

How Employers Are Making Cell and Gene Therapy Coverage Work

Real Stories. Practical Takeaways.

These 3 brief case studies were developed through blinded, primary research interviews of employee benefit consultants and brokers and were sponsored by Johnson & Johnson. Collectively, they demonstrate how employers across industries are responding to cell and gene therapies by highlighting:

- What worked
- What they learned
- How you can apply it

Coverage decisions for cell and gene therapies are multifaceted. Following a thorough evaluation, some employers may choose not to provide coverage for these therapies. In contrast, others may determine that offering coverage aligns with the organization's values and serves the best interests of their employees. The subsequent case studies demonstrate a variety of employer decision-making processes, along with the factors and considerations that influence those decisions.

These case studies and outcomes are not to be considered entirely replicable by other parties or applicable to all employers. Readers should consider using these examples to support discussions with their plan carrier, PBM, consultants, or brokers.

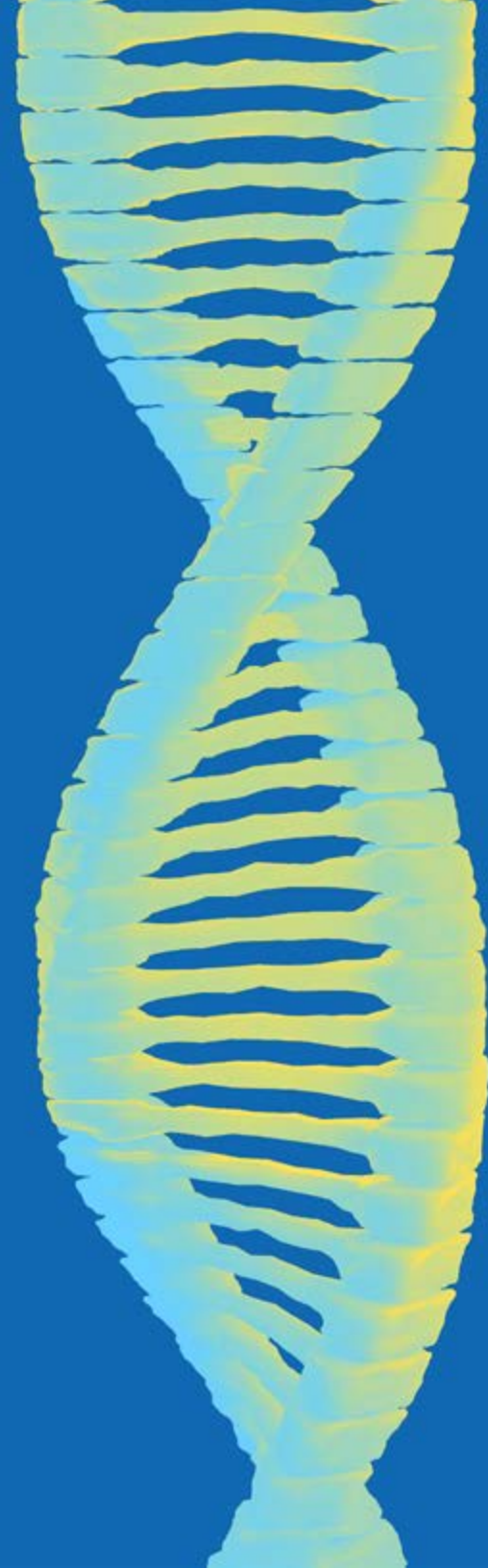


Table of contents



Case Study 1

Leveraging Ready-Made Solutions to Provide Class-Wide Cell Therapy Coverage for Employees

