GuyCarpenter

GENE AND CELL THERAPIES: DEALING WITH RISING COVERAGE COSTS

Gene and cell therapies are an amazing innovation and boon to society. They are also a possible economic-risk freight train coming right at the healthcare industry. There is no doubt that these innovations, in addition to offering hope and wellness for thousands, will be positive forces for carriers and providers. The challenge is who pays for it, in that the healthcare industry isn't one cohesive body with internally fungible economics, but rather a massive and complex value chain with winners and losers for every disruption to the status quo.

By changing the timing and duration of the treatments for conditions targeted by gene and cell therapies, different groups realize the increased benefits and costs. Risk takers are scrambling to develop strategies to pay for these expensive new therapies, align with beneficiaries and ensure the fulfillment of hoped-for benefits. Innovation in risk financing has been slow. While this hasn't been penalized so far, the pace will need to accelerate to accommodate the robust pipeline of therapies in development. Guy Carpenter is working with Marsh, Oliver Wyman and Mercer to anticipate market developments and guide clients toward successful strategies.

Nearly all reinsurers currently provide coverage for all (non-experimental) approved and pipeline gene and cell therapies within standard excess of loss (XoL) reinsurance contracts. With the continued approval of new high-cost gene and cell therapies, reinsurers may begin excluding coverage or pricing coverage such that a market-clearing price is not achieved. This is very difficult to sustain, as the number of eligible patients and the cost of therapies continues to escalate.

- There are currently 22 therapies approved by the Food and Drug Administration (FDA), with the most costly ranging from hundreds of thousands of dollars to over USD 2 million[1]—for the therapy alone. Additional medical claims associated with treatment can further increase the overall cost.
- Group and individual carriers (47%) account for the largest share of total cost, but Medicare (33%) and Medicaid (20%) payers will bear costs as well.
- Some states have carved out high-cost gene and cell therapies (e.g., Zolgensma) from Medicaid payers.
- As of first quarter 2021, there are nearly 3,500 therapies in preclinical and clinical development, with 77 therapies in Phase III clinical trials.[2]
- By 2025, an estimated 95,000 individuals will be eligible for gene or cell therapy at an estimated cost to healthcare payers of USD 25 billion.[3]

Year	Patients Eligible	Total Cost (Annual—USD Billions)	Medicare (USD Billions)	Medicaid (USD Billions)	Private
2021	44,000	11.0	4.6	1.7	4.8
2022	75,000	15.5	6.3	2.4	6.8
2023	88,500	19.5	7.2	3.4	9.0
2024	93,000	22.5	7.9	4.1	10.5
2025	95,000	25.0	8.2	4.9	11.9

Source: Marsh & McLennan Agency (MMA) Rx Solutions

1. https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/approved-cellular-and-gene-therapy-products
2. https://pharmaintelligence.informa.com/~/media/informa-shop-window/pharma/2021/files/infographic/asgct_pharma_intelligence_quarterly_report_q1_2021.pdf
3. Based on research conducted by Marsh & McLennan Agency (MMA) Rx Solutions

Anticipating Future Risk Transfer Landscape for Gene and Cell Therapies

Replacing the current risk-transfer market will require development of novel approaches addressing multiple facets of risk for gene and cell therapies, including:

Structured/financial reinsurance to spread cost over time

- Traditional backstops in the stop-loss and reinsurance markets may begin to withdraw as early as 2023 renewals.
- Employers may consider sponsoring captive insurers that pre-fund costs for gene and cell therapies. In addition, more advanced risk-sharing agreements can be built with stakeholders across the value chain, from pharmaceutical manufacturers, to pharmacy benefit managers (PBMs), providers and employers.
- New specialized reinsurance entities may arise that can effectively manage even the extremely high costs of cell and gene therapies, similar to what has occurred in the organ transplant space.

Value-based care contracts aligning drug cost with medical outcomes

- Outcomes-based payment provides the opportunity to move from high upfront costs to paying for actual achieved performance.
- This helps spread costs over multiple budget years, offering financial protection against treatment failure. It also helps lower overall therapy costs and ensures clinically appropriate access.

Pooling arrangements to spread risk among multiple parties (payers, employers, reinsurers, government)

- When risks are difficult for individual entities to understand and quantify, they frequently become underestimated. When underestimation leads to underinsurance–carrying potential societal impacts–public-private partnerships can help respond.
- This can work in several ways: a government-managed pooling mechanism funded by carrier assessments may be one approach, or governments may provide funds that private insurers pay back over time.

Portability options protecting payers from members who receive a therapy and subsequently move plans.

- A portable patient registry helps ensure that payers receive the maximum value from their outcomes-based agreements.

How Guy Carpenter is Approaching This Developing Risk

One single solution will not fit all. Our broad industry relationships help risk bearers identify the best partners to help **prepare, manage and finance** gene and cell therapies.

Range of cost and care management services available through third-party service providers

PREPARE

Predictive analytics

- Determine ground-up, per-member per-month (PMPM) costs by population to help ascertain true bottom-line expenditures.
- Pharmacogenomics–using a person's unique genetic makeup to determine his or her response to gene and cell therapies to help ensure the best outcomes.
- Provide ratemaking and pricing support.

Pipeline analysis

- Therapy pipeline by stage, including approval pipeline, to get the best current picture of how the gene and cell therapy environment is evolving.
- Examine estimated utilization, prevalence and cost metrics by therapy.

MANAGE

Care management

- Tracking patient outcomes and clinical data to help evaluate appropriateness, safety and efficacy of therapies, including prior authorization review.
- Review orphan drug billing charges, and audit claims to help ensure payments are efficient and appropriate.

Plan design & evaluation

- COE and network development to help optimize care and improve outcomes and cost.
- Formulary and plan benefits to help clarify eligible therapies and how they would be covered.
- Negotiating contracts for payers with providers and manufacturers.

FINANCE

Value based care

- Help develop pay-for-performance contract agreements.
- Marketplaces for payer/pharmaceutical interaction, so both entities can understand each other’s priorities.

Risk financing

- Carve-out solutions to take over the risk of unexpected high-cost gene therapy and cell therapy claims.
- Pooling arrangements to manage actuarial risk and execution challenges.
- Structured payment plans
- Traditional reinsurance

Gene and Cell Therapies Approved To Date

Recently approved and anticipated therapies (with cost per patient of the therapy only):

- **Zolgensma (USD 2.1 million):** Gene therapy for children under two years of age with spinal muscular atrophy.
- **Luxterna (USD 850,000–both eyes):** Gene therapy to treat blindness caused by retinal dystrophy.
- **Abecma (USD 420,000):** Cell therapy used as a fifth line of defense against multiple myeloma.
- **Anticipated FDA approval of Roctavian (estimated cost of USD 2-3 million)** in 2022, and multiple therapies targeting sickle-cell disease will accelerate need for alternative financing solutions.

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About Guy Carpenter

Guy Carpenter & Company, LLC is a leading global risk and reinsurance specialist with more than 3,300 professionals in over 60 offices around the world. Guy Carpenter delivers a powerful combination of broking expertise, trusted strategic advisory services and industry-leading analytics to help clients adapt to emerging opportunities and achieve profitable growth. Guy Carpenter is a business of Marsh McLennan (NYSE: MMC), the world's leading professional services firm in the areas of risk, strategy and people. The Company's 81,000 colleagues advise clients in 130 countries. With annual revenue over $19 billion, Marsh McLennan helps clients navigate an increasingly dynamic and complex environment through four market-leading businesses including Marsh, Mercer, and Oliver Wyman. For more information, visit www.guycarp.com and follow us on LinkedIn and Twitter.