Benefits Insights

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Managing Costs Associated With Cell and Gene Therapy

Employers continue to struggle with controlling rising health care costs and providing employees with affordable and quality care options. Of particular concern is the high costs associated with specialty drugs. The specialty drug industry has grown from a few available drugs in the 1990s to more than 300 specialty drugs today. For most employer-sponsored health plans, the cost of specialty drugs is their fastest-growing expense. As these treatments become more widely available, employers will likely be forced to address even higher specialty drug costs.

The recent rise of cell and gene therapy (CGT) may create even more concern for employers. These treatments typically range from $250,000 to $3.5 million per individual. While CGT is currently limited to a handful of orphan drugs and extremely rare conditions, this is expected to change in the next few years. Investment in regenerative medicine has grown 16% in 3 years, hitting a record high of $23.1 billion in 2021. As investment in this market continues to grow, the Business Research Company expects it to reach $34.31 billion in 2030. Therefore, without effective solutions in place, employers may be forced to contend with extreme and, in some cases, unsustainable medical costs.

This article explores strategies for managing the high costs associated with CGT.

What Is CGT?

CGT is a treatment that modifies a patient's genetic code to treat or cure specific diseases. This is accomplished by modifying a patient's genetic code, replacing a disease-causing gene or introducing a new or modified gene to treat the disease. Patients generally receive CGT through injection or infusion in a specialty setting. These treatments have the potential to enhance patient care and outcomes, but they come at a very high cost.

Currently, there's an urgency to bring CGT to an even wider market because these treatments offer hope to individuals suffering from rare and debilitating diseases. However, these treatments also create massive affordability challenges for employers. Therefore, the high costs associated with these therapies require employers to examine their coverage decisions.

Why Is CGT So Expensive?

One of the main reasons CGT is extremely costly is that developing and manufacturing the treatment takes a significant amount of time and resources. Developing CGTs can cost more than $5 billion, more than five times the average cost of developing traditional drugs. Additionally, these treatments are manufactured using manual processes and are typically produced in small quantities. This limits the production capability of these therapies. As a result, the current demand for CGT is outpacing manufacturing capacity. As of 2022, approximately 75,000 patients will be eligible for CGT, which could cost more than $15 billion. That number is expected to grow to 100,000 patients over the next three years and cost more than $25 billion. The increased demand in CGT is forcing therapy developers to outsource treatment production and manufacturing, which is often very complex, resulting in increased production time and costs.

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Another reason CGT is so expensive is these treatments serve only a small patient population. As a result, they are not mass-produced like traditional biologics. Additionally, since this is a relatively new industry, there is a shortage of skilled workers to produce and manufacture the treatments, driving up manufacturers' labor costs. To address these issues, the CGT industry is trying to automate more of the production and manufacturing processes to improve overall efficiency, which could lead to faster, safer and more cost-effective CGT production. Regulatory considerations, longer inpatient stays and the use of specialty pharmacies are additional reasons CGT costs more than traditional treatments.

What Can Employers Do to Manage CGT Costs?

With many employers already struggling to control the rising costs of specialty drugs, they mustn't put off planning and implementing strategies to manage CGT costs until it's too late. While the number of available CGTs is currently modest, the U.S. Food and Drug Administration estimates it could be approving between 10 and 20 annually by 2025. So, even if employers are not dealing with the costs of CGT now, they likely will in the near future.

The best strategies for managing CGT costs will likely vary depending on the organization's needs, size and demographics; however, embracing a combination of strategies will likely be the most effective approach. The following are some strategies employers can consider for managing CGT costs:

- **Managed access**—Some employers have started to use independent third parties when prior authorization is required for expensive specialty drugs and treatment. This helps employers to mitigate against pharmacy benefit managers' use of rebates and prior authorization, which can result in increased approval for CGT, creating more savings for employers.
- **Exclusions**—Some employers have limited or outright excluded plan coverage of certain specialty drugs, including CGT. However, limiting or excluding CGT from health plan coverage may result in compliance risks.
- **Nontraditional payment models**—CGT operates very differently from traditional treatments. These treatments are generally administered once or twice over a patient's lifetime. With traditional treatments, a drug is administered and paid for over time as the prescription is filled, and patients receive the health benefits incrementally. With CGT, payment occurs upfront, and the patient experiences health benefits over time. As a result, employers can explore nontraditional payment models offered by insurance and pharmaceutical companies to help offset treatment costs. For example, some insurance companies have implemented programs to mitigate CGT's upfront costs. Cigna allows employers to contribute less than $1 per member per month (the patient would not have to pay out of pocket for the treatment), and CVS Health offers financial protection solutions, such as stop-loss coverage and installment payments.

Summary

CGT shows immense potential for improving patient outcomes. As the number of available CGTs continues to grow, employers will need to consider creative solutions to manage the costs of these therapies. Understanding CGT and its potential impact on health care costs allows employers to better prepare and implement effective cost-mitigating strategies.

Reach out to Apex Benefits for more information on managing health care costs.