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2023 PBMI Annual National CONFERENCE

MANAGEMENT STRATEGIES FOR HIGH-COST CELLULAR AND GENE THERAPIES

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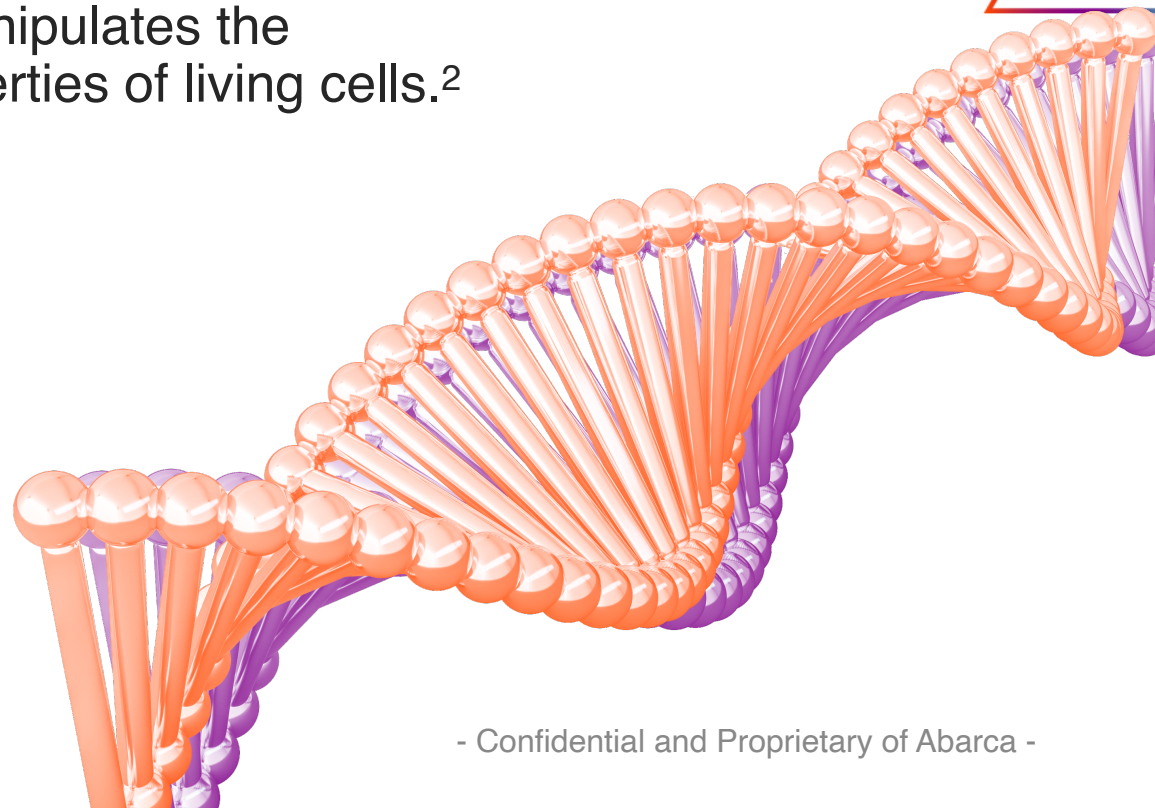
What are Cell and Gene Therapies

