The State of Delaware

Gene and Cellular Therapy Landscape – GHIP Programs

SEBC Combined Subcommittee Meeting

July 15, 2024

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Overview of Cell and Gene Therapy (CGT)

Type of therapy	How they work	Examples
Cell therapy	Transfers specific **cells** (can be a patient's own cells, or donor cells) into a patient to prevent or treat disease	Stem cell transplants
Gene therapy	Adds **genetic material** into a cell to prevent or treat disease, usually in one of the following ways:	
	• Brings 'instructions' to a cell to make the specific gene that is not working today	Adstiladrin, Elevidys, Hemgenix, Luxturna, Roctavian, Skysona, Vyjuvek, Zolgensma, Zynteglo
	• Prevents activity of a gene already present in the cell	CRISPR technology
	• Corrects select pieces of the gene inside the cell	CRISPR technology
Gene-modified cell therapy	Combination of gene and cell therapy, removes cells and genetically modifies them before transferring them back to a patient	CAR T-cell therapy TIL therapy (Amtagvi) Casgevy, Lyfgenia
Immunotherapy	Enhances a person's immune system to fight cancer	CAR T-cell therapy TIL therapy (Amtagvi) Cancer drugs: Keytruda, Opdivo

Key Considerations

- Genetic testing should be required (and covered by the medical plan) to ensure a patient has the exact gene variation targeted by the drug
- Positive/Curative clinical outcomes are NOT guaranteed
- There is the risk of an immune response to the 'foreign' material in the body
- Long-term effects of gene editing are still unknown

Sources: American Society of Gene + Cell Therapy: https://www.asgct.org/education/different-approaches. Cancer.org: https://www.cancer.org/cancer/managing-cancer/treatment-types/immunotherapy/what-is-immunotherapy.html

CGT approvals through 2024

- **33 currently approved therapies by the FDA**
- **10-20 therapies expected to be approved every year starting in 2025**

2017	2019	2020	2021	2022	2023	2024
Kymriah® ($475k) - cancer **Luxturna®** ($850k) - eye condition **Yescarta®** ($373k) - cancer	**Zolgensma®** ($2.2M) - spinal muscular atrophy	**Tecartus™** ($373k) - cancer	**Abecma®** ($420k) – cancer **Breyanzi®** ($410k) - cancer	**Adstiladrin®** ($260k) - cancer **Carvykti®** ($470k) - cancer **Hemgenix®** ($3.5M) - Hemophilia B **Skysona®** ($3.0M) - neurological disorder **Zynteglo®** ($2.8M) - blood disorder	**Casgevy™** ($2.2M) - sickle cell **Elevidys®** ($3.2M) - Duchenne Muscular Dystrophy **Lyfgenia™** ($3.1M) - sickle cell **Roctavian®** ($2.9M) - Hemophilia A **Vyjuvek®** ($500k/yr) - skin condition	**Amtagvi™** ($515K) – cancer **Lenmeldy™ (**$4.25M) – metachromatic leukodystrophy **Beqvez™** ($3.5M) – Hemophilia B

Estimated cost (AWP) in parentheses

- Estimated cost (AWP) is for the drug cost only. CAR-T treatments like Kymriah and Yescarta may exceed $1M after processing and administration
  - According to one industry report, in 2021 the median CAR-T drug claim was $411,711 and ranged from $275,244 to $2,101,934. The median cost for the total episode was $610,999, ranging from $358,980 to $2,235,658
  - Carrum Health offers a COE program for CAR-T that pre-negotiates the additional fees into one ‘bundled’ cost to lower plan costs
- CAR-T treatments are available in select treatment centers, and Zolgensma is available for buy-and-bill exclusively through Orsini and Accredo (an ESI/Cigna company)
- The vast majority of CGTs are given only once (i.e., Zynteglo, Hemgenix), however, a small number of locally acting gene therapies can be dosed regularly (i.e., Adstiladrin, Vyjuvek)