3



Case Study 2

Deciding to Cover Gene Therapies Due to Employees' Critical Health Needs

10



Case Study 3

Preexisting Gene Therapy Coverage Enabled Swift Access for Employees

16



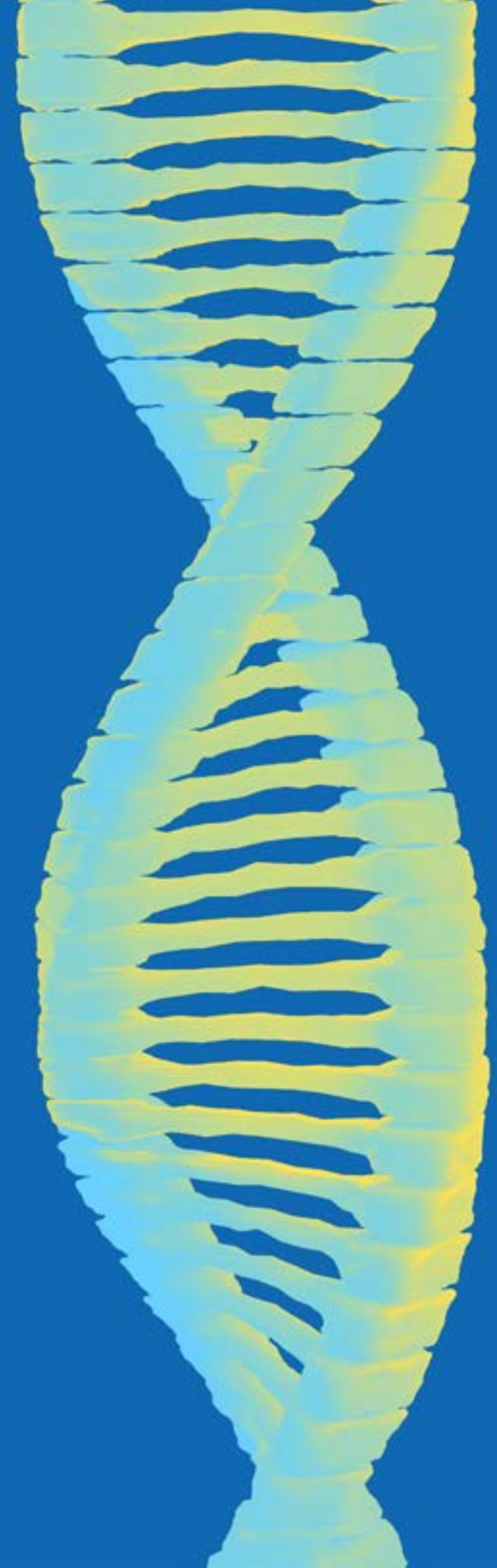
Case Study 1

Cell and Gene Therapy Employer Coverage

Leveraging Ready-Made Solutions to Provide Class-Wide Cell Therapy Coverage for Employees

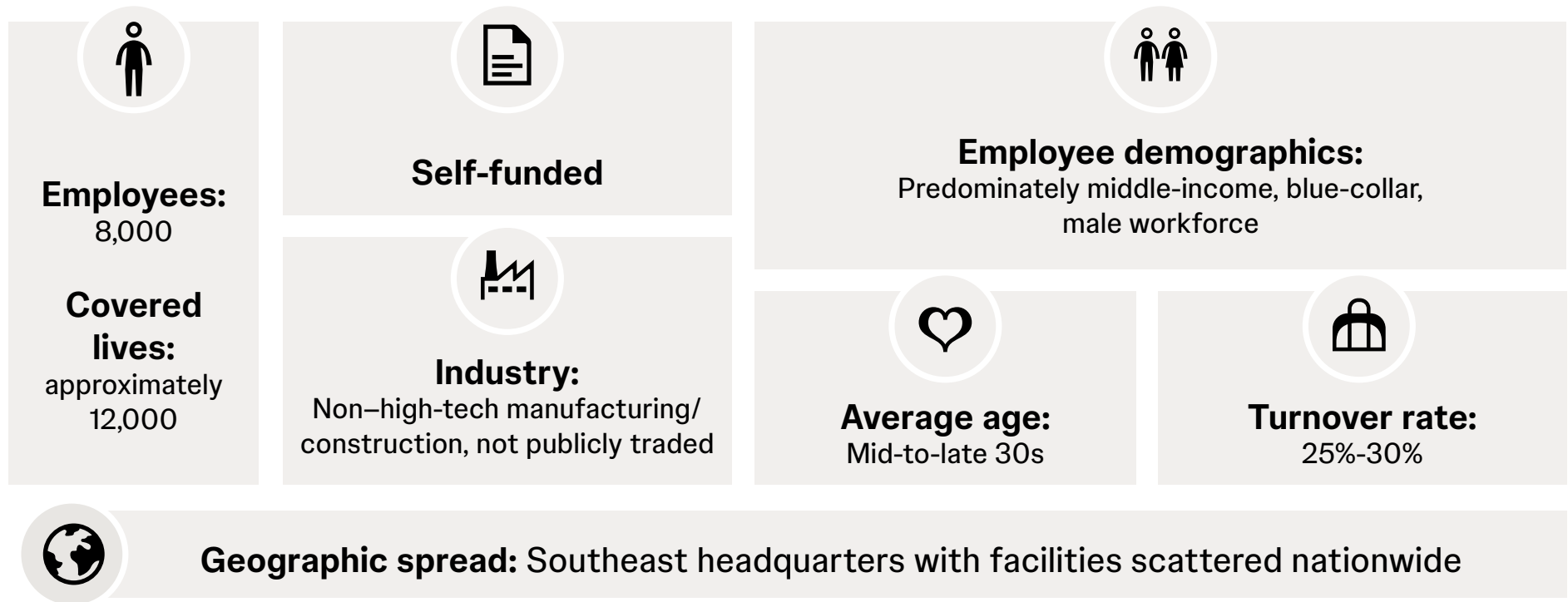
A self-insured manufacturing company in the Southeast partnered with their benefits consultant to gain a deeper understanding of the value of cell therapy. Through this collaboration, they recognized that **offering coverage for the entire cell therapy class** was not only attainable and valuable, but also **achievable with manageable financial risk**.¹

