



For self-funded employers

Key Considerations for Cell and Gene Therapy Coverage

A Health Benefits Design Checklist

This comprehensive checklist of considerations is designed to provide organizations with information on health benefits design, especially as it pertains to the coverage and management of CGTs. This may be used in conjunction with discussions with a plan carrier, PBM, consultants, or brokers.



Terms to know

Addendum: An addendum is an addition to a base health plan policy that either adds or removes coverage for a particular circumstance, such as a medication. It can be incorporated at any time if either the insurer or the policyholder feels the need to adjust coverage.¹

Case-rate agreements: Also known as single-case agreements, these are one-time contracts between an insurance company and an out-of-network provider. They allow patients to use their in-network benefits, meaning they pay their usual in-network co-pays only after meeting any in-network deductible. The session fee covered by the insurance company is negotiated between the insurer and the provider as part of the agreement.²

Center of Excellence (COE): A healthcare COE focuses on a specific type of medicine or care delivery. These are groups of healthcare providers who offer high-quality, efficient care at reasonable and predictable prices, often resulting in reduced overall costs and improved outcomes. For example, a COE for cell and gene therapy specializes in advanced treatments in this field.³

Certificate of coverage (COC): A COC outlines an individual's health insurance benefits with their insurer, detailing covered services, exclusions, and conditions like deductibles and co-pays. It can usually be obtained from the insurer at no cost.⁴

Genetic testing: Biomarker and genetic testing are used to determine if a patient may be eligible for a CGT.^{5,6} These are modalities of precision medicine that can be used to inform diagnosis, prognosis, therapy selection, and to monitor how well therapy is working.^{6,7}

Group captives: Also referred to as captive health insurance, this is a specialized form of self-insurance. It involves a group of companies—usually from the same industry or with similar risk profiles—creating their own insurance company, known as a “captive.” This captive insurer is dedicated exclusively to providing health insurance coverage for the member companies and their employees.⁸

Laser: A laser sets a higher specific deductible for plan members who have a greater likelihood of illness or higher healthcare costs, instead of increasing the deductible for everyone.⁹

Risk pool: Multiple employers allocating a portion of their premium revenue or healthcare budgets into a shared, specialized fund. When a patient's medication costs surpass a preset limit, payments are made from this fund to cover the excess.¹⁰

Stop-loss: A financial safeguard, administered by a third-party insurer or a plan carrier, that provides protection against unexpected high-cost claims and cumulative exposure. It operates and renews on an annual premium basis.¹¹

Support services: Services provided to support patients throughout the course of their treatment by simplifying the process. These services, often referred to as HUB services, act as a central point connecting patients, prescribers, manufacturers, specialty pharmacies, and insurers. HUB services can include insurance verification assistance, patient education and counseling, end-to-end case management, refill prompts, adherence programs, data repository connectivity, and support for travel and logistics expenses.¹²

Executive summary

Integrating CGTs into health benefits design

Integrating CGTs into self-insured employer health benefits design demands thorough pre-implementation considerations and strategic planning for successful implementation. This resource will provide details across the following stages of health benefits design development and ongoing management:

1 Incorporating CGTs into a health plan design

Understand CGTs

- Collaborate with partners to learn more about the clinical value of CGTs
- Explore variations in care and administration methods

Assess coverage under the COC

- Review COC for CGT coverage under medical benefits
- Pay attention to cost distribution and **case-rate agreements**
- Examine employee out-of-pocket arrangements (co-pays or coinsurance)

Become familiar with coverage requirements

- Understand medical policies and prior authorization processes
- Clarify procedures for treatment access and coordination



2 Optimizing CGT coverage

Understand COE models

- Understand how COEs handle CGTs
- Develop clear implementation plan for integration

Consider **stop-loss** policy coverage

- Review stop-loss policy terms and coverage limits specific to CGT treatments
- Verify if the policy has **lasered** or excluded these claims

Explore industry-specific **risk pools**

- Research options and evaluate benefits
- Collaborate with peers for risk management strategies

