Massachusetts Institute of Technology

NEWDIGS

FoCUS

Financing and Reimbursement of Cures in the US

RESEARCH BRIEF

By MIT NEWDIGS FoCUS Project
28 April 2022

2022F204v055

How can self-insured employers prepare for the portfolio impact of high-cost gene therapies coming to market? Self-insured employers (SIEs) currently rely on traditional stop-loss insurance to protect against unexpected high-cost claims, including those for cell and gene therapies. Given that current approvals are in rare diseases, this approach has succeeded so far. However, as more cell and gene therapies treatments are approved in more prevalent patient populations, this status quo approach may not be sustainable for stop-loss vendors or employers.

Innovative products are now available in the healthcare market to help mitigate the actuarial and financial risk associated with cell and gene therapies. Now is the time for SIEs to evaluate their current situation with regards to cell and gene therapies and consider these solutions in addition to current stop loss coverage, with an aim towards developing a sustainable, flexible strategy that can address future developments.

DEVELOP A STRATEGY NOW TO PAY FOR CELL AND GENE THERAPY

1. Access consultant support: Is my consultant providing timely information on my exposure?

SIEs rely heavily on their benefit consultants to identify, market, recommend, and administer benefit programs. This support is even more critical as the pace of approvals for high-cost cell and gene therapies increases. Consultants must regularly update SIEs on the evolving pipeline for cell and gene therapies. This information is essential to assess potential exposure based on disease prevalence and the unit cost of notable treatments. Medical plan administrators may also be helpful with predicting exposure.

Key takeaways

SIEs are currently relying on stop-loss insurance to mitigate the risk of high-cost cell and gene therapies.

Stop-loss alone may not be adequate as more cell and gene therapies are approved in more prevalent conditions.

Reviewing current consultant support and stop-loss coverage are crucial first steps towards developing a strategy to manage the future financial impact associated with cell and gene therapies.

Innovative solutions are available for SIEs to evaluate now for applicability to a SIE's coverage.

An overall strategy for mitigating the actuarial and financial risk associated with cell and gene therapies includes short- and long-term activities, budgetary considerations, and monitoring.

Communication of plan changes is an integral part of the strategy.

2. Review risk exposure and tolerance: What is my current stop-loss coverage? What is the impact of lasering patients with known conditions?

In addition to consultant support, reviewing current risk exposure and tolerance is a crucial step towards building a strategy for future cell and gene therapy costs. For SIEs, this likely translates into a deep-dive into current stop-loss coverage for high-cost therapies.

Specific (or individual) stop-loss coverage transfers the risk of claim costs above a defined deductible (for instance, $200,000 on each enrolled member during the coverage period) to the stop-loss carrier. In most instances, that same $200,000 deductible applies to every member covered by the plan. However, when a member has a known condition that exists prior to the start of the coverage period, the stop loss carrier may request a higher deductible on that particular individual – for instance, $800,000 instead of $200,000, or exempt them from coverage all together. This underwriting concept is referred to as "lasering". As more high-cost cell and gene therapies are approved that can treat known conditions within a SIE's population, this "lasering" process has the potential to turn stop-loss coverage into "swiss cheese" – that is, with lots of holes exposing the employer to substantial financial risk and gaps in coverage.

Thus, while stop-loss insurance is functioning effectively in today's self-insured market, this may change rapidly with new approvals. New financial solutions are being launched to target this problem and should be evaluated further.

3. Evaluate the current products: What solutions in the current marketplace could meet my needs?

Searching the market to identify potential solutions that can mitigate future risk and costs is the next step for the SIE. This is where a knowledgeable medical plan administrator, pharmacy benefits manager, or benefits consultant can be quite helpful. Many organizations and major medical carriers have already developed targeted solutions help finance gene and cell therapy for self-insured customers. Some are available only to existing clients while others sell to new clients as well.

Larger coalitions are also creating products that may address gene and cell therapy and should not be ignored. Key questions to consider include:

1. How much do these products/services cost?
2. Do they have a return on investment?
3. How difficult are they to administer?
4. What is the 'lift' going to be for my organization? Do I need a partner to manage this?

The overall goal of this evaluation step is to finalize a list of current and future solutions that are worthwhile for the employer.

4. Develop the strategy: what activities are vital for successful implementation?

The overall strategy for an SIE to address paying for future gene and cell therapies should detail short- and long-term activities that are essential for successful implementation. Short-term activities include making necessary benefit design changes to support the plan. For example, ensuring coverage for gene and cell therapy falls under the medical benefit only and is not covered under the pharmacy benefit. When doing this, it is always good practice to compare all aspects of pharmacy and medical coverage for any potential conflicts in coverage.

Longer term activities might include a decision point or set of criteria that determine when a solution could or must be implemented. Therefore, part of long-term activities are also based around monitoring, to allow a prompt response when these criteria are met. Each long-term activity should be assigned an owner and include an estimated time commitment and budgetary impact.

5. Communicate the plan: Who needs to know what, and when?

Communication must be planned once the strategy is finalized. Clearly outlining the key communication points and target audiences are the minimum necessary components. Consider upward communication, to the C-suite, as well as front line management and employee communications. Communication plans are typical service offerings of benefit consultants, and they could be leveraged for this component.

LOOKING FORWARD

The landscape for cell and gene therapies is complicated and evolving rapidly. SIEs should plan now and develop a preemptive flexible strategy to prepare for ongoing approvals. A sustainable strategy requires oversight and management, but this can be overseen by a knowledgeable benefit consultant.

ADDITIONAL RESOURCES

FoCUS provides a resource organized as a web-based toolkit which can support your assessment of the impact of cell and gene therapies on your organization. Key areas of interest for benefit advisors include:

- Nine financial models addressing the challenges of paying for gene and cell therapy
- Clinical and contracting considerations for providing access to gene and cell therapies.
- Worksheets to estimate an organization's pipeline impact or the impact of approvals of specific gene or cell therapies.

The SIE work group from MIT's FoCUS project surveyed organizations and their financial solutions for cell and gene

therapies in early 2021. A white paper detailing the results is available here.

ABOUT FOCUS

The MIT NEWDIGS consortium FoCUS Project (Financing and Reimbursement of Cures in the US) seeks to collaboratively address the need for new, innovative financing and reimbursement models for durable and curable therapies that ensure patient access and sustainability for all stakeholders. Our mission is to deliver an understanding of financial challenges created by these therapies leading to system-wide, implementable precision financing models. This multi-stakeholder effort gathers developers, providers, regulators, patient advocacy groups, payers from all segments of the US healthcare system, and academics working in healthcare policy, financing, and reimbursement in this endeavor.

Research funding

This research was wholly funded by the FoCUS Consortium in the MIT Center for Biomedical Innovation NEWDIGS Initiative. It received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Please cite using

MIT NEWDIGS Research Brief 2022F204-v055 Self-Insured Employers

OTHER RESEARCH BRIEFS

- Outcomes Tracking
- Medicaid Best Price, January 2019
- CAR-Ts
- Model Contracts
- Projections
- COEs
- Reinsurance
- Patient Mobility
- Orphan Reinsurer Benefit Manager
- Actuarial Risk
- Framework for Precision Financing
- Payer Segmentation
- Payer Survey
- Portfolio Analysis Modeling

Our series of research briefs and white papers can be found at https://newdigs.mit.edu/papers-publications or using the code below.