These case studies and outcomes are not to be considered entirely replicable by other parties or applicable to all employers. Readers should consider using these examples to support discussions with their plan carrier, PBM, consultants, or brokers.



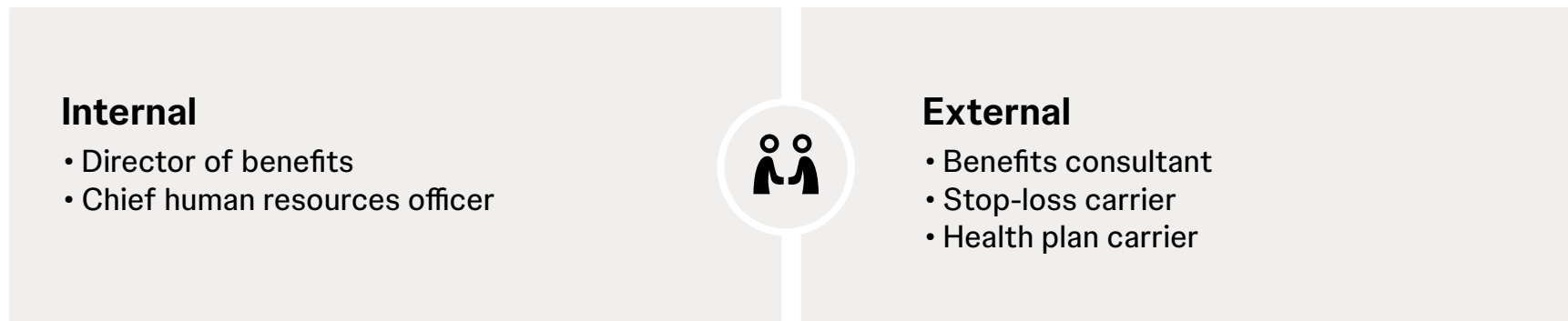


Company profile



Key stakeholders

The following stakeholders played a role in the decision to cover cell therapy:





Decision-making rationale

This employer identified several critical factors that influenced their choice to provide coverage for all available treatments in the cell therapy class:

- ✓ A clear understanding of the **potential clinical risks and benefits** provided by cell therapies
- ✓ Evidence of demonstrated clinical and **real-world data**
- ✓ Knowledge that many carriers use **class-level coverage policies for cell therapies**, which gave credence to the idea that benefit integration could be relatively straightforward
- ✓ Awareness of **risk mitigation options**



“When I guide my clients to cover cell therapy, the conversation is not drug by drug, but as a class-wide basis in terms of benefit coverage decisions.”

- Benefits Consultant



“As a clinician, living in the age of potentially curative therapies is really cool. So helping my employer clients unpack this more is very important.”

- Benefits Consultant



Identifying and activating coverage

The following steps were taken to cover cell therapy:

1



Assessed coverage plan to determine gaps

- The employer's benefits consultant flagged that this organization **was not covering cell therapies** in their benefits design
- Upon assessing their aggregated medical and pharmacy claims data, the consultant determined cell therapy coverage was **feasible and recommended**

2



Received education on the potential value of cell therapy

- The benefits consultant conducted a series of **educational sessions** to help the employer learn more about cell therapies, including:
 - The nature of cell therapies
 - Differences between cell and gene therapy
 - In certain cases, serve as a potential one-time treatment and may even be the first and only treatment available
 - Uptake
 - Cost

