FoCUS Project

Financing and Reimbursement of Cures in the US

RESEARCH BRIEF

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Payers Open to Innovative Financing Mechanisms for High Cost Gene Therapies.

In a broad survey, payers favor performance based milestone contracts and risk pools strategies to absorb the surge of high cost gene therapy products expected to enter the market over the next three to five years. The current financing model employing premium increases, higher patient out-of-pocket costs, reinsurance and stop-loss policies is viewed as unsustainable, although the critical issues vary by payer type. Medicaid is further constrained by regulatory requirements and has less flexibility than other payer segments to actively manage these new costs.

By **MIT NEWDIGS FoCUS Project**

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Gene therapies promise potentially durable clinical benefit from a single treatment course. They also promise high up-front costs for the extended, perhaps lifetime, benefits they confer. Estimating the number of gene therapies that will gain approval and launch in the five years can inform the planning by all stakeholders to ensure that patients gain appropriate access as rapidly as possible.

Gene therapies promise potentially durable clinical benefit from a single treatment course. They also promise high up-front costs for the extended, perhaps lifetime, benefits they confer. Feedback from payers on the need and operationally feasibility of implementing new financing mechanisms can inform the planning by all stakeholders to ensure that patients gain appropriate access as rapidly as possible.

Understanding the payer perspective and the challenges they face in delivering affordable health care coverage while ensuring access to medical innovation is critical to the sustainability of research and development of new cures.

The NEWDIGS FoCUS project sought to gain insights on the payer perspective regarding financing and reimbursement of durable gene therapies. A small sample of financial decision makers from payer organizations were interviewed in August and September 2017. All payer segments were represented including commercial, self-insured employer, Medicare, Medicaid, integrated delivery systems and reinsurers, with a minimum of 3 interviews per segment (Figure 1). Nearly two-thirds of interviewees held financial or actuarial positions and over one-third were clinicians. Plan size ranged from 4,000 lives to over 4 million lives.

Variation exists in awareness of the gene therapy pipeline and the potential financing challenges. Some payers recently became aware or were made aware of high cost gene therapies through the interview process, some demonstrated a status of watchful waiting, while others reported engagement in active management.

Over half of payers interviewed supported the current approach to management, leveraging existing

financing and reimbursement strategies. Of the newly proposed financing tools presented, performance based milestone contracts and risk pooling were of greatest interest.

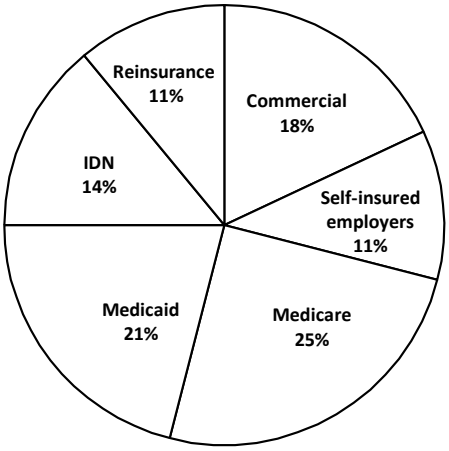

Figure 1: Percent of Interviews by Segment. *Some payers represented more than one segment

Key concerns expressed broadly by most payers included regulatory barriers to adoption of new financing strategies, plan turn-over and its impact on long-term outcome measures, provider mark-ups on already expensive treatments and treatment of conditions with high prevalence and/or incidence. Uncertainty related to cost and utilization was also impacted by uncertainty relative to the duration of the cure. Concerns and preferences identified by payer segment included:

- **Commercial plans**: Large plans with substantial reserves report the ability to absorb and manage these new costs with existing tools. Smaller plans have less ability to absorb unexpected high cost cases, but need to cover these treatments to remain competitive in their markets. Generally favor performance based milestone contracts.
- **Self-insured employers:** Rely on stop-loss reinsurance to protect against the volatility of unpredictable high cost claims. Favor expanded risk pools if reinsurance premiums become unaffordable.
- **Medicare:** Government provides catastrophic coverage for Part D drug plans. Medicare Advantage plans may rely on reinsurance. Early Medicare bid submissions (May for the next plan year) challenges incorporation of newly approved treatments in plan year premiums.

KEY FINDINGS

1. **Variation exists** in payer awareness of and ability to absorb new high cost gene therapies.
2. **Regulatory constraints** hamper Medicaid's ability to address new cost challenges – gene therapies will aggravate this existing condition.
3. **Precision financing** that targets the specific challenges of each payer segment will be needed.
   a. **Financial predictability is key**
   b. Performance based milestone contracts and expanded risk pooling are preferred strategies
   c. Preferred financing **tools align to payer segments** and generally augment existing financing mechanisms

- **Medicaid:** Least ability to manage new costs given current regulations. States set premiums which may be insufficient to cover the cost of new innovations. States may carve out these treatments or redistribute premiums based on experience. Change will require a 50 state agreement. Generally favors expanded risk pools.
- **Integrated Delivery Networks (IDN):** Pressured from their delivery side to cover new innovations early. Relatively small plan size with the complexity of multiple lines of business.
- **Reinsurers/Stop-loss Vendors:** Balance competitive pressure to keep premiums low with rapid escalation in premiums driven by leveraged trend. Favors expansion of risk pools.

Given the complexity of multiple payer segments, precision financing that targets the specific challenges of each payer segment will be needed.

About FoCUS

To learn more about the FoCUS Project, visit https://newdigs.mit.edu/focus

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