



INDUSTRY GUIDE

Before the claim arrives

An employer's guide to cell and gene therapy readiness

DATA AND METHODOLOGY

MarketScan® findings in this guide are based on Truven's analysis of MarketScan Treatment Pathways data for commercially insured active members from January 2022 through December 2025, with claims paid through January 2026. Pipeline, treatment-landscape, patient-journey, and funding-model discussions draw on Truven subject-matter expertise, MarketScan analysis, and published industry research. Financial projections are illustrative scenarios designed to show how employers can evaluate potential exposure as clinical, regulatory, pricing, eligibility, and uptake assumptions evolve.



Understanding the bigger picture

Cell and gene therapies (CGT) are changing what is possible in modern medicine. They are also changing how employers are navigating benefit management.

Breakthrough treatments, multimillion-dollar price tags, and a growing development pipeline are moving CGT from a rare-event concern toward a strategic benefits planning issue.

For many employers, the questions on cell and gene therapies are becoming more immediate:

- How relevant is this for my population?
- Should I be worried about these costs today?
- What can I realistically do now?
- How do I prepare without overcorrecting current plans?

In the search for answers, it is easy to focus on the therapy journey itself: the approval, the treatment, the claim.

But those moments are only part of a much larger story.

By the time a member receives a cell or gene therapy, years of signals may already have appeared across disease prevalence, treatment pathways, clinical development, and population-level health trends.

The challenge is not just understanding what treatment could cost. It is knowing where to look earlier, before a high-cost claim appears.

A growing need for readiness

Between 2022 and 2025, [MarketScan](#) data indicate that CGT utilization increased more than 40% to 4.6 patients per 100,000, while allowed spend nearly tripled to \$16.90 PMPY.

At the same time, across the industry, nearly 50 cell and gene therapy products have been approved and hundreds more remain in development.

That makes readiness less about reacting to an isolated event and more about connecting the data, trends, and operational decisions that shape employer exposure over time.

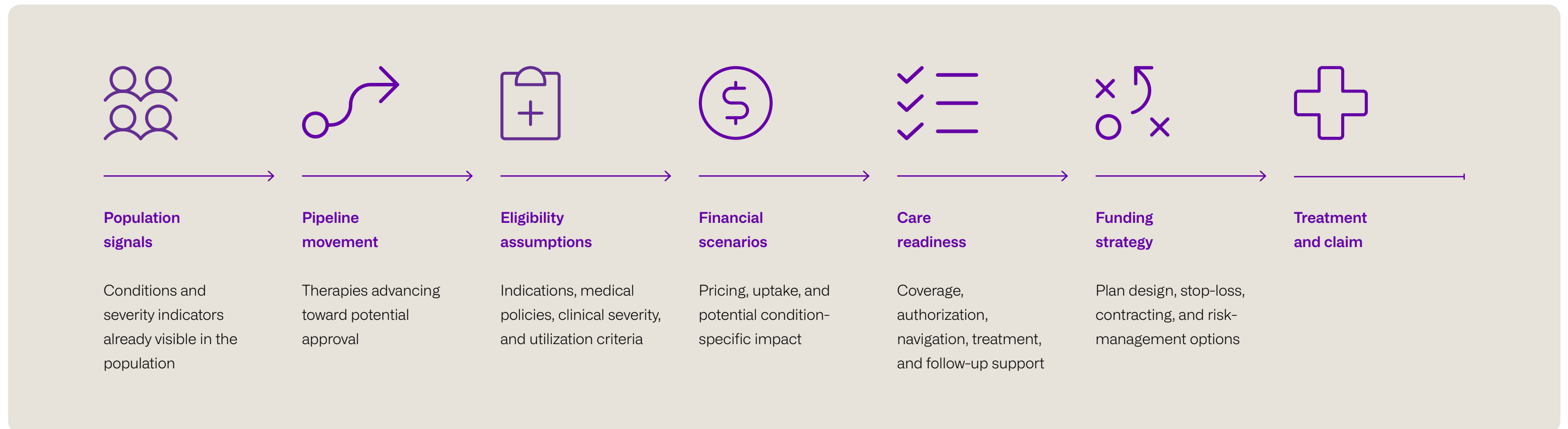
This guide shows how employers can use data to prepare earlier: understanding population risk, monitoring the pipeline, modeling potential exposure, strengthening care coordination, and evaluating funding strategies **before high-cost claims arrive.**



The signals before the claim

A cell and gene therapy claim may be the most visible event, but the groundwork often starts much earlier.