3



Determined a plan for financial risk mitigation

- The employer considered ways to mitigate financial risk, and opted to increase their **stop-loss insurance coverage**
- The employer considered other factors but **opted not to take additional action** at this time
- The employer **communicated their cell therapy coverage decision** to their stop-loss vendor to ensure they were aware



4



Communicated with health plan carrier to ensure coverage was added

- The employer contacted their health plan carrier to incorporate cell therapy coverage into the health plan's existing policy
- Coverage included all therapies in the class, as well as required **genetic testing, hospital costs, and posttreatment care** related to the procedure

5



Received notification regarding an eligible employee

- After making the decision to add cell therapy coverage, the employer was notified by their health plan carrier that **an employee was approved** by the plan to receive a cell therapy

6



Conducted ongoing management

- The **cell therapy was administered successfully** to an employee
- The employer **received reimbursement** from their stop-loss vendor within 30 days
- At the time of this discussion, the employee in question was **still employed** by the organization
- The employer plans to **continue offering** cell therapy coverage

i

Despite adding cell therapy coverage, the employer experienced no impact on employee premium or stop-loss rates within the same plan year, and patient's out-of-pocket maximum remained the same throughout the plan year



Key learnings

This employer's experience in offering comprehensive cell therapy coverage provides several key takeaways:

1

Clear and open communication among all stakeholders, particularly with stop-loss providers, emerged as a key factor in preventing coverage gaps or underwriting issues related to exclusions

2

Engaging in coverage discussions with an **open mind** and working closely with consultants and health plan carriers may help to **explore and identify viable coverage options**

3

Potential best practices include thoroughly **evaluating organizational risk tolerance** with consultants and aligning it with current stop-loss coverage



“ [In this case,...it was just a case of telling the plan carrier our client wants to turn on [cell therapy] coverage with your standard UM [utilization management] policies in place. Our client signed, and the coverage was effective 1/1. ”

- Benefits Consultant



Partner with your health plan carrier, consultant, and/or broker to develop a plan for cell and gene therapy coverage that's right for you and your employees.

