

Five steps to help you prepare for a data-driven discussion on gene therapy



Gene therapies have life-changing potential, but they can be complicated to understand and sometimes stressful for plans that are making proactive, informed decisions on coverage strategies. We'll guide you to a better understanding of gene and cell therapies by:

- + Looking ahead to what's coming in the pipeline
- + Giving you the support you need to move forward
- + Guiding your organization's leaders in making informed decisions for your plan

See the following pages for **five steps** you can take to prepare for a data-driven discussion on a gene therapy coverage strategy.



[Sign up for the Evernorth® Health Services newsletter](#) to get access to new content and exclusive opportunities to learn more about the gene therapy pipeline.

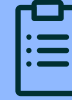


STEP 1

Educate yourself about gene therapies.

With so much complex, highly clinical information out there on gene therapies, we've curated and consolidated some key resources for you.

- + Gene therapies 101: Answers to the most frequently asked gene therapy questions
- + A Brief History of Gene Therapy: How we got here and where drug innovation is going
- + Gene Therapy vs. Cell Therapy: The differences between these types of therapies and why it matters
- + Near-Term Gene and Cell Therapy Pipeline Overview: Review the chart below to understand the speed and scope at which these condition-specific therapies are projected to enter the market



More than 900 gene therapies are in clinical development.*

APPROVED GENE AND CELL THERAPIES AS OF JUNE 2024

2010-2021	2022	2023-2024+
PROVENGE [®] (<i>sipuleucel-T</i>) Prostate cancer	CARVYKTI [®] (<i>ciltacabtagene autoleucel</i>) Multiple myeloma	VYJUVEK [®] (<i>beremagene geperpavec-svdt</i>) Dystrophic epidermolysis
IMLYGIC [®] (<i>talimogene laherparepvec</i>) Melanoma	ZYNTGLO [™] (<i>betibeglogene autotemcel</i>) Beta-thalassemia	ROCTAVIAN [™] (<i>valoctocogene roxaparvec-rvox</i>) Hemophilia A
KYMRIAH [®] (<i>tisagenlecleucel-T</i>) ALL, DLBCL	SKYSONA [™] (<i>elivaldogene autotemcel</i>) Adrenoleukodystrophy	ELEVIDYS [®] (<i>delandistrogene moxeparvec-rokl</i>) Duchenne muscular dystrophy
YESCARTA [®] (<i>axicabtagene ciloleucel</i>) DLBCL	HEMGENIX [®] (<i>etranacogene dezaparvec-drlb</i>) Multiple myeloma	LANTIDRA (<i>donislecel</i>) Transplant
ABECMA [®] (<i>idecabtagene vicleucel</i>) Multiple myeloma	ADSTILADRIN [®] (<i>nadofaragene firadenovec</i>) Bladder cancer	CASGEVY [®] (<i>exagamglogene autotemcel</i>) Sickle cell
LUXTURNA [®] (<i>voretigene neparvec</i>) Retinal dystrophy		LYFGENIA [™] (<i>lovotibeglogene autotemcel</i>) Sickle cell
ZOLGENSMA [®] (<i>onasemnogene abeparvec</i>) SMA		AMTAGVI [™] (<i>lifileucel</i>) Melanoma
TECARTUS [®] (<i>brexucabtagene autoleucel</i>) ALL, MCL		LENMELDY [™] (<i>atidarsagene autotemcel</i>) Metachromatic leukodystrophy
BREYANZI [®] (<i>lisocabtagene maraleucel</i>) DLBCL		OMISIRGE [®] (<i>omidubicel</i>) Transplant
		BEQVEZ [™] (<i>fidanacogene elaparvec-dzkt</i>) Hemophilia B

ALL = Acute lymphoblastic leukemia; DLBCL = Diffuse large B-cell lymphoma; SMA = Spinal muscular atrophy; MCL = Mantle cell lymphoma

THERAPY CLASSES

ONCOLOGY	CARDIOVASCULAR	HEMATOLOGY	RHEUMATOLOGY	TRANSPLANT	METABOLIC DISORDERS
DIABETES	OPHTHALMOLOGY	IMMUNOLOGY	DERMATOLOGY	NEUROLOGY	GENETIC DISORDERS

*Puthumana J, Egilman AC, Ramachandran R, et al. "Early experience with the FDA's regulatory review of novel gene therapies." *BMJ Evidence-Based Medicine* 2022;27:195-198. <https://ebm.bmj.com/content/27/4/1952>



STEP 2

Understand your coverage options and the decisions you'll need to make.