Population data, pipeline developments, potential eligibility, care requirements, and financial considerations may give employers opportunities to prepare well before treatment occurs.



The claim is not the first signal. It is the point at which the earlier signals become impossible to ignore.



A practical guide for CGT readiness

Therapy approval often prompts immediate planning questions. But population and pipeline analysis can begin much earlier.

Employers can prepare well before a therapy reaches their population by examining risk, pipeline activity, possible financial exposure, care coordination, and funding options together.

Note: These areas are not intended to represent a formal scoring model or sequential methodology. They are a practical way to connect the data, pipeline, care, and funding considerations explored throughout this guide.

This guide organizes readiness into five connected planning areas:

01

Population risk

What conditions associated with cell and gene therapy already exist in your population?

02

Pipeline monitoring

What therapies are progressing through development that could affect your workforce?

03

Financial modeling

What would future treatment scenarios mean financially?

04

Care coordination

Can your benefits ecosystem support the patient journey?

05

Funding strategy

How will your organization manage risk when treatment occurs?





PLANNING AREA 1

Population risk

The next GLP-1 moment?

Ten years ago, few employers viewed GLP-1 medications as a strategic planning priority. Today, they materially influence healthcare budgeting, benefits design, and long-term workforce planning.

Cell and gene therapy may be approaching a similar inflection point.

[Truven](#) experts compare today's CGT landscape to where GLP-1 medications were a decade ago: an emerging category with the potential to become a much larger benefits-planning consideration.

The comparison matters because healthcare transformation rarely happens all at once. New therapies move through development, evidence builds, indications expand, and adoption follows. That is how a treatment category that once seemed distant can become a meaningful planning issue.

Employers that recognize those patterns early gain something valuable: Time. And with more time comes a longer runway to prepare, prioritize, and plan for what's ahead.

What the data is showing

Analysis of MarketScan data shows the same shift: utilization is increasing, while allowed spending is rising faster.

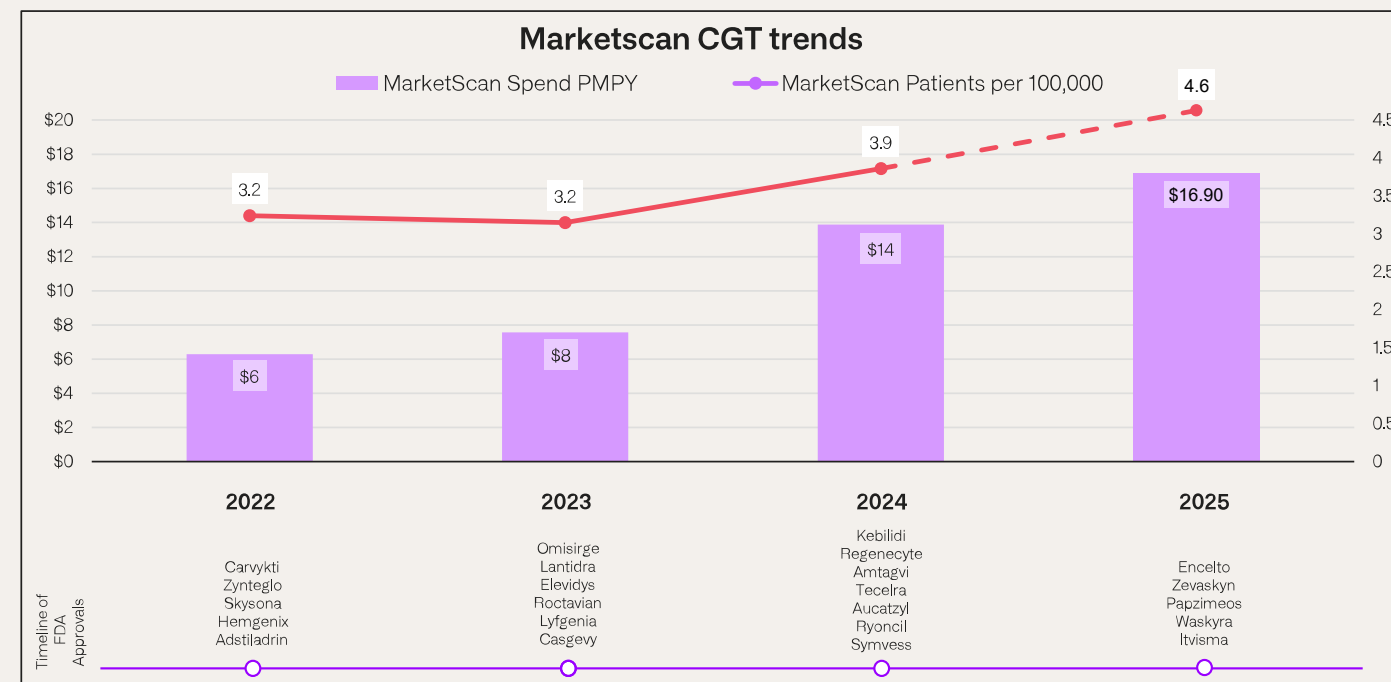
As mentioned earlier, between 2022 and 2025, CGT utilization increased more than 40%, from 3.2 to 4.6 patients per 100,000. During the same period, allowed spend nearly tripled, from \$6.30 to \$16.90 PMPY.