Reference

1. Data on file. Market research interview. Janssen Biotech, Inc. January 9, 2025.



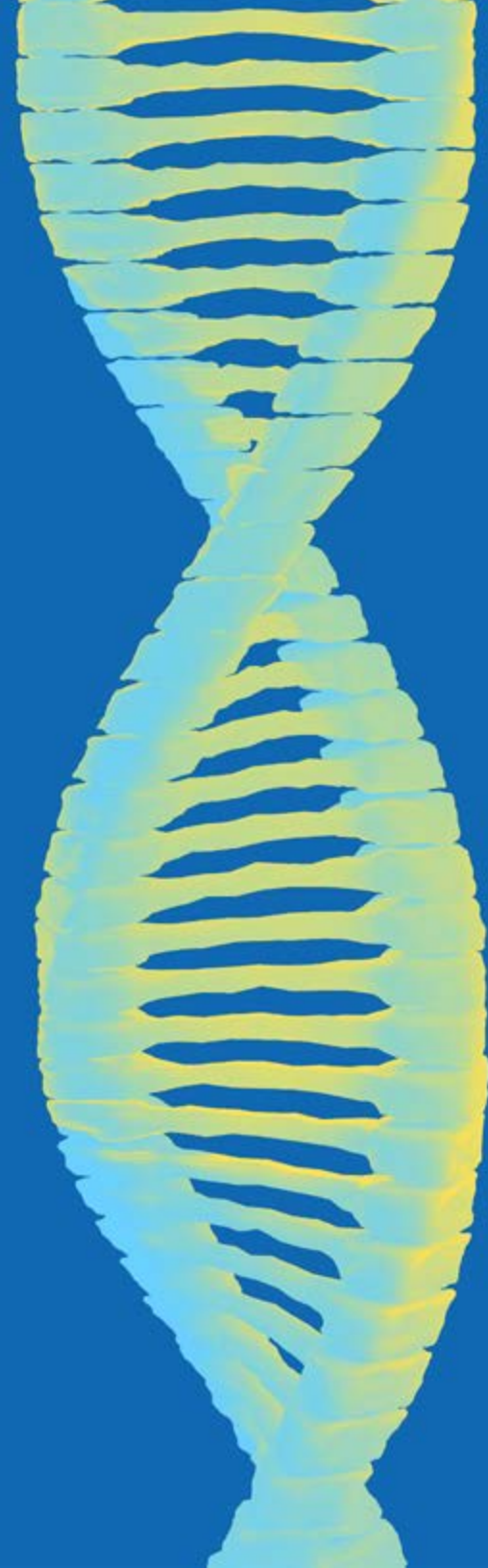
Case Study 2

Cell and Gene Therapy Employer Coverage

Deciding to Cover Gene Therapies Due to Employees' Critical Health Needs

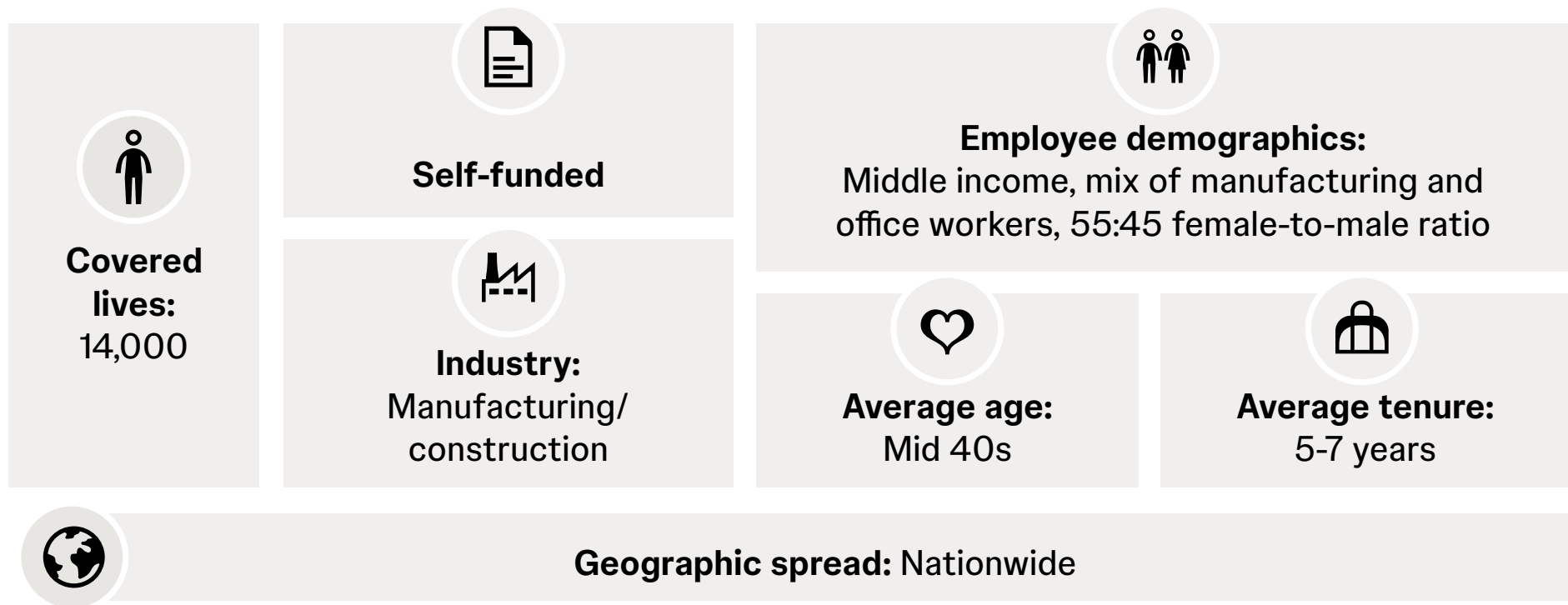
A large firm in the manufacturing and construction sector discovered that 2 employees located in different regions of the country had been diagnosed with a **rare genetic disorder**. Fortunately, this condition was treatable with a newly approved gene therapy. Demonstrating their commitment to employee well-being, the organization **prioritized providing access** to this potentially life-changing treatment for their valued team members.¹

These case studies and outcomes are not to be considered entirely replicable by other parties or applicable to all employers. Readers should consider using these examples to support discussions with their plan carrier, PBM, consultants, or brokers.