Source: Food and Drug Administration. Approved Cellular and Gene Therapy Products. Accessed on January 4, 2023, at: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products

PBM and Health Plan-driven offerings relevant to the State

- Plan sponsors are looking at solutions offered by their PBMs and medical carriers to address these high-cost therapies
- These programs are intended to help mitigate the costs of CGT medications
- Chart below reflects currently available programs offered by current GHIP vendor partners only; other PBMs and medical carriers offer their own programs for existing customers

Company	Program	Products currently covered	Components
Aetna	Aetna Institutes™ Gene-Based, Cellular and Other Innovative Therapies (“GCIT”)	Luxturna, Zolgensma, Zynteglo, Spinraza, Skysona, Hemgenix, Amtagvi, Casgevy, Elevidys, Lyfgenia, Qalsody[1], Roctavian	No additional fee for Aetna medical clients. Drugs will be steered for administration at a facility within Aetna’s designated network, with case-specific pricing negotiations and travel/lodging support for members.
CVS Health	CVS Financial Protection	Luxturna, Zolgensma, Zynteglo, Skysona, Hemgenix	Offers three individual stop-loss (ISL) levels: $30K, $250K, $400K. Cost will be quoted at client request. Existing members won’t be lasered. NOT offered with existing stop loss in place.
Synergie Medication Collective (Highmark)	Gene+	Casgevy, Elevidys, Hemgenix, Lyfgenia, Roctavian, Vyjuvek, Zolgensma, Zynteglo	No lasering with covered existing diagnoses. Refunds obtained from manufacturers if therapies don’t deliver expected outcomes.

1 Qalsody is not technically a CGT, but is included in Aetna’s GCIT network as it is another innovative therapy.

Overview of CGT coverage for the GHIP

- Both medical carriers currently have utilization management protocols in place to ensure the clinical appropriateness of these services
  - Includes site-of-care steerage to the most clinically appropriate place of service, with prior authorization required
- Both medical carriers have designated centers of excellence (COEs) for CGT treatment
- CGT is currently covered under the GHIP for Highmark and Aetna non-Medicare plan participants; Medicare covers some CGT, usually under Part B
  - Utilization of these therapies under the GHIP is very low; there are no members currently using under Aetna or Highmark
  - Future utilization of at least one additional CGT may be possible: Hemgenix for hemophilia (approved by FDA on 11/22/2022, with price tag of $3.5M for a one-time administration that replaces ongoing treatment)

Aetna's GCIT network

- Effective for the GHIP July 1, 2023
- Available for the following CGT services:
  - ***Luxturna***: diseases of the retina can cause night blindness, light sensitivity, progressive vision loss
  - ***Spinraza*** and ***Zolgensma***: spinal muscular atrophy
  - ***Amtagvi***: skin cancer
  - ***Casgevy*** and ***Lyfgenia***: sickle cell
  - ***Elevidys***: Duchenne Muscular Dystrophy
  - ***Hemgenix*** and ***Roctavian***: hemophilia
  - ***Skysona***: neurological disorder
  - ***Zynteglo***: blood disorder
- GCIT Network consists of over 200 centers of excellence across the country delivering high quality care
  - Includes providers in Delaware or surrounding states such as Nemours Children's Hospital Delaware and Children's Hospital of Philadelphia
  - Note that participating providers in Aetna's GCIT network may not offer all GCIT services

Aetna's GCIT Network *reduces total cost of care* for the GHIP and its Aetna members, with the following *trade-off*: requires members to *use narrower network* of high-quality providers to access selected CGT at a *lower total cost*

Source: https://www.aetna.com/content/dam/aetna/pdfs/health-care-professionals/GCIT-designated-providers.pdf.