Readiness takeaway

Population risk assessment establishes the baseline: which CGT-relevant conditions are present, how prevalence is changing, and where higher-severity members may require closer monitoring.

Data highlight: CGT utilization increased more than 40%, while CGT spend nearly tripled between 2022 and 2025.

Utilization and spend on cell & gene therapies (CGTs)



MarketScan Treatment Pathways, Actives, January 2022 – December 2025 (paid through January 2026).
Source: FDA Approved Cellular and Gene Therapy Products. Excludes HPC / Cord Blood.



PLANNING AREA 2

Pipeline monitoring

The traditional CGT story has often centered on rare or highly specific conditions. But the pipeline is expanding beyond one-time cures for ultra-rare diseases to include treatment options for high-acuity members with more common conditions.

There are nearly 50 approved cell and gene therapy products available today on the market, with hundreds more in development, including roughly 40 with anticipated approvals by 2028. That is to say, the number of CGT products could nearly double over the next few years.

The more useful question is not necessarily how many therapies are coming, but which conditions they will treat, and how prevalent those conditions are in employer populations.

Pipeline note: The conditions listed in this section represent areas of active therapy development and should not be interpreted to mean that an FDA-approved CGT is currently available for every condition.

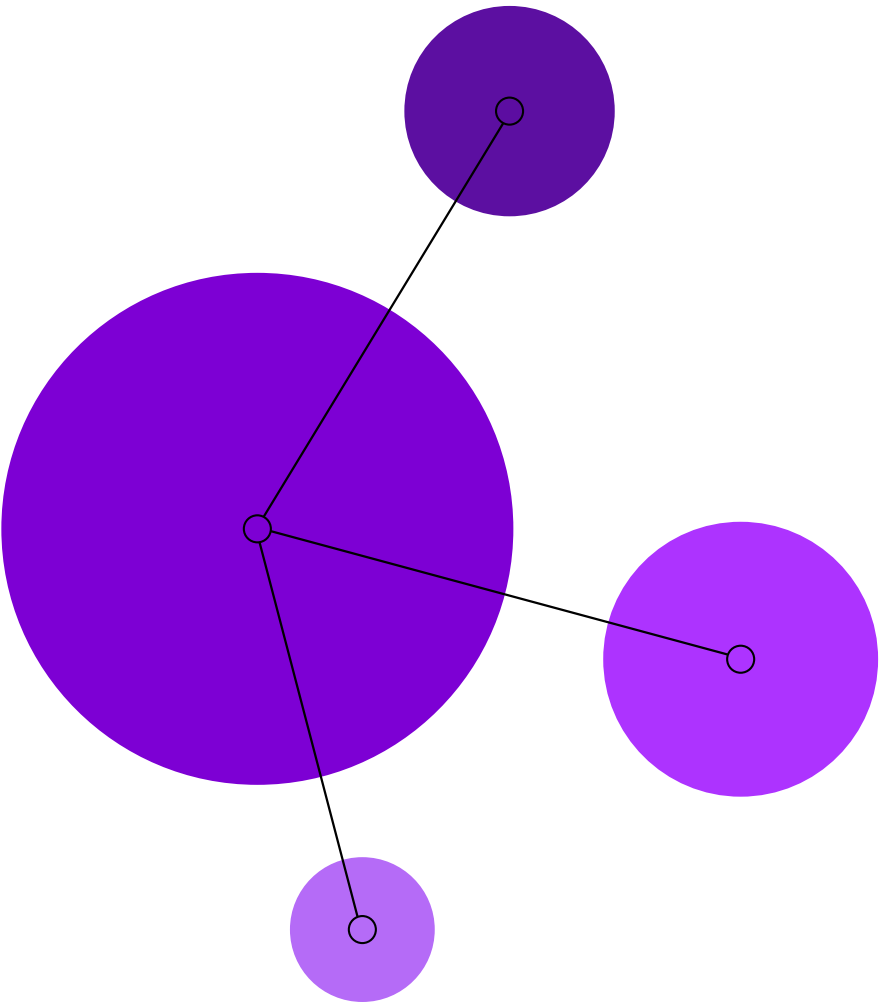
Oncology leads the pipeline

Oncology remains one of the largest pipeline drivers, especially for hematologic cancers such as multiple myeloma, lymphoma, and leukemia.

The pipeline also includes therapies for screenable cancers, which makes closing screening gaps an important readiness priority for employers and plans.

The development pipeline includes therapies for:

- Breast cancer
- Colon cancer
- Leukemia
- Lung cancer
- Lymphoma
- Multiple myeloma
- Prostate cancer





Why immunology and metabolic CGTs could become a major inflection point for employers

According to Truven experts, immunology could become one of the larger CGT impact areas for employers and health plans because several pipeline conditions are more common and more familiar to benefits teams.

Therapies are currently being developed for:

- Crohn's disease
- Psoriasis
- Lupus
- Rheumatoid arthritis
- Multiple sclerosis
- Ulcerative colitis

For employers and health plans, this creates a more practical management challenge: how to evaluate emerging CGTs alongside existing specialty drugs, biosimilars, and condition-management strategies already in place.

The metabolic disease wildcard

The pipeline also includes therapies targeting:

- Type 1 diabetes
- Metabolic syndrome
- Type 2 diabetes
- MASH
- Obesity

Other areas of pipeline growth

Beyond oncology, immunology, and metabolic disease, the CGT pipeline extends even further. Neurology includes therapies in development for conditions such as Duchenne muscular dystrophy, ALS, Huntington's disease, Parkinson's disease, and Alzheimer's disease.

Ophthalmology includes therapies for inherited retinal diseases as well as macular degeneration. While these populations may be smaller, they reinforce the importance of maintaining visibility across the broader pipeline rather than focusing only on today's most common indications.

Readiness takeaway

While many CGTs still focus on rare or highly specific conditions, the pipeline is expanding into areas employers and health plans already manage, including immunology, oncology, ophthalmology, and metabolic disorders. Pipeline monitoring helps employers see potential exposure while there is still time to size it, model it, and plan around it.





PLANNING AREA 3

Financial modeling

The claim is not the first signal

Many employers begin asking questions after a therapy has already been given to a patient. Forward-looking employers ask them earlier. Rather than waiting for treatment, they begin with prevalence.

Start with population exposure.

The first question isn't: What does the therapy cost?

The better question is: How many people in our population have conditions associated with that therapy?

Prevalence turns a broad concern into something employers can size, monitor, and plan around. It establishes the baseline, not the final projection.