Company profile



Key stakeholders

The following stakeholders played a role in the decision to cover this gene therapy:





Identifying and activating coverage

The following steps were taken to develop a plan for implementing the pre-identified gene therapy into the benefits design:

1



Held initial budget and clinical discussions

- The employer, in collaboration with their broker, conducted an **annual budget review** and identified potential funds available for reinvestment into their organization
- Concurrently, the broker performed a clinical review of the employer's data to **analyze trends** in high-cost categories
- This review highlighted a particular **genetic disorder** as a key area of focus

2



Identified an employee in need of gene therapy coverage

- The process began to gain momentum when an **employee diagnosed with this genetic disorder** raised the topic of gene therapy coverage with human resources; soon after, another was also identified as eligible through a clinical review of claims data
- Recognizing this as an opportunity, the employer **prioritized investing in gene therapy coverage** for 14 specific conditions
- Key stakeholders convened to align on **budgetary considerations, coverage requirements, and the organization's goals** for employee retention and satisfaction

3



Explored gene therapy coverage options

- The employer decided to pursue gene therapy coverage and collaborated with their broker's pharmacy, client services, and actuary teams to evaluate the following **coverage and payment approaches**:
 - **Direct payment**
 - **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 basis²
 - **Amortized payments**: Therapy paid in installments spread over a predetermined time period (monthly or annually for a prespecified length of time or remaining lifetime of the patient) to mitigate immediate financial impact^{2,3}



“ There were discussions about [direct payment], and the organization was prepared to do so if need be. But they chose an amortized payment plan, allowing them to pay over time. ”

- Broker

4



Selected and implemented a coverage and payment plan

- The organization ultimately chose to add on an existing **gene therapy coverage program** offered by their health plan carrier*
- Through this program, a selection of gene therapies[†] was made available at a discount to the employer through a **provider network of credentialed hospitals/Centers of Excellence**
- The organization chose to pay for the full cost of treatment; however, they opted to **amortize the payments** over 3 to 4 years

5



Conducted ongoing management

- One employee **successfully underwent the gene therapy procedure** after completing the required genetic testing, which was available through their plan's testing coverage benefits
- Comprehensive **wrap-around clinical and support services** were provided to the employee through the health plan carrier and gene therapy manufacturer
- Payment for the treatment was ongoing at the time of this conversation
- At the time of this discussion, **the employee remained with the organization** and expressed profound gratitude toward their employer for providing access to the gene therapy

i

From budget review to implementation, this process took just 4 months to complete

*At the time of launch, this program was available as an add-on for self-insured employers and included as part of the medical benefits for fully funded employers.⁴

[†]Currently, this program covers 14 gene therapies.⁵



Key learnings

This employer's journey in deciding to provide gene therapy coverage offers valuable insights and best practices for other organizations considering similar initiatives:

1

Early **alignment across key stakeholders** may help facilitate a smooth and efficient decision-making process

2

Organizations may benefit from preparing for and navigating **potentially conflicting priorities** among internal teams

3

Exploring **multiple financial risk mitigation strategies** can help identify a payment plan that best aligns with the organization's need and goals

4

Assessing **existing ready-made coverage programs** or packages from health plan carriers may offer a more straightforward path to implementation

5

External partners—such as brokers, consultants, and pharmaceutical companies—can be helpful sources of **early education** on clinical, financial, and strategic considerations

- When working with a broker or consultant, it can be helpful to ask the main point of contact to **engage experts** on these topics at their organization, including actuaries and their clinical team



“ It is helpful to get your ducks in a row early on; know which players to include internally and eliminate others to create a small internal circle of decision makers. ”

- Broker



Partner with your health plan carrier, consultant, and/or broker to develop a plan for cell and gene therapy coverage that's right for you and your employees.

References

1. Data on file. Market research interview. Janssen Biotech, Inc. March 6, 2024.
2. Lopata E, Terrone C, Gopalan A. Opportunities and challenges surrounding financial models for high-investment medications: a survey of access decision-makers and employers. *J Manag Care Spec Pharm*. 2023;29(7):782-790.
3. Slocomb T, Werner M, Haack T, Valluri S, Rader B. New payment and financing models for curative regenerative medicines. *Regenerative Medicine In Vivo*. August 2017. Accessed December 15, 2024. https://alliancerm.org/wp-content/uploads/2018/05/ARM_Curative_Regenerative_IV1707_LRS.pdf
4. PR Newswire. Aetna launches Gene-Based, Cellular and Other Innovative Therapies™ (GCIT) designated network. October 27, 2021. Accessed January 27, 2025. <https://www.prnewswire.com/news-releases/aetna-launches-gene-based-cellular-and-other-innovative-therapies-gcit-designated-network-301409598.html>
5. Aetna Inc. Aetna Institutes® Gene Based, Cellular and Other Innovative Therapy (GCIT®) designated centers. APN# 3141506-08-01. 2024. Accessed January 27, 2025. <https://www.aetna.com/content/dam/aetna/pdfs/health-care-professionals/GCIT-designated-providers.pdf>