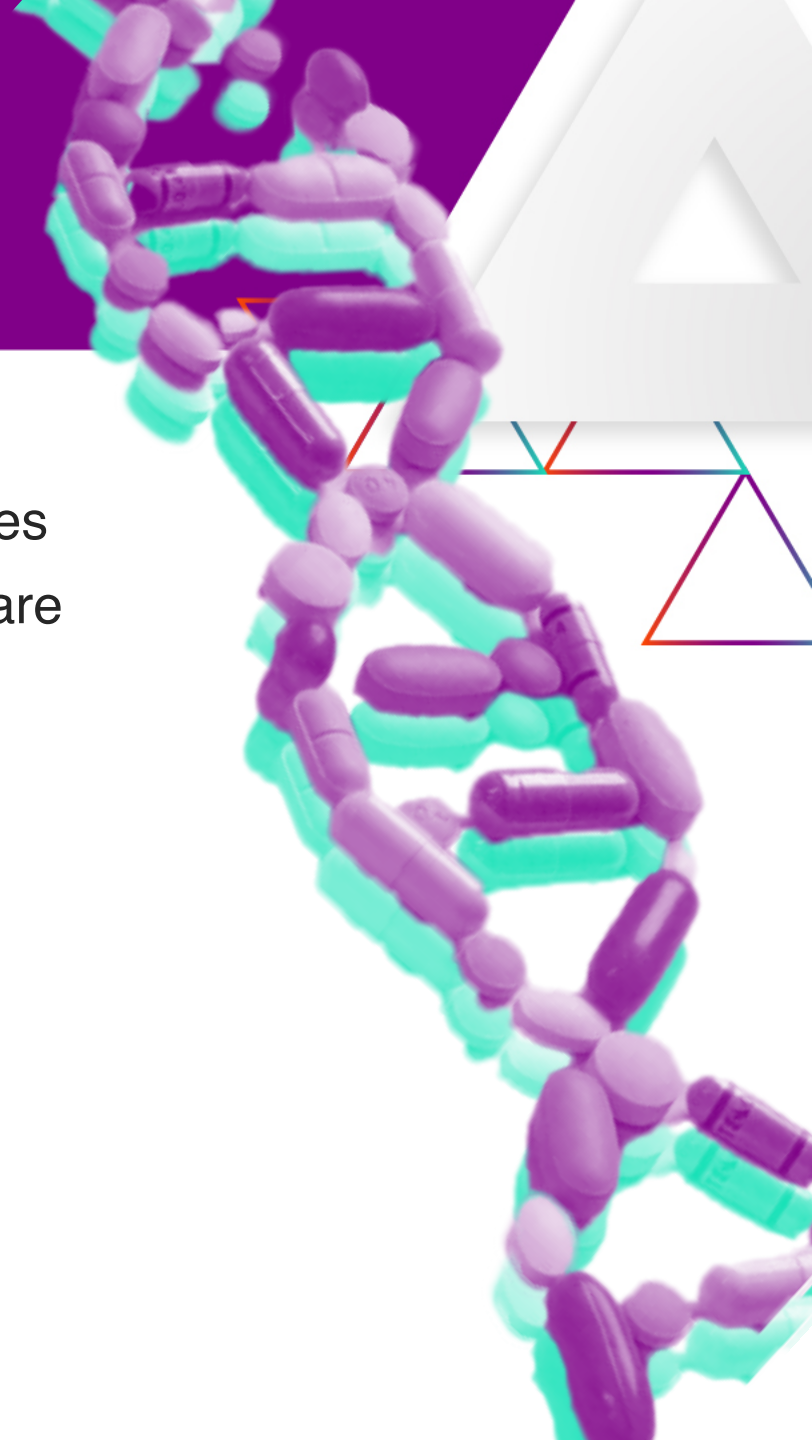
- Cell therapies are therapies that transfer autologous or allogenic cellular material into a patient.[1]
- Gene therapies are therapies that modifies or manipulates the expression of a gene or alters the biological properties of living cells.[2]



1. American Society of Gene and Cell Therapy. *Gene & Cell Therapy FAQs.* (2021). Available online at: https://asgct.org/education/more-resources/gene-and-cell-therapy-faqs (Accessed July 25, 2023)
2. Long Term Follow-Up After Administration of Human Gene Therapy Products; Guidance for Industry, January 2020