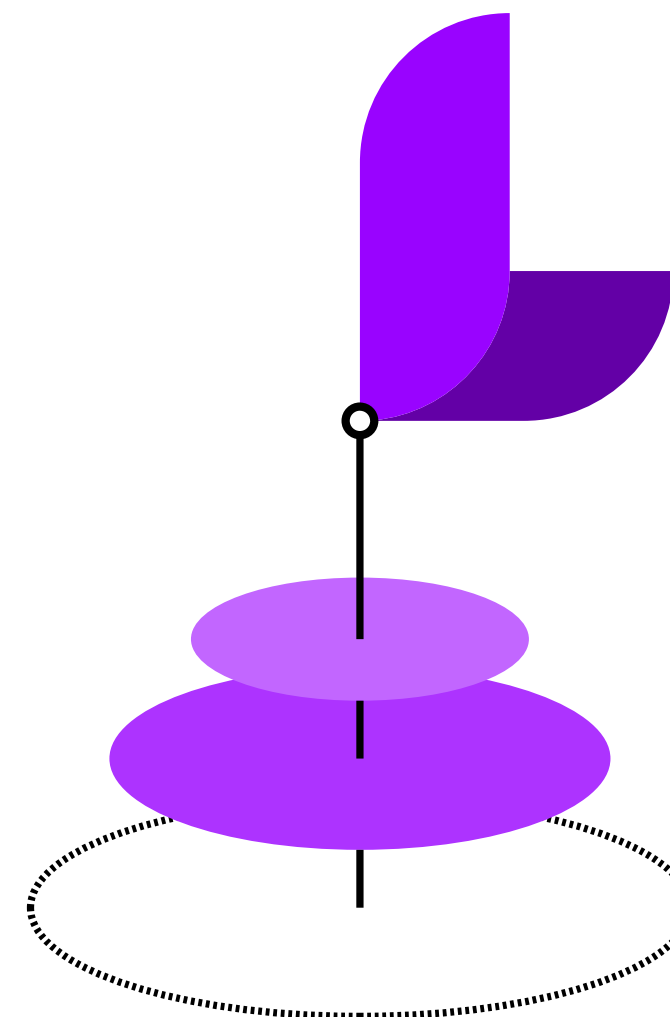
Not every person with a related condition will meet future eligibility criteria or elect treatment. More refined modeling may consider approved indications, medical policy requirements, disease severity, treatment history, utilization, anticipated uptake, and other relevant factors.

Then build scenarios.

Once prevalence is understood, organizations can:

- Layer in pricing assumptions
- Estimate eligibility
- Model adoption scenarios
- Forecast possible financial outcomes

The goal is not to predict every outcome. It is to reduce the number of surprises.





Featured example: Before approval, adoption, or the first claim

The investigational cell therapy Zimislecel for Type 1 diabetes shows how readiness can begin before commercialization. Discussed as a Phase 3 therapy with potential FDA review anticipated in 2027, it offers a useful example of how employers can model exposure before a therapy reaches the market.