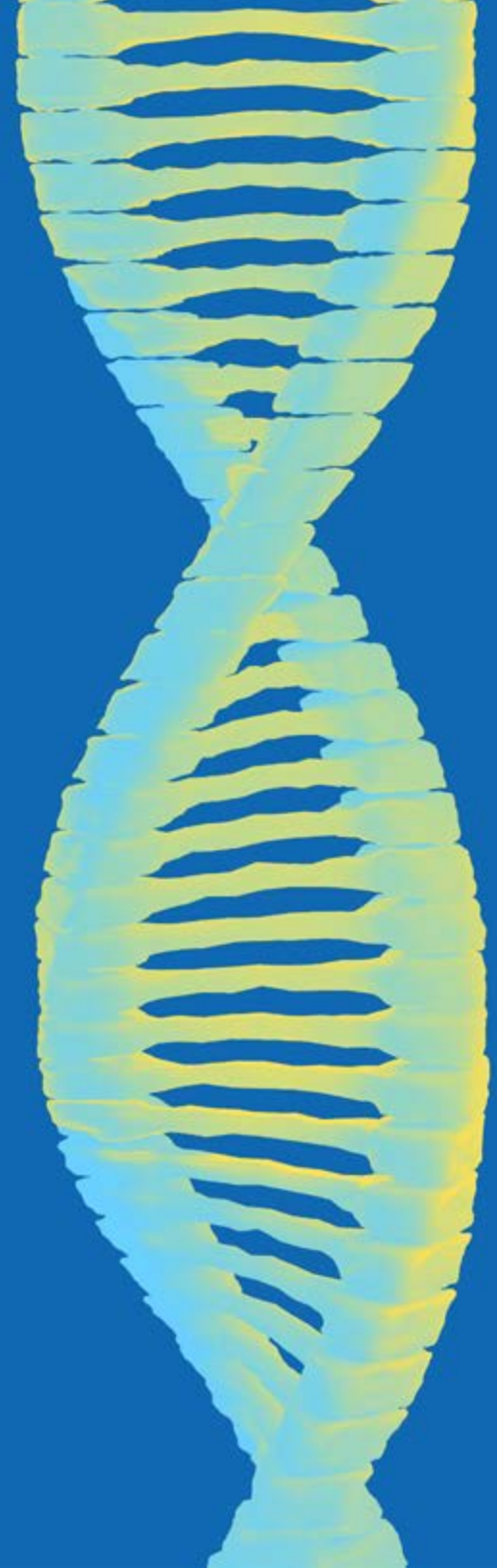
Case Study 3

Cell and Gene Therapy Employer Coverage

Preexisting Gene Therapy Coverage Enabled Swift Access for Employees

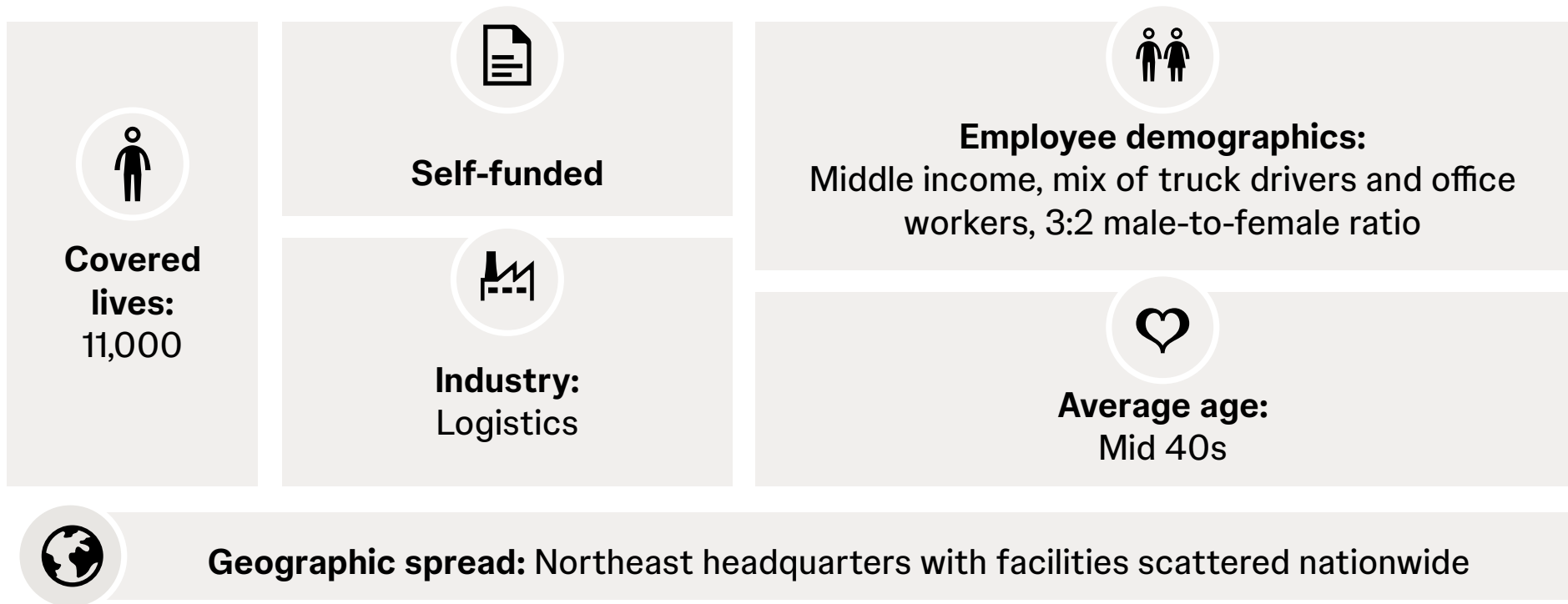
An organization in the logistics field has a **strong history of providing gene therapy coverage** for its employees. When a retrospective claims analysis revealed that an employee's dependent might be eligible for a novel gene therapy, the organization was **well positioned to take swift action** and implement a plan.¹