Examine **support services**

- Explore support services offered by manufacturers (eg, HUB services, which may include travel support or insurance verification)



3 Ongoing management

Collaborate with stakeholders

- Establish and engage with cross-functional support teams
- Regularly review and update coverage strategies

Stay updated on financial risk mitigation solutions

- Stay informed about advancements and emerging trends
- Evaluate feasibility and benefits of new financial risk mitigation programs offered by payers and other third parties

Data analytics utilization

- Use platforms for predictive insights and resource optimization
- Implement data-driven strategies for risk management

Incorporating CGTs into a health plan design

Factors when formulating an employee health benefits plan:



1. Understand CGTs

- Collaborate with healthcare partners, including a health plan carrier, PBM, consultants/brokers, pharmaceutical manufacturers, and even network HCPs to gain a baseline knowledge of the clinical significance and value of CGTs
- Recognize the distinctions between CGTs, including their unique mechanisms, administration protocols, and monitoring requirements throughout the treatment journey



2. Assess how CGTs are covered under the COC

- Conduct a comprehensive review of the COC to determine if CGTs are covered, keeping in mind they are traditionally covered under the medical benefit¹³
- Understand covered expenses vs employee responsibilities, such as drug costs vs hospital stays associated with treatment
- Explore health plan design options affecting cost distribution, including co-pays or coinsurance for patient out-of-pocket expenses
- Note the use of case-rate agreements, which are commonly used by health plans and COEs in the CGT space^{2,14}
- If CGTs, **genetic testing**, and/or counseling are not currently covered in the COC, explore avenues for inclusion, such as through an **addendum**



Note: Not all plans may cover all FDA-approved CGTs. Understand which therapies are covered in the COC, focusing on limitations such as the number of treatments allowed or prerequisites for treatment after previous failures. Note that CGTs are distinct from each other; evaluate coverage separately under medical and pharmacy benefits to ensure comprehensive access for both categories.^{13,15}

Incorporating CGTs into a health plan design (cont'd)



3. Become familiar with coverage requirements and the prior authorization process for CGTs

- Understand medical policies regarding CGTs, including necessary genetic testing, biomarker, and counseling requirements
- Clarify procedures for accessing treatment within or outside of the network and understand the role of the health plan in coordination of benefits
- Consider educating employees on the significance of biomarker and genetic testing, as well as associated counseling, in optimizing CGT treatment efficacy and safety

Implementing CGT coverage

Steps to ensure comprehensive employee support and financial risk mitigation when integrating CGTs into a health benefits design:



1. Understand COE models

- COEs are an emerging approach to optimize treatment outcomes and cost of care.³ Learn about this model and how a plan will cover specific sites where CGTs may be required to be administered

Questions to consider asking a health plan carrier and the COE include:

- What options are available if preferred COEs are not covered by the plan?
- How is coverage handled for COEs located out of state?
- Will my organization or the health plan carrier handle the selection and management of COEs?

Additional questions to ask around COE selection include:

- How are COEs selected and vetted for quality and expertise in administering CGTs?
- What criteria are used to measure the success and outcomes of CGTs at COEs?
- Are there opportunities for collaboration and communication between COEs and the employer to ensure seamless coordination of care?
- How do COEs handle posttreatment support and follow-up care for employees being treated with CGT?
- Are there mechanisms for ongoing evaluation and feedback from employees who have received CGTs at COEs to continually improve the quality of care?



Note: Thoroughly understanding the COE model ensures high-quality care and optimal outcomes for employees receiving CGTs while effectively managing costs and financial risks.³



2. Consider leveraging a stop-loss plan to mitigate financial risks associated with high-cost claims¹⁶

- Review stop-loss policy terms and coverage limits specific to CGTs and verify if the policy has lasered or excluded these claims¹⁶
- Analyze claims data to identify patterns and trends in CGT use and associated costs
- Adjust stop-loss coverage as needed to align with the organization's risk tolerance and financial objectives

Implementing CGT coverage (cont'd)



3. Explore participation in industry-specific risk pools to reduce overall financial exposures

- Research risk-pooling options tailored to CGTs and associated costs
- Evaluate the benefits and drawbacks of participating in industry-specific risk pools vs traditional insurance arrangements



Note: Participation in risk pools can be accomplished through means such as purchasing into **group captives** (often done in conjunction with other employers of similar risk profiles) or buying groups.⁸ Consultants or brokers can provide more information.