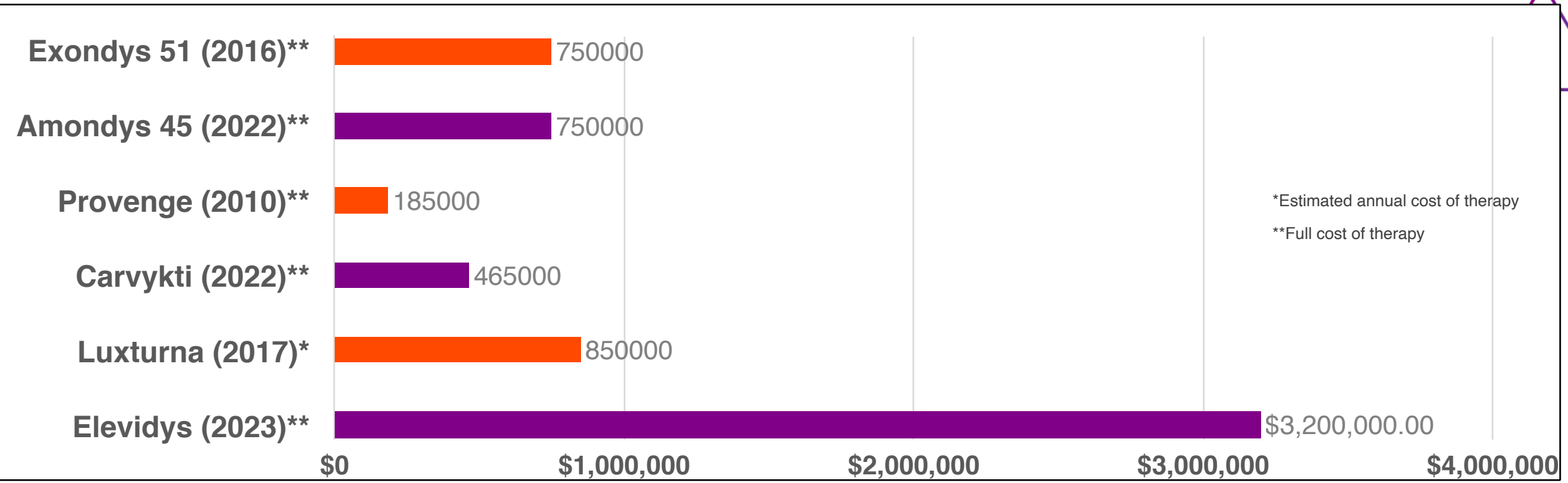
State of the industry

- The drug pipeline is increasingly filled with cell and gene therapies
- These therapies no longer only apply only to rare diseases and are being developed to treat more larger populations
- Half of payors surveyed see gene therapies as a top concern[1]
- Costs can reach $3.5 million per course of treatment