These case studies and outcomes are not to be considered entirely replicable by other parties or applicable to all employers. Readers should consider using these examples to support discussions with their plan carrier, PBM, consultants, or brokers.





Company profile



Key stakeholders

The following stakeholders played a role in the decision to cover this gene therapy:





Decision-making rationale

This employer had already built a gene therapy coverage approach that included all 9 gene therapies that were approved at the time. Key factors that had prompted this action were:

- ✓ **Early education** and awareness of gene therapy
- ✓ Partnership with **broker and stop-loss carrier** to gain awareness of payment programs
- ✓ Recognition that the **prevalence** of eligible cases is likely to **remain low**, based on a population impact assessment
- ✓ Prioritization of the **well-being of employees** and their families
- ✓ Acknowledgment of the **positive impact** on the organization's public image and reputation



“ This organization viewed gene therapy coverage as a long-term investment. ”

- Broker



By the time a beneficiary was identified as eligible for a gene therapy, this employer had already had a plan in place for over a year and was prepared to manage the financial outlays associated with gene therapy



Identifying and activating coverage

The following steps were taken to ensure the employer's existing gene therapy coverage would be sufficient for the individual in need:

1



Identified an individual in need

- The broker's clinical team performed a **retrospective claims analysis** using a dashboard that provided both aggregate-level and employee-level data to assess therapy costs and potential eligibility
- The assessment found an employee's dependent who was **eligible for a recently approved gene therapy**

2



Assessed existing gene therapy coverage

- The employer had already decided to pursue gene therapy coverage and was satisfied that the following measures would **effectively provide coverage** for the employee's dependent while **managing the employer's financial risk**:
 - **Stop-loss**: Reinsurance for over \$1 million, specific to gene therapy
 - **Health plan carrier program**: All gene therapies made available via existing health plan program

3



Conducted ongoing management

- The eligible individual was notified by the health plan carrier that they have the **option to receive gene therapy**
- The employer continued to have quarterly meetings with their broker team
- At the time of this discussion, the employee's dependent was in the process of deciding whether to begin gene therapy



Key learnings

This employer's experience in offering gene therapy coverage provides several key takeaways:

1

Establishing a path for coverage **proactively** and early vs reactively and late may put the organization in a better position

2

Using both **aggregate-level and employee-level data**, when accessible, may support a more accurate assessment of financial risk

3

Organizations may find value in learning from others and seeking out **knowledge-sharing opportunities** through brokers, plan carriers, or at industry conferences



“Cell and gene therapies have the potential to alter the course of progression of some of the most complex conditions we’ve ever had.”

- Broker



Partner with your health plan carrier, consultant, and/or broker to develop a plan for cell and gene therapy coverage that's right for you and your employees.

Reference

1. Data on file. Market research interview. Janssen Biotech, Inc. March 15, 2024.