

The State of Delaware

Gene and Cellular Therapy Landscape – Update

SEBC Health Policy & Planning Subcommittee Meeting

September 16, 2024

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Context for today's discussion

- At the July 2024 Combined Subcommittee meeting, WTW presented an overview of cell and gene therapy (CGT), including coverage provisions within the GHIP and other offerings within the State's medical carriers and PBM to manage the cost of these therapies
- Subcommittee members had several questions about the availability of offerings in the broader market to manage the cost of these therapies
- Today's discussion will focus on addressing those questions

Refresher: PBM and Health Plan-driven offerings relevant to the State

- The July 2024 meeting materials included an overview of the programs currently offered by the State’s medical and PBM partners
- These programs are intended to help mitigate the costs of CGT medications
- Most plan sponsors look to their medical carriers and PBMs for assistance with managing these high-cost therapies
- 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	<i>In place for the GHIP today.</i> 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	<i>Not in place for the GHIP today.</i> Offers three individual stop-loss (ISL) 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). NOT offered with existing stop loss in place.
Synergie Medication Collective (Highmark)	Gene+ Outcomes Program Cell & Gene+ Patient Navigation Program	Casgevy, Elevidys, Hemgenix, Lyfgenia, Roctavian, Vyjuvek, Zolgensma, Zynteglo	<i>Gene+ Outcomes Program: In place for the GHIP today.</i> No lasering with covered existing diagnoses. Refunds obtained from manufacturers if therapies don’t deliver expected outcomes. <i>Cell & Gene+ Patient Navigation Program: Available beginning in January 2025.</i> Program works behind-the-scenes to secure best rates (Highmark, BlueCard out-of-area or third-party contracted through Emerging Therapy Solutions) and reduce total cost of care associated with these therapies.

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

Stop loss insurance

Question: Should the State consider purchasing stop loss insurance to cover the potential liability for CGTs?

Answer:

- WTW doesn't recommend purchasing stop loss insurance that specifically covers CGTs only.
- While CGTs are very high cost, they remain rarely utilized; in general, a \$2.5M Zolgensma claim is far less likely to occur compared to a \$2.5M premature newborn claim, which is exponentially more likely to occur.
- The GHIP has no members currently using these therapies.
- Cost for stop loss products specifically for CGTs varies by insurer; typical range in the market is \$1 - \$3 PMPM.
 - Based on this range, the estimated annual cost for the GHIP would range between \$2M and \$5M.

Stop loss insurance

Question: Should the State consider purchasing stop loss insurance to cover the potential liability for CGTs?

Answer (continued):

- The State should consider its risk philosophy with respect to any decision to procure stop loss insurance for protection against high-cost claims (not exclusive to CGTs only).
- Implementing stop loss insurance is a trade-off between accepting a greater level of financial predictability in monthly medical/Rx claims with the promise of higher spend overall due to additional insured premium payments.
- Based on WTW's benchmark data on stop loss premium rates, the State could expect to pay between \$5M and \$13M+ for this coverage¹, depending on the individual stop loss deductible selected (i.e., \$750k to \$1.5M in this example).
- There is potential for some of this additional cost to be offset by reimbursements for claims above the individual stop loss deductible, but those reimbursements are not likely to be large or frequent at these higher stop loss deductible thresholds.

¹ Range is also based on GHIP enrollment as of August 2024.

Organizations that have stop loss insurance for CGTs

Question: The July 2024 Combined Subcommittee meeting materials indicated that WTW's market research found that between 17%-29% of organizations surveyed during 2023-2024 confirmed that they have stop loss/reinsurance coverage that addresses gene therapies. Can further details be provided about the organizations that responded affirmatively to this question or the demographics of their employee populations?

Answer:

- This statistic was sourced from WTW's 2023 Best Practices in Healthcare Survey, which included responses from over 450 organizations with 100 or more employees
- The organizations captured by the statistic above are fairly evenly distributed across industries, size and for-profit status
- Out of these organizations, the most common characteristics are:
 - Manufacturing as the top industry represented (25% of total)
 - Organizations with 1,000 – 4,999 employees as the most common employer size (43% of total)
 - For-profit, publicly traded organizations as the most common status (49% of total)
- These results closely follow the break-down of the same characteristics across all survey respondents
- Additional details about the employee demographics for the organizations captured by the statistic above are not available

Alternative payment models and contracting arrangements

Question: Are there other alternative payment models or contracting arrangements for CGTs?

Answer:

- While this is still an evolving area of the market for CGTs, the following are some examples of alternative payment models and other contracting arrangements that are emerging in this space. These have not been widely adopted and some have limited availability. WTW will continue to keep the State updated as new developments occur.

Alternative payment models	Benefits	Considerations
Amortized loan products	<ul style="list-style-type: none"> Amortizes total amount over a multi-year loan that is portable (travels with the member) and can be paid down over time using manufacturer warranties leading to lower overall costs 	<ul style="list-style-type: none"> Drug coverage must be consistent across member's plans for the portability functionality to work (one known company offering this is Octaviant Financial) Questionable legal capability to carry payment for prior services to a future employer
Installment Payment Plan	<ul style="list-style-type: none"> Mitigate the budget impact to payors in any given year 	<ul style="list-style-type: none"> Though the cost is spread over an extended period, the payor is still responsible for the entire cost at the time of administration regardless of whether the patient will continue to be covered under the payor's plan for the entire payment period Example: Available through CVS Specialty pharmacy for select FDA-approved gene therapy products
Value-Based Contracting a.k.a. Outcomes-Based Agreements	<ul style="list-style-type: none"> Manufacturers refund a portion of the cost if the therapy fails to achieve and sustain expected clinical outcomes, effectively linking cost to efficacy 	<ul style="list-style-type: none"> Requires long-term patient monitoring and engagement, which is further complicated if the patient changes medical carriers over time May not be available if the therapy is provided through certain distributors (e.g., a self-insured PBM arrangement) CMS innovation center is testing an outcomes-based arrangement approach for Medicaid <ul style="list-style-type: none"> Negotiating with manufacturers that choose to participate, initial focus is sickle cell Individual state Medicaid agencies can choose to enter into agreements based on CMS' negotiations starting January 2025

Next steps

- Subcommittee members to consider whether to recommend the SEBC consider further evaluation of additional cost-management options for CGTs
- WTW and the SBO will continue monitoring this item on an annual basis and report any significant changes in the market to this Subcommittee