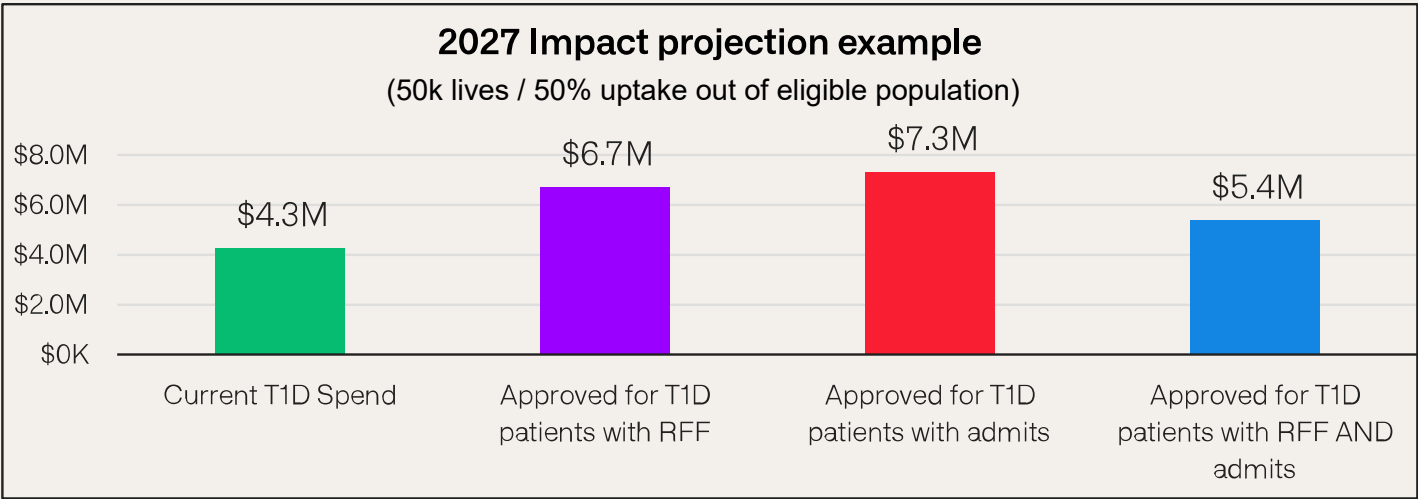
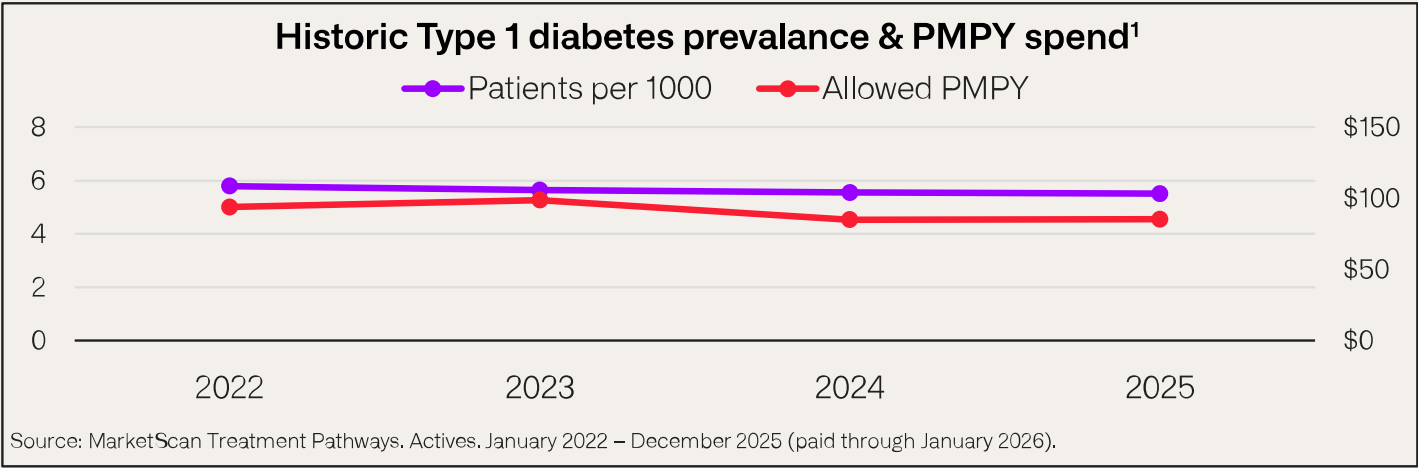
For modeling purposes, a treatment cost assumption of at least \$300,000 per patient was used. Because the treatment involves cell transplantation, patients would be expected to require chronic immunosuppressant therapy to help prevent rejection.

In a 50,000-member plan, projected condition-specific spending increased by an estimated 26% to 71%, depending on the eligibility definition applied and assuming 50% uptake among modeled eligible patients (with eligible patients making up generally less than 10% of all T1D patients). The analysis highlights how eligibility criteria and adoption assumptions can materially affect projected costs and should not be interpreted as a forecast of actual plan experience.

Estimates should be refined as FDA timing, approved indications, pricing, medical policies, and uptake assumptions become clearer.

Readiness takeaway

Financial modeling is not about certainty. It is about narrowing uncertainty before a high-cost claim appears.



Zimislecel is being evaluated for T1D patients with severe hypoglycemic events. Definition of an eligible population may vary based on CMS/FDA direction and health plan medical policy. Eligible populations generally make up less than 10% of all T1D patients. Examples of ways to identify these patients - such as T1D patients with Renal Function Failure (RFF) or evidence of a T1D admission - are included above.



PLANNING AREA 4

Care coordination

A complex journey beyond the treatment itself
This is where CGT readiness is often underestimated. Cell and gene therapy is not a single treatment moment. It can require coordination across benefits, sites of care, clinical follow-up, member support, and vendor partners.

Depending on the therapy and associated long-term risks, regulatory or clinical follow-up may continue for several years and, in some gene therapy circumstances, for up to 15 years.

The therapy is only one part of the journey

Diagnosis through post-therapy follow-up — Up to 2 years in duration



Sources: NCBI/CADTH – Casgevy Journey | St. Jude – SCD Gene Therapy | BMS – CAR-T Treatment Process | Claritas Rx – Patient Journey | NIH Genome.gov – SCD FAQ | ASCO/JCO – CAR-T Hospitalization | Georgia Tech Medtech – CGT Journey



For employers, the coordination challenge extends beyond medical coverage. A CGT case may involve pharmacy and medical benefits, laboratory and imaging services, inpatient and outpatient care, travel support, leave considerations, behavioral-health resources, and caregiver needs. The more fragmented those components are, the harder the journey can become for the member and the benefits team supporting them.

