SUSTAINABILITY IN HEALTHCARE: ACTUARIAL APPROACHES FOR FUNDING INNOVATIVE THERAPIES

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SUSTAINABILITY IN HEALTHCARE: ACTUARIAL APPROACHES FOR FUNDING INNOVATIVE THERAPIES

THE PROMISE AND CHALLENGES OF CELL AND GENE THERAPIES (CGTs)

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300 MILLION PEOLE IN THE WORLD SUFFER FROM RARE DISEASES

There are **7000 rare diseases** identified.

No cure exists for **95%** of them.

80% of these diseases have a **genetic cause**.

30% of children with a rare disease **die before age 5.**

Accurate **diagnosis** often takes **4+ years.**

Source: The landscape for rare diseases in 2024 - The Lancet Global Health

THE PROMISE AND CHALLENGES OF CELL AND GENE THERAPIES

Innovative **cellular and human gene therapies (CGTs)** have the **potential to cure** previously incurable conditions and to transform millions of lives. However, these therapies carry a **one-time very high cost** that challenges healthcare budgets and creates new financial risks.

Cellular therapy	Human gene therapy
Includes cellular immunotherapies, cancer vaccines, autologous and allogeneic cells for certain therapeutic indications, hematopoietic stem cells and adult and embryonic stem cells.	Therapies that seek to modify or manipulate the expression of a gene or to alter the biological properties of living cells for therapeutic use.

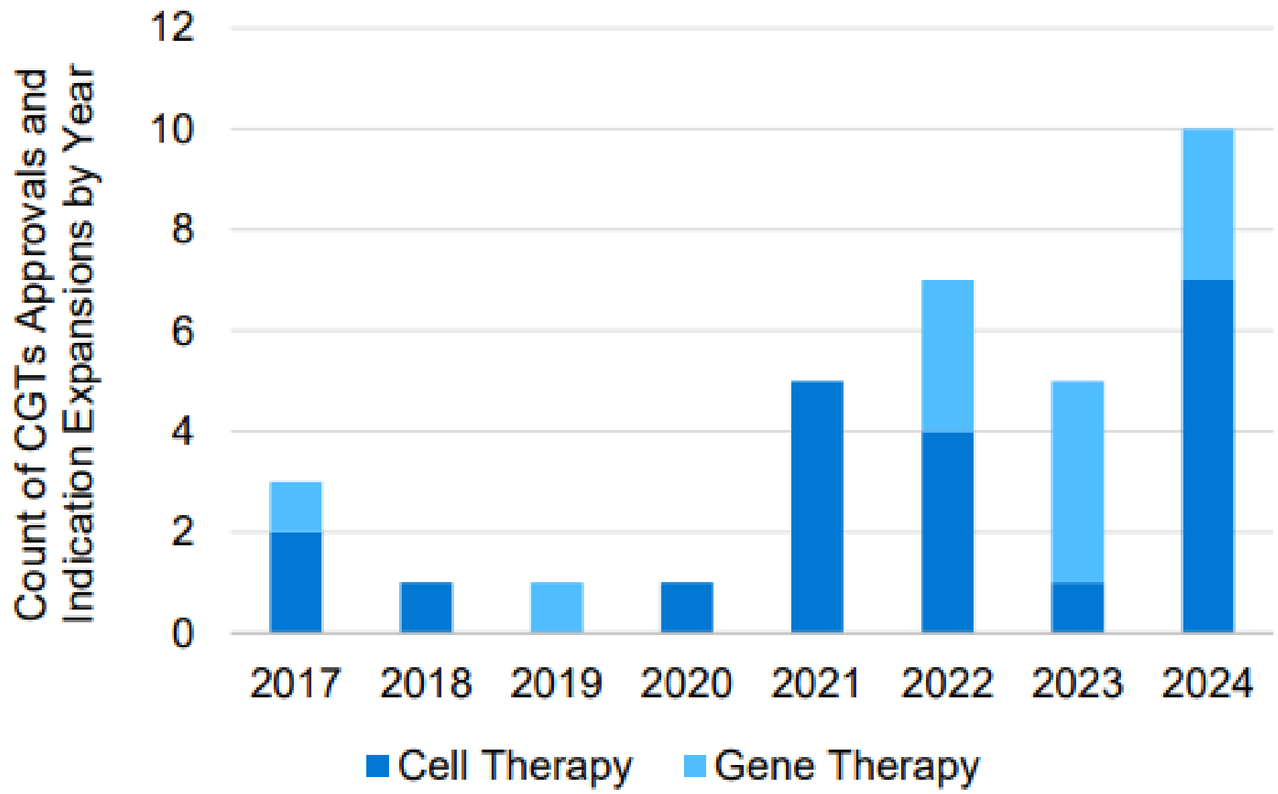
Source: Cellular & Gene Therapy Products | FDA

A growing number of single-administration cell and gene therapies (CGTs) have been approved in the U.S. in recent years.

In addition, several CGTs received approval for new indications, expanding the population potentially eligible for treatment.