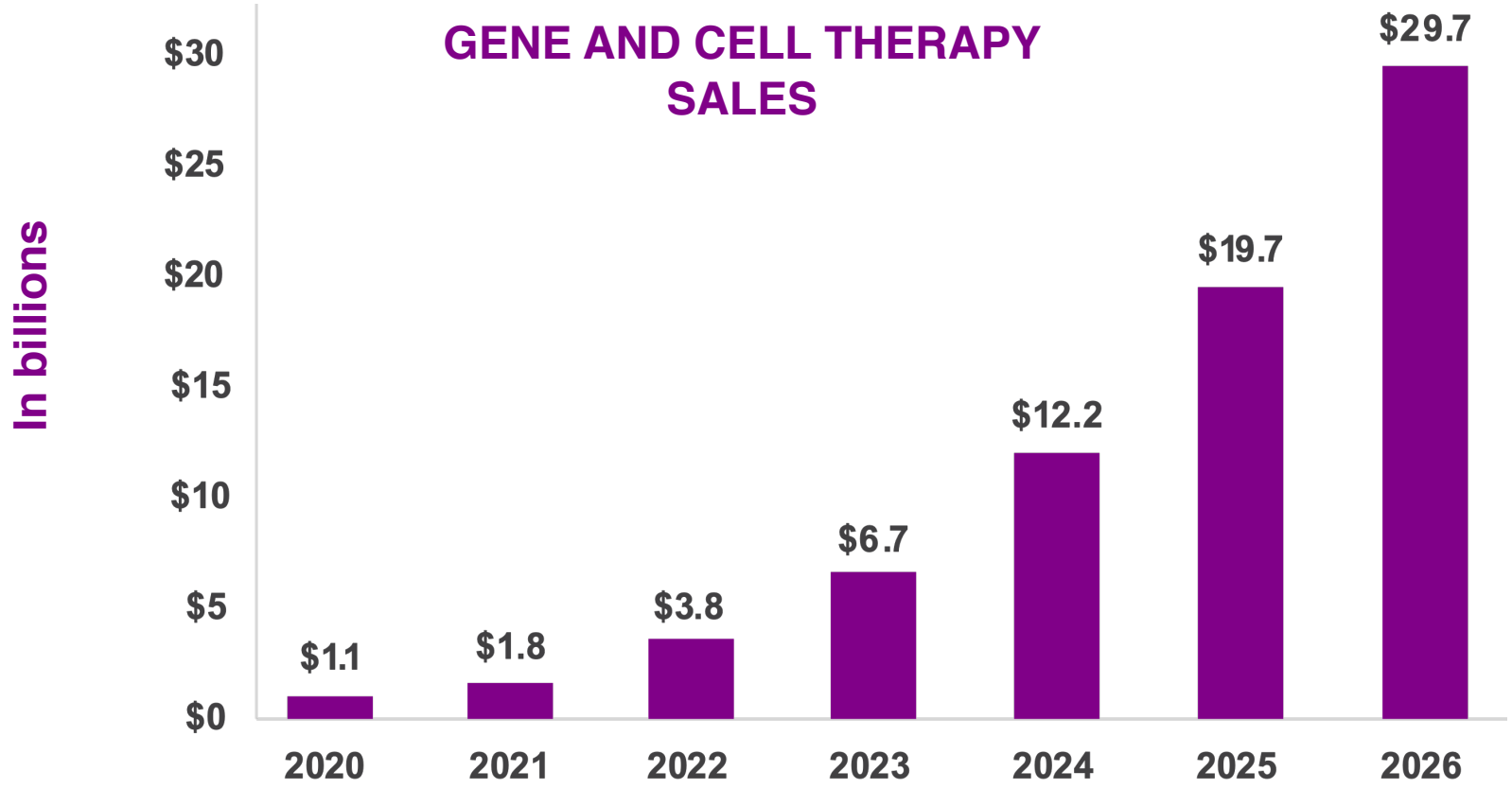
State of the industry:
CGT approvals

Gene and cell therapy approvals first approval and latest approval



IPD Analytics. Antisense Oligonucleotides, https://secure.ipdanalytics.com/User/Pharma/MechanismOfAction/Antisense-oligonucleotide. Accessed 03 Feb. 2023.
IPD Analytics. Small Interfering RNA (siRNA), https://secure.ipdanalytics.com/User/Pharma/MechanismOfAction/Small-interfering-RNA-siRNA. Accessed 03 Feb. 2023.
IPD Analytics. Cellular Immunotherapy, https://secure.ipdanalytics.com/User/Pharma/MechanismOfAction/Cellular-immunotherapy. Accessed 02 Feb. 2023.
IPD Analytics. Gene Therapy, https://secure.ipdanalytics.com/User/Pharma/MechanismOfAction/Gene-therapy. Accessed 02 Feb. 2023.

State of the industry:
Projected CGT Spend



Source: Evaluate Pharma

IPD Analytics. Antisense Oligonucleotides, https://secure.ipdanalytics.com/User/Pharma/MechanismOfAction/Antisense-oligonucleotide. Accessed 03 Feb. 2023.
IPD Analytics. Small Interfering RNA (siRNA), https://secure.ipdanalytics.com/User/Pharma/MechanismOfAction/Small-interfering-RNA-siRNA. Accessed 03 Feb. 2023
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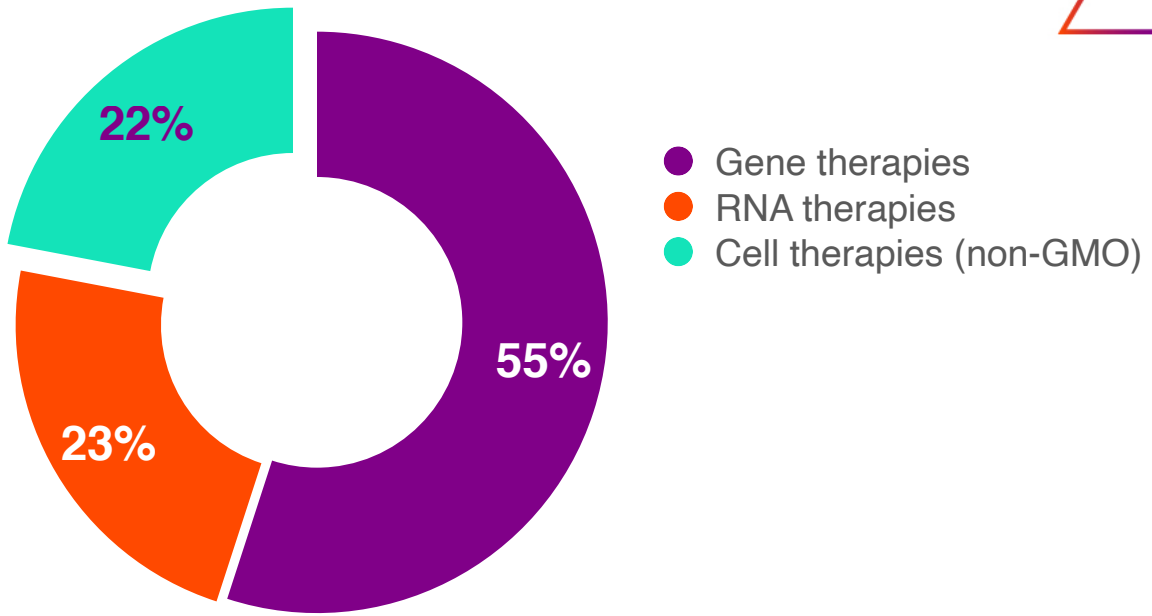
IPD Analytics. Gene Therapy, https://secure.ipdanalytics.com/User/Pharma/MechanismOfAction/Gene-therapy. Accessed 02 Feb. 2023.