There's a wide spectrum of thoughts regarding coverage strategies for gene therapies. At one end, your plan may choose not to cover gene therapies at all. **While this choice may offer predictability and affordability, it leaves members and their families on their own to cover these costly treatments—sometimes when there are no other or very limited treatment alternatives.**

At the other end, your plan could select a per-member-per-month solution (PMPM). These solutions offer a predictable PMPM cost structure, with more drugs and therapies to be added in the future, and can ensure no copay to the member. **But not all PMPM solutions include protection—via no copay to the member—which can make these therapies unaffordable to families, even when your plan has good intentions in making a coverage decision.**

You can also consider stop-loss-based solutions. However, these may prove to be hazardous to your plan and members because rates are not held in place, so you risk them going up as more drugs enter the market. **And even more concerning, not all stop-loss solutions cover the expense of gene therapies.**

AVAILABLE COVERAGE STRATEGIES FOR GENE THERAPIES

	PMPM solution	Specialty pharmacy pay over time	Traditional stop-loss coverage	Client pays out of pocket	Exclusion of gene therapy from coverage
Access	✓	✓	✓	✓	
Affordability for member	✓*				
Affordability for client	✓	✓	✓		✓
Predictability	✓	✓			✓

*Be sure to check that the PMPM solution you're evaluating offers cost protection for your members.



Not all specialty pharmacies have access to and experience with gene therapies.

Accredo[®] by Evernorth, is the only specialty pharmacy with access to the majority of approved gene replacement therapies to date—and one of the only pharmacies with experience in handling, packaging and shipping these sensitive medications. To deliver a better payer, patient and physician experience, Accredo by Evernorth has implemented innovative operational technologies and a dedicated GeneAXS[®] team to support the needs of gene therapies.



STEP 3

Utilize sophisticated modeling tools to understand the pipeline and its impact to your plan.

Developing a well-informed approach up front is critical for your plan. Although any huge impact may be a couple of years off, if you're not considering your organization's strategy on gene therapy, you could be caught by surprise. Plan-specific forecasting can help you get started. **However, some forecasting methods are more helpful than others as you prepare. A forecasting method with a detailed methodology will best achieve realistic estimates on drug costs for gene therapies in the pipeline.**

Many forecasting tools available today use disease prevalence and incidence data only. Instead, consider a more sophisticated modeling tool that incorporates assumptions around actual utilization and is based on clinical trial information and potential approved indication parameters.

Not every approved gene therapy will be appropriate for every member, especially for those therapies serving larger populations. Each drug needs an evaluation that also considers patient demographics, disease severity, clinical trial data and literature, and client-specific mix. When you utilize these parameters during a forecasting exercise and allow for dynamic client-specific inputs, the output summarizes potential impact at the pipeline drug level while incorporating client-specific detail. In other words, **you'll get a highly customized report tailored to your organization.** See the differences in modeling strategy in the table below.

ACCURATE PREDICTIONS NOW MAY SAVE YOU COSTLY PAIN LATER .