4. Investigate support services for comprehensive healthcare management

- Explore opportunities to integrate employee support programs offered by various stakeholders, including health plans, manufacturers, COEs, and the organization
- Review existing policies to determine coverage for wrap-around services associated with CGTs, including travel and lodging expenses, within the COC
- Consider engaging with CGT manufacturers to explore available support services such as HUBs, which may include insurance verification assistance, treatment site identification, or other services aimed at alleviating financial burdens related to travel, lodging, and treatment costs
- Establish metrics to evaluate the effectiveness of support services in optimizing CGT outcomes and minimizing complications



Note: When an employee needs a certain CGT, it may be helpful to check the manufacturer's website for more information.

Ongoing management

Guidelines for continued management of CGT-related policies:



1. Collaborate with stakeholders to identify suitable solutions tailored to the organization's needs

- Establish cross-functional teams to assess the organization's CGT coverage and management needs
- Engage with traditional partners such as a health plan, PBM, consultants, and brokers, as well as newer stakeholders like medical benefit managers and laboratory benefit managers to align coverage policies and ensure efficient coordination of care
- Regularly review and update CGT coverage and management strategies in collaboration with relevant stakeholders



2. Review CGT-specific emerging solutions for financial risk mitigation

- Stay informed about advancements in CGTs and associated financial risk mitigation strategies
- Monitor industry developments and emerging trends in CGT reimbursement and insurance coverage
- Evaluate the feasibility and potential benefits of adopting new financial risk mitigation solutions for CGTs within the organization



3. Leverage data analytics tools for predictive insights into CGT utilization, outcomes, and costs within the employee population

- Use data analytics platforms to analyze CGT utilization patterns, treatment outcomes, and cost trends
- Identify opportunities for optimizing CGT coverage and management based on predictive insights
- Implement data-driven strategies to proactively manage CGT-related risks and optimize resource allocation for maximum benefit to employees and the organization
- Collaborate with industry peers and stakeholders to share best practices and insights on risk management strategies



Conversation starters

Asking plan carriers, PBMs, consultants, or brokers the following questions can help ensure appropriate CGT coverage:

- 1 What is the likelihood that our organization will see a claim for a CGT, based on our employee population and current market availability?**
- 2 How are CGTs covered under our COC?**
 - a. Does our COC include all CGTs, or only select therapies?
 - b. Are they covered under the pharmacy benefit or the medical benefit?
 - c. What CGT-related cost limits and requirements for out-of-pocket expenses are specified within our current policy?
- 3 Is there a prior authorization process for CGTs within our current policy?**
 - a. What are the criteria, and who will support claim review and approval decisions?
- 4 How does our plan cover CGTs in the case of referrals into COEs?**
- 5 Does our plan cover relevant genetic testing?**
- 6 How are we currently protecting our risk in the event of a CGT claim?**
 - a. With these solutions, how much would we pay for each CGT claim, and how can we enhance our options to better protect against financial exposure?
- 7 How does our stop-loss insurance cover CGT claims?**
 - a. Does it include all CGTs or only select therapies?
 - b. Are there CGT-specific riders or policies?
 - c. Are there specific limitations, exclusions, lasers, or adjusted cost sharing we should be aware of?
- 8 Are we eligible to enroll in other programmatic offerings from national plan carriers or third parties?**
 - a. What services do they provide, and what are the associated costs and benefits?



Navigating the integration of CGTs into a health benefits design requires careful planning and ongoing management. By referring to these key considerations, comprehensive support can be provided to employees while managing financial risks effectively.

CGT=cell and gene therapy.

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