Source: Approved Cellular and Gene Therapy Products | FDA

FIGURE 1: FDA-APPROVED SINGLE-ADMINISTRATION CGTS THROUGH SEPTEMBER 2024



Note: Approval counts in the graph include original approvals and indication expansions.

Source: Milliman DNA Gene and Cell Therapy Forecasting; v3.3.0, September 2024 release. Gene therapies include gene therapies and gene editing technology, cell therapies include CAR-T, and one tissue therapy.

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INSURANCE COVERAGE AND PATIENT AFFORDABILITY

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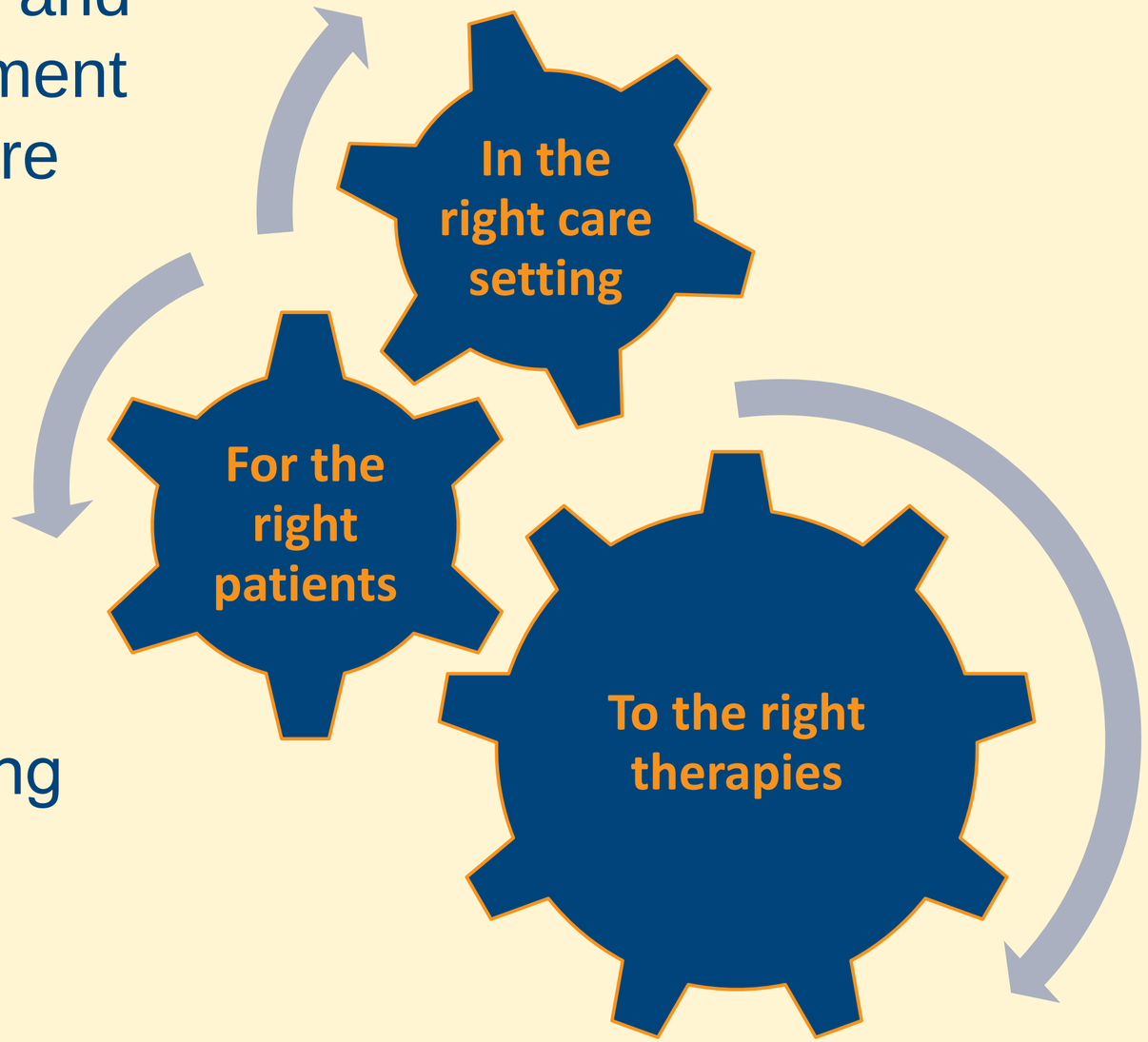
THE ROLE OF THE ACTUARY: BALANCING COVERAGE, REIMBURSEMENT, AND PREMIUM LEVELS

Insurance coverage and patient affordability are critical in the funding of innovative therapies

Without coverage, **investments in innovation** would not happen

Actuaries and clinical professionals play a **key role** by determining insurance **coverage** and **reimbursement** rates for new treatments

Careful benefit design and successful reimbursement negotiations can ensure access…



… while also preserving the sustainability of healthcare systems.

