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Managing risks related to gene and cell therapies for self-insured employers with stop-loss coverage

Opportunities and considerations for multiyear contracting

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Self-insured employers and stop-loss carriers should be planning for the wave of gene and cell therapies expected to enter the market in the next decade. A multiyear contracting strategy may mitigate some financial and performance risks.

Gene and cell therapies are beginning to enter the market, and they are ushering in a new era of medicine. Unlike most traditional therapies, gene and cell therapies typically have a short or one-time treatment administration and are anticipated to provide long-term clinical benefits. Currently, there are only a few gene and cell therapies approved in the United States, and they are all indicated for rare diseases. From a self-insured employer's perspective, gene and cell therapies may appear to share characteristics with other risks that are often managed with stop-loss coverage. However, it may be prudent to challenge the hypothesis that stop-loss coverage will be cost-effective in mitigating the financial risk associated with gene and cell therapies. Additionally, some manufacturers are signaling interest in providing multiyear performance-based payment contracts to better align the mismatch of long-term clinical benefits with the large up-front costs.[1] Self-insured employers and stop-loss carriers can benefit from multiyear performance-based payment arrangements, but the current healthcare system presents challenges to these long-term arrangements.

The goal of this paper is to introduce why self-insured employers with stop-loss coverage may still be exposed to some of the costs of gene and cell therapies, to explore considerations and a potential imbalance of financial risk for the self-insured employer and stop-loss carrier when implementing a multiyear performance-based payment arrangement, and to discuss potential ways to efficiently contract between the self-insured employer, stop-loss carrier, and manufacturer to better share the financial risk.

Stop-loss coverage for self-insured employers

Self-insured employers are responsible for covering the healthcare costs incurred by their participating employees and dependents during a plan year. Approximately 60% of self-insured employers purchase stop-loss insurance to limit their liabilities for low-probability, high-cost medical events incurred during the year.[2] Stop-loss coverage is intended to be used as a traditional insurance product—a safety net for unanticipated high-cost claims events. However, not all patients who may be indicated for a particular gene or cell therapy are unknown to the stop-loss carrier. For example, patients with hemophilia may already be identified by the stop-loss carrier due to their current factor replacement product consumption. In these cases, stop-loss carriers have mechanisms to shift the risk of costs incurred by known high-risk members back to the employers.

Stop-loss carriers collect per member per month (PMPM) premiums from their employer clients. Stop-loss carriers generally underwrite a covered population annually, and so any identifiable risks can be included in the premium rate. The premiums may increase for all employer clients in anticipation of the utilization of gene and cell therapies. Alternately, a stop-loss carrier could increase the deductible for a covered member who is expected to have higher costs (a practice known as lasering). In the case of a patient who is known to have a medical condition for which a gene or cell therapy has become available, the stop-loss carrier could feasibly raise the deductible for that patient to include the cost of the drug and administration. For this reason, treatment costs are more likely to be mitigated by stop-loss for patients who are diagnosed with conditions that require immediate treatment upon diagnosis as opposed to patients with chronic conditions or who are on longer-term treatment regimens. Other tactics to maintain competitive stop-loss premiums could be to offer lower coverage levels for gene and cell therapies (perhaps sharing costs at 50%

[1] Walker, J. (January 8, 2019). Biotech proposes paying for pricey drugs by installment. Wall Street Journal. Retrieved December 26, 2019, from https://www.wsj.com/articles/biotech-proposes-paying-for-pricey-drugs-by-installment-11546952520.

[2] Kaiser Family Foundation (October 3, 2018). 2018 Employer Health Benefits Survey. Retrieved December 26, 2019, from https://www.kff.org/report-section/2018-employer-health-benefits-survey-section-10-plan-funding/.

rather than 100% for these types of claims over the specific deductible), to more narrowly define the conditions and patients eligible for gene and cell therapy stop-loss coverage, or to recommend employers purchase coverage for gene and cell therapies through separate carve-out policies or third-party insurers.

Multiyear payment contracts

Multiyear payment arrangements spread the cost of the therapy over time, which smooths the unexpected cost burden of gene and cell therapies for the payer. These multiyear contracts may also include performance-based components. A benefit of this type of contract is that subsequent payments are only due if the therapy performs as expected, based on predefined outcomes or biomarkers; thus, the manufacturer assumes some or all of the risk related to the lack of efficacy or durability of the therapy. Additional potential benefits of contracting with a manufacturer for a multiyear performance-based payment contract is that the manufacturer may handle patient tracking, provider reimbursement, and remove the uncertainty of supply-chain markups.