State of Industry:
CGT pipeline breakdown

- **2,874 therapies** are in development, ranging from preclinical through pre-registration.
- **55% (2,053)** are gene therapies, including genetically modified cell therapies.
- **22% (827)** are non-genetically modified cell therapies.

Pipeline Therapies by Category

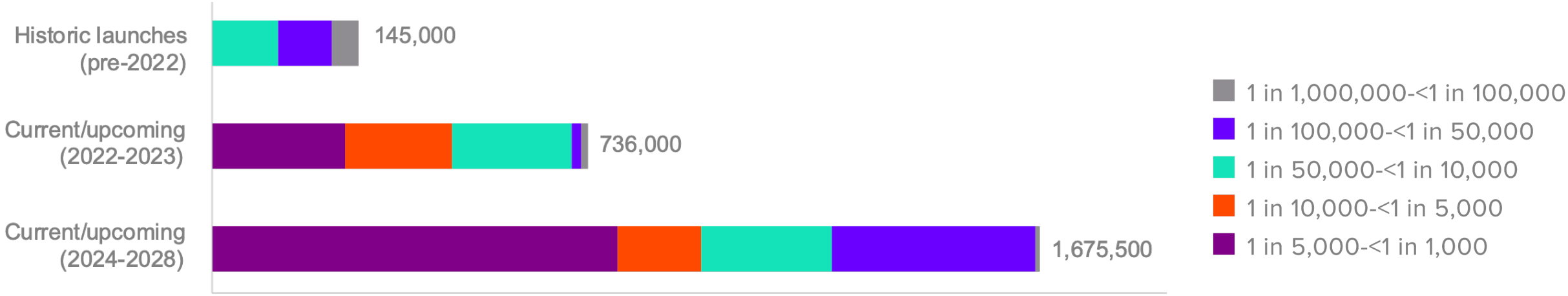


Source: Pharmaprojects I Citeline, January 2023

Expanding on pipeline related to this category/challenge

Rapid Growth Expected

- Increased number of approved cell and gene therapies annually and expanding into conditions with higher incidence (100,000s vs. 100s)
- 500+ gene-based therapies in clinical pipeline as of 2023



Source: Evaluate Pharma, ARM, Oliver Cyman Analysis

What does this mean?

Payers need to implement new strategies to manage these costs and challenges.

- Small plans and employers will be disproportionately impacted
- Who is responsible for members over their lifetime?

Different considerations need to be taken depending on the line of business and payer type

- State Medicaid programs
- Medicare
- Commercial health plans and employer groups

PBMs can help mitigate the impact on health plans.