Aetna’s GCIT network (continued)

- Discounted pricing negotiated with CGT manufacturers
  - Savings achieved by Aetna negotiation with providers to maintain reimbursement for these therapies at cost with no mark-up and improved quality of care

- Aetna clinical care coordination team supports members through entire process
  - Integrated with Aetna One Advisor care management program (in place today)
  - Including member assistance with travel plans and cost
    - Travel and lodging reimbursement is available for patients and a companion who must travel over 100 miles from the member’s residence
    - This benefit is the same as the travel and lodging allowance that is available to GHIP members when using Aetna’s Institutes of Excellence/Quality networks

- No additional cost or administrative fees associated with adopting the GCIT network

Synergie Medication Collective for Highmark members

- Established by a group of Blue Cross and Blue Shield affiliated companies to improve affordability and access to high-cost therapies
- Is a medication group purchasing organization jointly owned by all Blue plans, leveraging greater scale to drive strategic negotiations for cell and gene therapies
- Synergie is offering the following solutions to help Blue plans and their group customers manage cell and gene therapy utilization and spend:
  - Gene+ Outcomes Program – available today for Highmark Delaware members
  - Cell & Gene+ Patient Navigation Program – future capability

Synergie Gene+ Outcomes Program has been effective since 1/1/2024;
Synergie Cell & Gene+ Patient Navigation Program will be available starting January 2025.

Source: Highmark

Synergie Gene+ Outcomes Program

- Combines value-based contracts and comprehensive data tracking to offer investment protection, allowing clinically appropriate access to novel gene therapies while limiting associated financial risk
- Streamlined processes to capture and track comprehensive outcomes data over time, regardless of if member stays with plan or group
  - Evio Pharmacy Solutions is the value-based administrator of the program, building data collection portal and analyzing clinical and claims data to determine if contract payment threshold achieved
  - Contracts will refund Highmark and ASO customers if drug does not provide the expected outcomes in a member as guaranteed per specific contract
- Highmark will continue to create and administer its own medical drug policies and medical UM process, with Synergie providing specific policy criteria requirements to qualify for contracts
- Live as of January 1, 2024 for all clients who have these in-scope gene therapies covered through Highmark's medical drug benefit

Source: Highmark

Synergie Cell & Gene+ Patient Navigation Program

- Provides robust, national network of providers that meet cost and quality standards for providing complex cell and gene therapies to help members receive the best care at the most affordable cost
- Program is powered Synergie vendor, Emerging Therapy Solutions (ETS), who has contracted a robust, quality-based network of providers and facilities nationwide with decades of expertise negotiating nationwide transplant networks with Centers of Excellence
- Highmark can compare ETS-contracted rates for in-scope therapies to Highmark's direct rates and out-of-area rates through BlueCard (via local Blues plan) and realize savings for plan and group customers if ETS-contracted rates are lower
- Member experience with their physician and chosen treatment facility does not change - program will be running behind the scenes to secure best rates and reduce total cost of care associated with these high-cost therapies
- Highmark finalizing enrollment terms and conditions and filings with state regulators (as applicable)

Source: Highmark

Stop Loss Insurance

- Spreads the risk of incurring high costs associated with gene therapies across a large number of payers
- WTW's market research indicates that between 17%-29% of organizations surveyed during 2023-2024 confirmed that they have stop loss/reinsurance coverage that addresses gene therapies
- National clients with more than 1,000 employees have been interested in evaluating stop loss solutions through the insurance carriers and have gone as far as getting quotes, but the total cost of stop loss insurance that covers gene therapy has been cost prohibitive for most organizations
- PBMs have also started offering a stop loss product specifically for cell and gene therapies administered through the prescription drug benefit
  - WTW has a limited number of clients that have adopted these products, which include the CVS Financial Protection Program for CGT
    - Focus for most clients has been on addressing CGT that are administered through the medical plan
  - This program offers three individual stop-loss levels: $30K, $250K, $400K
  - Cost will be quoted at client request
  - Existing members won't be lasered (i.e., excluded from coverage under this program)
  - Program is NOT offered to plan sponsors with existing stop loss coverage in place

Next Steps

- Would Subcommittee members like the SBO and WTW to continue exploring the opportunity of adding stop loss coverage?