There may be an imbalance of financial risk between the self-insured employer and stop-loss carrier for gene and cell therapies.

Multiyear contracts have the potential to mitigate some of the financial and clinical risks associated with gene and cell therapies for self-insured employers. However, each contract would be unique because of the various manufacturers, disease areas, therapy performance measures, and contract terms. Additionally, the long-term clinical benefits and contract terms conflict with the short-term nature of the annual healthcare coverage plan year. Because multiyear performance-based payment contracts are a new concept, most self-insured employers may not understand how to initiate, negotiate, and execute them with manufacturers. Ideally, self-insured employers should be able to benefit from multiyear performance-based payment contracts without needing to be highly informed or dramatically change the way they manage their healthcare benefits.

If a self-insured employer enters into a multiyear performance-based payment contract for gene or cell therapy, there are implications to both the employer and the stop-loss carrier providing secondary coverage. Depending on the contract terms of the multiyear contract, there may be an imbalance of financial risk between the self-insured employer and stop-loss carrier. The example below illustrates how costs may be shared between a self-insured employer and the stop-loss carrier for two different multiyear contract types. The examples below include paying annual installments for four years, contingent on continued success of the therapy (shown in Figure 1), and paying up-front for the therapy with a potential rebate or recovery paid back to the payer if the therapy fails during the four-year contract period (shown in Figure 2).

In Figures 1 and 2, we assume the following regarding the costs:

- The gene or cell therapy is incurred at the beginning of Year 1. It is priced at $1.5 million (between the initial list prices of Luxturna® (voretigene neparvovec-rzyl)[3,4] and Zolgensma® (onasemnogene abeparvovec-xioi)[5,6]), and it is paid up-front or in four annual installments of $375,000 per year. Both are contingent on continued "successful treatment."
- $500,000 in other medical costs are incurred and paid in the first year. Other costs include the direct medical costs associated with pretreatment, therapy administration, and patient monitoring, and the costs associated with adverse events of the therapy.[7,8]
- For simplicity, no additional costs ($0) are incurred in prior or subsequent years for the patient.

We assume the following regarding the stop-loss agreement:

- The specific deductible is $200,000 for the treated member.
- The employer is responsible for 100% of costs up to the deductible, and 0% of costs above the deductible.
- The contract is a 24/12 agreement, i.e., the contract covers claims that were paid in the plan year and incurred during the plan year or in the 12 months prior to the plan year.

In the example of the four-year installment payment option (Figure 1) with a 24/12 stop-loss contract, the self-insured employer is responsible for the majority of the costs ($1.15 million, or approximately 58% of the gross costs). If the self-insured employer entered into a four-year installment payment contract, only the costs incurred and paid in the contract period would be eligible for stop-loss coverage. For example, in the case of a 24/12 agreement, the contractual terms regarding

[3] Luxturna® (voretigene neparvovec-rzyl) is a registered trademark of Spark Therapeutics, Inc.

[4] At $850,000. See Tirrell, M. (January 3, 2018). A US drugmaker offers to cure rare blindness for $850,000. CNBC. Retrieved December 26, 2019, from https://www.cnbc.com/2018/01/03/spark-therapeutics-luxturna-gene-therapy-will-cost-about-850000.html.

[5] Zolgensma® (onasemnogene abeparvovec-xioi) is a registered trademark of AveXis, Inc.

[6] At $2.125 million. See Novartis (May 24, 2019). AveXis announces innovative Zolgensma® gene therapy access programs for U.S. payers and families. News release. Retrieved December 26, 2019, from https://www.novartis.com/news/media-releases/avexis-announces-innovative-zolgensma-gene-therapy-access-programs-us-payers-and-families.

[7] ICER (February 15, 2018). Chimeric Antigen Receptor T-Cell Therapy for B-Cell Cancers: Effectiveness and Value. Evidence Report. Retrieved December 26, 2019, from https://icer-review.org/wp-content/uploads/2017/07/ICER_CAR_T_Evidence_Report_021518.pdf.

[8] Zimmerman, M et al. Value in Health, Volume 22, Issue 2, 161-167.

incurred and paid dates preclude the stop-loss carrier from sharing in the costs paid beyond the second year since because the therapy was incurred at the beginning of Year 1.