Depending on the therapy, indication, and treatment model, the patient experience may include:

- Diagnostic confirmation
- Genetic testing and eligibility assessment
- Specialist referral
- Pre-treatment work-up
- Prior authorization, coverage review, and possible appeals
- Cell harvesting or apheresis, when applicable
- Cell manufacturing and modification
- Conditioning treatment, when applicable
- Therapy infusion
- Inpatient monitoring
- Outpatient follow-up
- Long-term outcomes tracking

Prior authorization and appeals may introduce delays, while manufacturing requirements can extend the timeline for some therapies by months.

Where employers can strengthen support

Journey point	Readiness consideration
Identification and diagnosis	Care-management outreach and financial-risk assessment
Genetic testing and specialist referral	Navigation support and access to appropriate specialists
Coverage and authorization	Prior authorization support, appeals management, and member communications
Treatment preparation and infusion	Centers of excellence, network strategy, travel support, and site-of-care planning
Recovery and follow up	Readmission monitoring, patient support, and short-term outcomes tracking
Long-term monitoring	Patient enrollment and long-term outcomes tracking

Readiness takeaway

Employers are not just preparing for a therapy. They are preparing for the care journey around it.





PLANNING AREA 5

Funding strategy

Once employers understand population exposure, pipeline movement, possible financial impact, and care coordination needs, they can evaluate funding options with more discipline.

Preparing for what comes next

Truven experts outline several funding and contracting approaches that employers and payers may explore, depending on plan design, risk tolerance, vendor relationships, and contracting strategy:

- **Outcomes-based agreements:** Payment or reimbursement terms are tied to predefined clinical outcomes or durability measures.
- **Installment models:** Spreading costs over time to reduce upfront financial strain.
- **Stop-loss and reinsurance:** Protecting against catastrophic claim exposure.
- **Risk pools:** Distributing financial exposure across multiple organizations.
- **Manufacturer warranties or guarantees:** The manufacturer reimburses or refunds an agreed portion of the cost if specified performance measures are not achieved.

- **Subscription models:** Paying a fixed fee for access to a defined therapy portfolio, treatment site, or coverage arrangement.
- **Third-party contract negotiation and management:** Using specialized partners to support negotiation, outcomes tracking, payment execution, and rebate processing.
- **Combined models:** Using multiple mechanisms, such as risk pooling, stop-loss protection, installment payments, and manufacturer guarantees, to address different components of financial risk.

No single funding model is appropriate for every organization. Availability, contractual terms, member mobility, outcome measurement, stop-loss provisions, regulatory requirements, and administrative capabilities can materially affect how each approach performs.

Readiness takeaway

Funding decisions are stronger when they are grounded in real exposure, not last-minute reaction.



CGT readiness checkpoint

The five planning areas explored throughout this guide are interconnected. Organizations do not need to have every answer today, but this checkpoint can help clarify where planning is strongest and where additional discussion may be needed.

Where employers can strengthen support

Readiness area	Key question	Status
Population risk	Have we assessed CGT-relevant conditions in our population?	☐
Pipeline monitoring	Are we tracking therapies that could affect our workforce?	☐
Financial monitoring	Have we estimated potential exposure scenarios?	☐
Care coordination	Have we evaluated patient journey and support requirements?	☐
Funding strategy	Have we reviewed stop-loss, contracting, and risk-management options?	☐

If any area remains unchecked, these planning prompts may help guide the next discussion:



Assess population and pipeline risk.



Review plan language and coverage processes.



Evaluate care-management and centers of excellence.



Align funding and risk-management strategies.



Educate HR, benefits, and TPA teams.



The claim is the last signal, not the first.

Many organizations view a cell and gene therapy claim as the beginning of the story. In reality, it is often the final signal in a chain of events that began years earlier.

The condition already existed. The patient journey had already begun. The therapy was already progressing through development. The exposure was already visible.

Employers will be better positioned when they can identify potential exposure before a claim reaches the plan. Readiness does not begin when treatment arrives.

It begins when the data shows where risk may be forming.

Ready to move from awareness to planning?
Truven can help employers use data to identify population risk, monitor the pipeline, model potential financial exposure, and prepare benefits strategies before high-cost claims arrive.

Contact Truven today →

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