

# Navigating the financial landscape of cell and gene therapies

Understanding cost drivers &  
innovative payment solutions

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In today's rapidly evolving healthcare landscape, staying up-to-date on emerging treatments such as Cell and Gene Therapies (CGTs) is crucial for making well-informed decisions about employee health benefits.

## A significant shift in treatment

CGTs are unique when compared to traditional therapies—they are potentially curative, may only require a one-time administration, and typically come with a high upfront cost.<sup>1</sup>

This guide delves into the complexities of CGT costs, which can range from \$250,000 to \$3.5 million per individual,<sup>2</sup> and outlines various payment models to help manage these financial risks effectively.

# Factors contributing to high costs

## Research and development (R&D) challenges:

- CGTs require a complex, multi-stage R&D process that is more intricate and time-intensive than traditional therapies. This includes developing, testing, and launching precision medicines tailored to small and rare patient populations.<sup>2</sup>
- Recruiting appropriate patients for clinical trials is challenging due to the specificity of gene therapy, with many trials enrolling fewer than 20 patients.<sup>3</sup>
- Specialized infrastructure and a skilled workforce are essential to execute these trials, which must align with stringent FDA standards.<sup>4</sup>

## Manufacturing complexity and costs:

- CGT manufacturing involves biological materials that require careful handling due to their short shelf lives and temperature sensitivities.<sup>5</sup>
- High costs are incurred for raw materials, labor, and compliance with regulatory standards. For example, manufacturing costs per patient in clinical trials can reach up to \$300,000.<sup>4</sup>
- Innovations such as automation and advances in cell culturing techniques are promising developments that aim to reduce these costs by enhancing production efficiency and scalability.<sup>6</sup>

## Exploring payment models

1. **Stop-loss insurance:** Aims to protect employers from losing income due to high-cost medical claims by covering employee medical expenses once the employer's costs exceed a predetermined threshold.<sup>7</sup>
2. **Centers of excellence (COE):** COEs are recognized as leading institutions for the care and treatment of specific medical conditions. They supply a high concentration of expertise and resources to optimize treatment outcomes and cost of care.<sup>8</sup>
3. **Health plan risk pool:** Spreads the cost of high-risk treatments across a broader group, mitigating the financial impact on any single entity.<sup>9</sup>
4. **Annuity payment:** Allows for the cost of therapy to be spread over several years, easing the immediate financial burden.<sup>10</sup>
5. **Warranty programs:** Structured financial agreements where payment is contingent on the therapy's long-term efficacy and outcomes, ensuring that costs are aligned with promised benefits over time.<sup>11</sup>
6. **Outcome-based agreements:** Payment is tied to the achievement of specific health outcomes or milestones; payments are made based on the therapy's performance in delivering predefined clinical results.<sup>12</sup>

## Evaluating and choosing the right model

As more CGT treatments target more prevalent diseases, the eligible patient population—and consequently, the potential for sudden, unexpected, and sizable claims—will increase.<sup>1</sup> While the payment models outlined provide a starting point, a thorough analysis is essential to determine which model best aligns with your organization's risk tolerance and financial objectives. Each model has its nuances, and evaluating your organization's unique circumstances is crucial to making an informed decision.

## Understanding your impact as employers

**For self-insured employers, integrating CGT into health plans is a significant step towards advancing employee health care.** The information provided here includes insights into the financial challenges and solutions associated with CGTs, which may help you in making benefits decisions that align with your commitment to employee well-being and financial sustainability.

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