FIGURE 1: FOUR-YEAR INSTALLMENT PAYMENT METHOD (IN MILLIONS)

CLAIM COSTS (MILLIONS)	YEAR 1	YEAR 2	YEAR 3	YEAR 4	TOTAL
Gene/cell therapy	$0.375	$0.375	$0.375	$0.375	$1.5
Other medical	$0.5	$0	$0	$0	$0.5
Gross cost ($M)	**$0.875**	**$0.375**	**$0.375**	**$0.375**	**$2.0**
SELF-INSURED EMPLOYER	**YEAR 1**	**YEAR 2**	**YEAR 3**	**YEAR 4**	**TOTAL**
Deductible	$0.2	$0.2	$0	$0	$0.4
0% above deductible	$0	$0	$0	$0	$0
Costs outside 24/12 contract period	$0	$0	$0.375	$0.375	$0.75
Employer's responsibility ($M)	**$0.2**	**$0.2**	**$0.375**	**$0.375**	**$1.15**
STOP-LOSS CARRIER	**YEAR 1**	**YEAR 2**	**YEAR 3**	**YEAR 4**	**TOTAL**
100% above deductible	$0.675	$0.175	$0	$0	$0.85
Stop-loss carrier's responsibility ($M)	**$0.675**	**$0.175**	**$0**	**$0**	**$0.85**

FIGURE 2: UP-FRONT PAYMENT METHOD (IN MILLIONS)

CLAIM COSTS (MILLIONS)	YEAR 1	YEAR 2	YEAR 3	YEAR 4	TOTAL
Gene/cell therapy	$1.5	$0	$0	$0	$1.5
Other medical	$0.5	$0	$0	$0	$0.5
Gross cost ($M)	**$2.0**	**$0**	**$0**	**$0**	**$2.0**
SELF-INSURED EMPLOYER	**YEAR 1**	**YEAR 2**	**YEAR 3**	**YEAR 4**	**TOTAL**
Deductible	$0.2	$0	$0	$0	$0.2
0% above deductible	$0	$0	$0	$0	$0
Costs outside 24/12 contract period	$0	$0	$0	$0	$0
Employer's responsibility ($M)	**$0.2**	**$0**	**$0**	**$0**	**$0.2**
STOP-LOSS CARRIER	**YEAR 1**	**YEAR 2**	**YEAR 3**	**YEAR 4**	**TOTAL**
100% above deductible	$1.8	$0	$0	$0	$1.8
Stop-loss carrier's responsibility ($M)	**$1.8**	**$0**	**$0**	**$0**	**$1.8**

Note: The "up-front payment" method could also include a performance aspect in the form of a rebate paid by the manufacturer.

Alternately, the stop-loss carrier could laser the patient by raising the specific deductible in later years to avoid sharing in the costs. If the annual payments were lower than the specific deductible, then the self-insured employer would be responsible for the total cost of the therapy.

In the example of the up-front payment with potential rebate option (Figure 2), the stop-loss carrier is responsible for the majority of the costs related to the therapy ($1.8 million, or approximately 90% of the gross costs), because the costs exceed the specific deductible and are all incurred and paid in the contract year. This gives the self-insured employer incentive to front-load the cost of the therapy rather than pay in installments over multiple years. Additionally, if the self-insured employer holds the multiyear contract with the manufacturer and the drug does not perform as expected—meaning a rebate payment is paid from the manufacturer back to the self-insured employer—then the stop-loss carrier may not share in the rebate. In fact, the stop-loss carrier may not even be aware that there is a performance-based payment contract in place. If the therapy failed early in the contract period, it is feasible that the self-insured employer could receive a rebate from the manufacturer that is greater than the total amount paid by the employer because stop-loss covered the majority of the costs. The imbalance of financial risk in these two examples illustrates that there is a need for self-insured employers and stop-loss carriers to work together to find a solution that benefits both stakeholders.

Efficiently contract to share the financial and performance risks of gene and cell therapies

Ideally, the manufacturer, self-insured employer, and stop-loss carrier could benefit from the smoothing and stabilizing of costs afforded by a multiyear payment stream. This section will explore potential ways to efficiently contract between the self-insured employer, stop-loss carrier, and manufacturer regarding multiyear performance-based payment contracts.