THE ACTUARIAL TOOLKIT: COST CONTAINMENT STRATEGIES FOR PUBLIC AND PRIVATE HEALTHCARE SYSTEMS

FORMULARIES

DISCOUNTS/ REBATES

PRIOR AUTHORIZATION

GENETIC TESTING

SITE OF SERVICE/ SELECT PROVIDERS

MINIMIZING ANTI-SELECTION

REINSURANCE AND RISK POOLING MECHANISMS MAY NOT BE ENOUGH FOR CGTS

Reinsurance mechanisms and risk pooling are key features for the coverage of gene and cell therapies, as **one case can cost more than $1 million USD**.

However, **reinsurance only spreads the risk** without solving the long-term sustainability issue.

Most recently, **reinsurers have started to exclude gene therapies** (and associated diagnoses) from reinsurance policies, leaving insurers at risk.

Source: ICER-Gene-Therapy-White-Paper-030317.pdf

DUE TO THEIR HIGH UPFRONT COSTS, CGTS ARE IDEAL CANDIDATES FOR OUTCOMES-BASED REIMBURSEMENT STRATEGIES

Outcomes-based reimbursement links provider payment directly **to patient outcomes** (and their cost of care)

Outcomes-based reimbursement for CGTs has been **implemented in many countries**, allowing hundreds of patients to **access life-changing therapies** while **providing governments** (and other payers) with minimum **outcomes guarantees**

The **biggest challenges** with outcomes-based contracts are:

- Difficulty and cost of **collecting evidence** on outcomes
- **Defining "success"** and **"failure"** (what will be paid for/trigger a refund)

Source: ICER-Gene-Therapy-White-Paper-030317.pdf

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OTHER CONSIDERATIONS: ASSESSING “VALUE” AND MEETING PATIENTS WHERE THEY ARE

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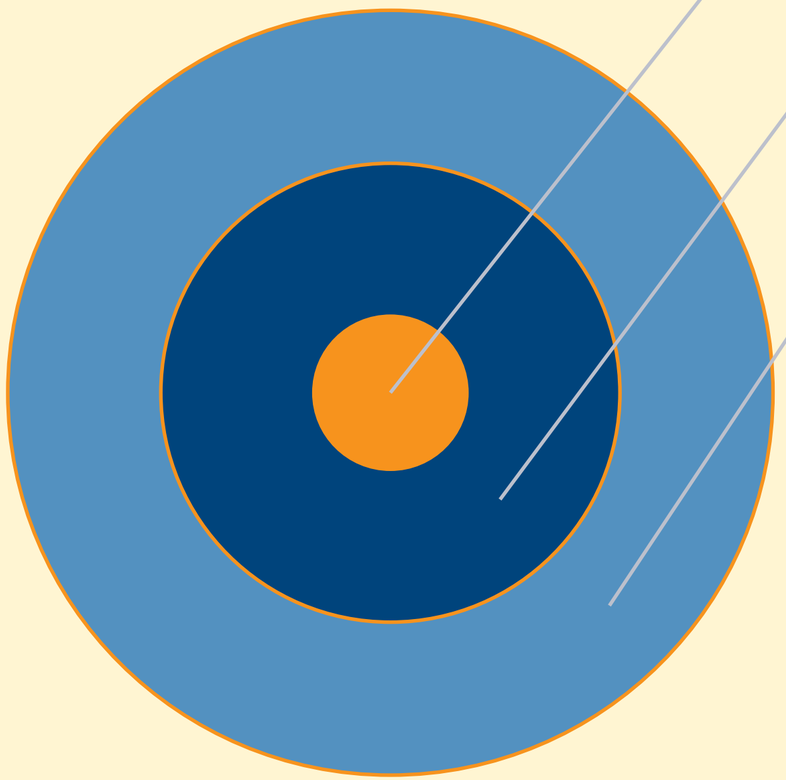
HOW TO DETERMINE THE VALUE OF INNOVATIVE THERAPIES?

Actuaries, economists, and clinicians can help **manage the risks associated with one-time high-cost treatments** that often replace the costs of lifetime maintenance therapies, disease progression, and disability



MEETING PATIENTS WHERE THEY ARE

Even the most innovative therapies must be accessible to patients to have a meaningful impact.

Patient assistance programs and subsidies for patients with low incomes can **help reduce out-of-pocket costs**, ensuring **broader access** to cutting-edge treatments.

This is particularly important in private healthcare systems.

IN SUMMARY

WORLDWIDE, THERE IS AN UNMET NEED FOR INNOVATIVE THERAPIES TO TREAT CURRENTLY INCURABLE GENETIC CONDITIONS

CELL AND GENE THERAPIES OFFER HOPE, BUT CAN PUT THE FINANCIAL SUSTAINABILITY OF HEALTHCARE SYSTEMS AT RISK DUE TO HIGH UPFRONT COSTS

REINSURANCE, RISK POOLING, AND OUTCOMES-BASED REIMBURSEMENT STRATEGIES, ALONG WITH ACTUARIAL TOOLS, ARE HELPING TO BRING INNOVATIVE THERAPIES TO THE APPROPRIATE PATIENTS

ACTUARIES PLAY A KEY ROLE BALANCING PATIENT ACCESS, AFFORDABILITY, REIMBURSEMENT, AND PREMIUM LEVELS, WHILE ASSESSING THE VALUE OF INNOVATIVE THERAPIES

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Thank you! Obrigado!

Questions?

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