TYPICAL MODELING TOOLS	SOPHISTICATED MODELING TOOLS
<p>Some marketplace estimates are broad, often based purely on disease prevalence.</p>	<p>Sophisticated tools create layers of adjustment to provide a finely tuned estimate of potential gene therapy utilization.</p>
<div style="border: 1px solid black; padding: 10px;"> <div style="background-color: #f0f0f0; padding: 5px; display: flex; align-items: center;"> Disease prevalence </div> <div style="display: flex; flex-wrap: wrap; justify-content: space-around; margin-top: 10px;"> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc; margin: 5px;"></div> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc; margin: 5px;"></div> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc; margin: 5px;"></div> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc; margin: 5px;"></div> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc; margin: 5px;"></div> </div> <div style="background-color: #004a5c; color: white; text-align: center; padding: 5px; margin-top: 10px;"> OUTCOME: BROAD ESTIMATE </div> </div>	<div style="border: 1px solid black; padding: 10px;"> <div style="display: flex; justify-content: space-between; align-items: flex-start; margin-bottom: 10px;"> <div style="display: flex; align-items: center;"> Pipeline evaluation </div> <div style="display: flex; gap: 10px;"> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc;"></div> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc;"></div> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc;"></div> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc;"></div> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc;"></div> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc;"></div> </div> </div> <hr/> <div style="display: flex; justify-content: space-between; align-items: flex-start; margin-bottom: 10px;"> <div style="display: flex; align-items: center;"> Disease prevalence and patient demographics </div> <div style="display: flex; gap: 10px;"> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc;"></div> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc;"></div> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc;"></div> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc;"></div> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc;"></div> </div> </div> <hr/> <div style="display: flex; justify-content: space-between; align-items: flex-start; margin-bottom: 10px;"> <div style="display: flex; align-items: center;"> Clinical trial data and literature </div> <div style="display: flex; gap: 10px;"> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc;"></div> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc;"></div> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc;"></div> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc;"></div> </div> </div> <hr/> <div style="display: flex; justify-content: space-between; align-items: flex-start; margin-bottom: 10px;"> <div style="display: flex; align-items: center;"> Drug-specific requirements </div> <div style="display: flex; gap: 10px;"> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc;"></div> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc;"></div> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc;"></div> </div> </div> <hr/> <div style="display: flex; justify-content: space-between; align-items: flex-start;"> <div style="display: flex; align-items: center;"> Client-specific mix </div> <div style="display: flex; gap: 10px;"> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc;"></div> <div style="width: 20px; height: 20px; border-radius: 50%; background-color: #ccc;"></div> </div> </div> <div style="background-color: #004a5c; color: white; text-align: center; padding: 5px; margin-top: 10px;"> OUTCOME: MORE ACCURATE ESTIMATE </div> </div>

STEP 4



Leverage your PBM or specialty pharmacy account team to help you prepare.

Your PBM or specialty pharmacy account executive can help you forecast prevalence within your plan and prepare for the conversation with your leaders. **Forecasting can be further customized by a specific gene therapy and by use of your plan's medical data.** For example, if you have additional information, such as medical diagnostic numbers for your member population, it will help us fine-tune your forecast even further.

Additionally, there are other decisions to make about gene therapy benefits beyond coverage approach, including which channel (medical or pharmacy) you want to cover each therapy under and what specialty pharmacy (or pharmacies) you want supporting these costly therapies and unique members.





Connect your coverage strategy recommendation to your enterprise strategy, key metrics and goals.

Planning for gene therapy coverage can help you meet your organization's goals. Identify your organization's primary goal and make your recommendation accordingly. Review the goals below to help you get started.



Is your goal better cost management?

Planning now for your approach to gene therapies will help you manage costs more predictably in the future.



Is your goal advancing health care and access to health care?

Making a coverage plan for gene therapies can help support health care technology that can engineer bodies to fight cancer and reverse rare diseases—all while giving hope to so many who didn't have it before.



Is your goal competitive benefits?

In today's competitive workforce, benefit plans are an increasingly important part of compensation considerations. Including gene therapy coverage in your benefit offering can help set your organization apart by illustrating your deep commitment to the health of your employees and their families.



Taking these first steps will help you be better prepared as an organization and set the stage to provide a better experience and important drug access for your members and their loved ones. By using the information available to you—including conversations with our experts—you can begin developing a clear vision for how you want to approach gene therapy coverage.

In the coming years, your plan will need protection from bills for million-dollar therapies while your members will expect these drugs to become more accessible and affordable.

We're here to help you find the right solution for your organization.



Evernorth Embarc Benefit Protection

Embarc Benefit Protection® is a comprehensive program that offers patients with genetic conditions simple, affordable and predictable access to life-changing and potentially curative treatments.

Embarc shields plans from the high costs of gene therapies and improves access to life-saving therapies for members.



Creates cost predictability via a set PMPM price



Connects members with best-in-class providers and care



Provides additional value through an annual surplus refund



Starting January 1, 2025, Embarc will include additional features for the new PMPM fee of \$1.25, including expanded inclusion of gene therapies, wider condition support and the removal of contractual limitations for select gene therapies.*

*Contractual limitations will be removed for ZYNTEGLO™, HEMGENIX® and ROCTAVIAN™ to increase member access.

Learn more about [Evernorth Embarc Benefit Protection](#).