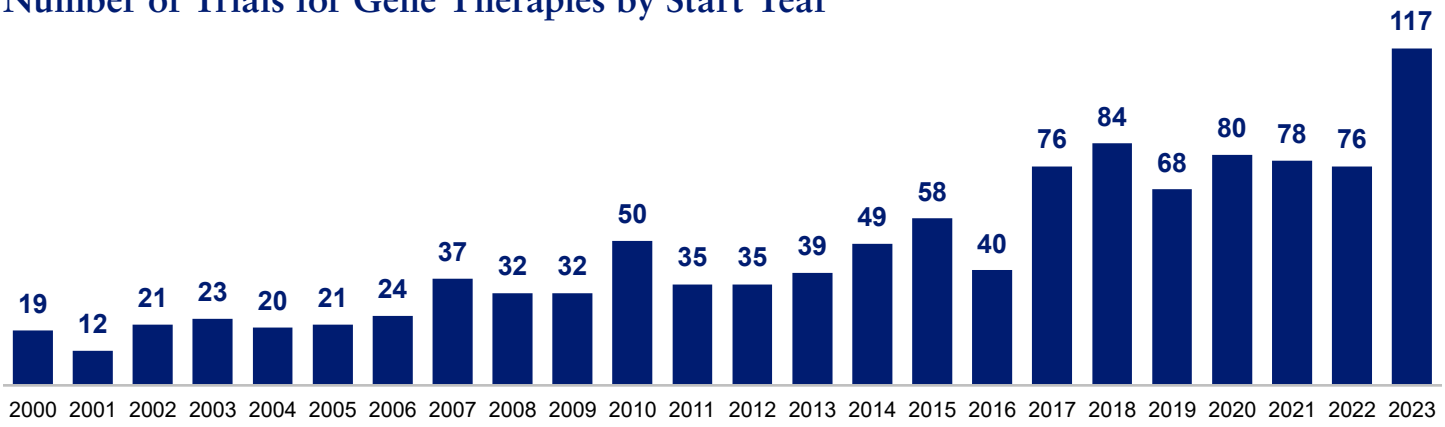
Statistics and Strategies for Health Plan Sponsors

Second Quarter 2024

Key statistics

Gene therapy is a novel approach to treat, cure or ultimately prevent disease by changing the expression of a person's genes. In recent years, there's been dramatic growth in the number of gene therapy trials.

Number of Trials for Gene Therapies by Start Year



Source: Segal using information about gene therapy trials on ClinicalTrials.gov

The growing gene therapy pipeline

The gene therapy pipeline is dynamic and continues to expand with a focus on addressing a wide range of diseases and conditions. 2023 was a breakthrough year, with seven gene therapies approved by the Food and Drug Administration (FDA). As of March 18, 2024, there are now 36 gene therapies approved by the FDA, with an additional 500 in the pipeline and the expectation that 10–20 will be approved annually by 2025.

Cancer is the area that holds most promise, with the potential for FDA approval of the first Chimeric Antigen Receptor T-Cell therapy (CART-T) for chronic lymphocytic leukemia. This approval would impact a large patient population. Furthermore, research is underway for gene therapy for osteoarthritis, a form of arthritis that affects over 32.5 million U.S. adults.

The growth of gene therapy has put pressure on plan sponsors to review strategies for their covered population, including financial implications and decisions about coverage criteria.

What is gene therapy and how much does it cost?

In general, gene therapy involves replacing a gene that causes a medical problem with one that does not, adding genes to help the body fight or treat disease, or turning off genes that cause medical problems. The administration of gene therapies is complex, often involving extended hospital stays, supplementary services and medications.

The total cost of gene therapy comes with a high price. While the number of people needing these therapies is currently small, the costs are extremely high. For example, a one-time injection of Hemgenix® for treatment of adults with hemophilia B costs $3.5 million. In December 2023, two new therapies to treat sickle cell disease were approved, Casgevy™ and Lyfgenia™, with treatment costing $2.2–3.1 million. These price points make gene therapies unaffordable for many plan sponsors.

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Financing protection solutions

To support sustainable reimbursement and patient access to high-cost treatments, plan sponsors are exploring innovative financing solutions, including:

- **Stop-loss insurance.** If the plan sponsor has stop-loss insurance, it is essential to contact the insurer about these therapies to make sure that coverage is in place to reimburse the plan sponsor's expenses. If the plan does not have stop-loss coverage, emerging gene therapies might provide another reason to assess the value of obtaining the coverage. A growing number of insurers are offering specific carve-out stop-loss coverage specifically for gene therapies.
- **Installments.** These arrangements allow plan sponsors to pay for gene therapies over several years, mitigating the immediate up-front costs and smoothing the financial impact to the plan.
- **Performance-based contracting.** Under these arrangements, payment methods are determined on an individual or population-level outcome basis. Manufacturers are paid if the outcomes are achieved, with price adjustments done either prospectively or retrospectively.
- **Subscription model.** These arrangements allow plan sponsors to pay manufacturers a set price, which helps with budgeting and provides protection from the risk of utilization that's higher than expected.

Coverage considerations

Best practices for managing this complex therapy include the following:

- **Coverage language.** Initially, plan sponsors should determine whether they will cover any or all of these novel therapies. Absent clear language specifically excluding coverage for them, it is likely that they would be covered by the general terms of most plans. One approach is to cover only therapies that have been FDA-approved, are not considered experimental and are considered medically necessary for a rare subset of patients. As new gene therapies are approved, expanded indications may occur, impacting a larger portion of a plan's population. That's why it's important for plan sponsors that cover gene therapy to have a process in place to monitor newly approved treatments and the associated risks.
- **Fertility preservation.** When designing benefits that include gene therapy coverage, evaluate coverage for related services, like fertility preservation. Individuals undergoing gene therapy may experience infertility due to medical treatments like surgery, chemotherapy or radiation. Some group insured health plans are required by state laws to cover certain fertility services.
- **Precertification/prior authorization.** This step, likely performed by the plan's utilization management (UM) provider, ensures that use of gene therapies meets at least the strict FDA-approved indications. Plan sponsors should check that their UM providers are up to date with their screening criteria and are ready to pre-certify gene therapies.
- **Network management.** There may be limited providers authorized to provide these new therapies due to the highly technical nature of the treatment, especially for rare diseases. Discuss with the network administrator the location of approved treatment facilities. The provider may be willing to add and contract with approved treatment facilities. If no in-network option is available, out-of-network reimbursement policies should be reviewed.
- **Patient and caregiver support.** The limited number of facilities (depending on gene therapy) providing a treatment may mean the center is far from a patient's home. To support these patients, many plan sponsors offer travel concierge support, including travel expense reimbursement. Some are also offering personalized patient outreach and education.

Compliance reminder

Implications of draft guidance on Part D plans for RDS and creditable coverage

Plan sponsors that offer retiree health benefits need to take a close look at that coverage in 2024 to ensure that it reflects new draft guidance from the Centers for Medicare & Medicaid Services that may affect creditability determinations in 2025. Plan sponsors also may want to consider whether a Medicare Advantage program might be the right solution for their retirees. Read more in our February 20, 2024 insight.

To discuss the implications for your plan of anything covered here, contact your Segal consultant or get in touch via our website, segalco.com.

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