Contracting directly between self-insured employers and manufacturers is challenging due to the large number of plans and potential manufacturers. The U.S. Department of Labor (DOL) reported there were 27,800 group health plans that were self-insured or partially self-insured in the United States in 2016,[9] and the Alliance for Regenerative Medicine reported that there are 155 U.S.-based companies actively developing these

[9] DOL (March 2019). Report to Congress: Annual Report on Self-Insured Group Health Plans. Retrieved December 26, 2019, from https://www.dol.gov/sites/dolgov/files/EBSA/researchers/statistics/retirement-bulletins/annual-report-on-self-insured-group-health-plans-2019.pdf.

therapies.[10] Even if only a handful of these manufacturers offer multiyear performance-based payment contracts, it is unlikely that many self-insured employers would know how to initiate, negotiate, execute, and manage them. Stop-loss carriers may be in a unique position to serve as liaisons between their self-insured clients and the manufacturers that offer multiyear performance-based payment contracts.

The majority of self-insured employers are insured by relatively few stop-loss carriers. The top 10 stop-loss carriers represent $14 billion in stop-loss premium[11] out of an estimated total stop-loss premium of $21 billion.[12] Each stop-loss carrier pools the experience of multiple self-insured employers, which increases the probability of experiencing a claim for gene or cell therapy. If manufacturers contracted directly with these stop-loss carriers, a large block of self-insured employers could benefit directly or indirectly from the partnerships. One example would be through an offering of carve-out insurance. The stop-loss carrier would provide 100% coverage for the therapies and related treatment, and in turn could negotiate reimbursement terms with the manufacturer and other providers. Holding the multiyear performance-based payments contract means the stop-loss carrier (in this case, acting as the primary insurer) would benefit from the spreading of payments over time—which could make setting premium rates for participating self-insured employers more predictable—and also allows the stop-loss carrier to share in the performance aspect of the contract if the therapy does not meet predefined performance expectations. The participating self-insured employers would only be responsible for a PMPM premium cost, which would stabilize their expenses related to gene and cell therapies.

Another alternative would be for the stop-loss carrier to continue in the role of traditional stop-loss (i.e., coverage above the specific deductible), but facilitate an agreement between the self-insured employer and the manufacturer. In this situation, the stop-loss carrier would see the request for preapproval for a gene or cell therapy by a member of one of their self-insured clients, and could extend a multiyear contract to the employer that had been pre-negotiated with the manufacturer. This scenario may require modification of current stop-loss policies to allow for stop-loss payments beyond the original policy term. This approach has several benefits:

- The party responsible for a majority of the claim cost (self-insured employer if the patient was lasered, otherwise the stop-loss carrier) would benefit from the spreading of payments over time.
- Employers would have access to the multiyear performance-based contract without proactively seeking and negotiating the contract with the manufacturer.
- Employers could cede the administrative burden of managing these unique contracts to a stop-loss carrier that will have a larger volume of these claims.
- The stop-loss carrier would benefit from knowledge of the contract terms, increasing the likelihood it would benefit from the performance aspect of the agreement.

In both scenarios described above, certain considerations would need to be evaluated if a patient or employer leaves the stop-loss carrier before the contract timeframe is over. Tracking patients and clinical outcomes is complex and could have legal implications if the patient is no longer a covered member. One solution would be to remove the performance aspect of the contract upon a patient ceasing coverage, such that the agreement becomes only a financial mechanism of spreading the remaining payments over time. Another solution would be for the self-insured employer to pay the net present value of the expected value of the remaining installment payments.

Regardless of the complexities of multiyear performance-based payment arrangements, there is an opportunity for self-insured employers to benefit from these types of contracts and for stop-loss carriers to competitively manage this new category of therapies by offering particular services, specialty coverage, or carve-out insurance to help stabilize gene and cell therapy costs for self-insured employer clients. Self-insured employers and stop-loss carriers should be aware of the potential financial implications related to gene and cell therapies and be open to discussing ways to efficiently contract between the self-insured employer, stop-loss carrier, and manufacturer to better share the financial and performance risks related to these therapies.

[10] Alliance for Regenerative Medicine (February 2019). Regenerative Medicine and Rare Disease. Retrieved December 26, 2019, from http://alliancerm.org/wp-content/uploads/2019/02/Rare-Disease-Report-2019-FINAL.pdf.

[11] MyHealthGuide Newsletter, November 11, 2019, edition.

[12] Bachler, R. & Sipprell, D. (April 2019). Health Plan Participation in the Employer Stop-Loss Market. Milliman White Paper. Retrieved December 26, 2019, from http://assets.milliman.com/ektron/health-plan-participation-stop-loss-market.pdf.

Caveats

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