THE WAY FORWARD

Alternatives to Traditional Full Service Coverage for Employer Groups and Health Plans

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Strategy #1
Stop-Loss and Reinsurance Coverage

Who are the players:

- Self-Insured Employers
- Health Insurers
- Stop-Loss Carriers
- Reinsurance Providers

How Does It Work:

- Self-insured employers secure stop-loss coverage to protect against individual catastrophic claims and/or overall risk exposure
  - When threshold is reached stop-loss carrier covers any excess costs
- Stop-loss carriers write policies annually and incorporate various methods to offer coverage
- Reinsurance providers provide protection to stop-loss and health insurance carriers

Strategy #1
Stop-Loss and Reinsurance Coverage

Pros

- Stop-loss coverage of CGT claims necessary to allow employers to maintain self-insured status
- Self-insured employers can maintain transparency to payments and ownership of data while being protected from catastrophic financial events

Cons

- With increasing numbers of qualifying patients for CGT, stop-loss coverage grows more expensive with more caveats and exclusions
- Requires underwriters/analysts at every level monitoring pipeline, tracking new treatments and new indications to estimate risk. Refining understanding patient level indicators necessary for best predicting risk.
- Subsequent thresholds may change when employer exposed to CGT claims in current benefit year. Subsequent premiums may be untenable driving groups away from self-insured status

Strategy #2

Arrangement with Vertically Integrated Health Insurers/PBM

Who are the players:

- Self-Insured Employers
- Health plans
- Vertically-integrated health insurers/PBMs

How Does It Work:

- Self-insured employers and health plans secure an arrangement with a vertically integrated health insurers/PBMS such as
  - Carving out coverage of CGTs to larger vertically integrated health insurers
  - Securing stop-loss coverage by larger integrated health insurers
- Larger vertically integrated health insurers/PBMs delegated responsibility for establishing authorization criteria, reviewing and determining coverage requests, provider network contracting, and risk analytics/underwriting

Strategy #2

Arrangement with Vertically Integrated Health Insurers/PBM

Pros

- Delegates coverage and/or risk of catastrophic financial claims to larger insurers better equipped to spread risk
- Can lean on expertise in larger insurer for analysis and risk evaluation
- Access established provider networks to administer and support CGT

Cons

- Limited options of vertically integrated insurers/ PBMs exist for employer groups and smaller health plans
- Employer groups and health plans lose transparency and access to data
- Can encourage further market share concentration in the health insurer/PBM industry

Strategy #3

Delegating to Third Party Consultants with Stand-Alone Provider Networks

Who are the players:

- Employer Groups and Health Plans
- Stop-Loss and Reinsurance carriers
- PBMs
- Third-party CGT network and clinical consultants
- Pharmaceutical manufactures

How Does It Work:

- Third party consultant providing educational, guidance, forecasting, underwriting tools, and contracted provider networks
- Stop-Loss and reinsurance carriers leaning on 3rd party to develop CGT coverage products and support annual underwriting/analysis; third party can connect to carriers
- Employer groups/health plans contracting with third party to access clinical criteria, clinical consultation (e.g. P&T support), and provider network
- Manufacturers share drug cost risk when outcomes do not meet expectations

Strategy #3

Delegating to Third Party Consultants with Stand-Alone Provider Networks

Pros

- Gain access to subject matter experts with resources to support underwriting efforts at employer group and health plans
- Gain access to focused CGT hospital/provider network
- Maintain transparency and access to data
- Can be paired with value-based contracting with manufacturers to offset cost when outcomes are inadequate

Cons

- Requires additional coordination between existing health plan and third party network provider

Considerations When Deciding on Solution

- Current or future health insurer and/or PBM
  - Vertically integrated vs. traditional independent insurers/PBMs

- Ability to establish coordination, reporting, and data sharing between multiple parties (health plan, employer group, third party network provider, providers, etc.)

- Access to and transparency of claims data and contracts

- Sophistication of internal underwriting and analytic teams

Comparing strategies

	Stop-Loss/Reinsurance	Vertically Integrated Insurer/PBM	Third Party Network Provider and Consultant
Employer group considerations	• Offers protection of self-funded status • Coverage subject to change as more patients qualify • Analytic support needed w/in employer group	• Most likely requires pre-existing delegation of pharmacy benefit to integrated PBM • Additional coordination by the employer group and their health plan if pharmacy benefit is carved out to the PBM	• Can supplement for lack of expertise and resources internally or with health plan • Gain access to a dedicated/ focused network of providers for CGT • Requires coordination with health plan partner
Health plan considerations	• Can fill gaps in existing reinsurance exclusions • Allows for management of provider network if expertise exists in house	• Most likely requires pre-existing delegation of pharmacy benefit to integrated PBM	• Can supplement for lack of expertise and resources • Gain access to a dedicated/ focused network of providers for CGT • Can be bundled with reinsurance carrier

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Any questions?

Thank You