InspiroGene™
By McKesson

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Article 3:

Commercializing your first CGT product: Value chain planning

Value chain planning: It's the strategic process of designing, coordinating and optimizing all the activities required to bring a therapy from development to commercialization. Unlike traditional therapies, there are no standardized value chain templates for cell and gene therapies (CGTs). Because patient cells or genetic materials are used to manufacture many of these therapies, a unique patient and product journey is created with the development of virtually every dose. That means that biopharma manufacturers must approach CGT value chain planning very differently.

While value chains for traditional drugs are built for volume and consistency, value chains for CGTs demand agility, precision, patient-and-site-of-care-specific coordination, and a much more complex degree of collaboration among stakeholders. If you're developing your first CGT product, here are five value chain best practices to keep in mind.

1) It's never too early to start value chain planning.

The complex and personalized nature of CGTs means that some value chain decisions must be made very early, while the product is still in development. Your commercialization plan will vary significantly based on whether your product is a cell or gene therapy. Early decisions range from how the therapy will be manufactured, to whether you will build the manufacturing function internally or outsource it to a contract manufacturing organization (CMO), to where and how your therapy will be administered. Questions about your product journey, such as whether patients will receive your CGT therapy on an inpatient or outpatient basis, or how many sites of administration you will need at launch, will shape your value chain planning and will help to determine what type of distribution model you may need, along with other factors. It's important to consider the long-term opportunities for the product, and the potential market for the therapy once it is approved. Developing manufacturing and site-of-care strategies that will enable you to scale your therapy efficiently and effectively, post approval, will help to support commercial success.

2) Don't underestimate the complexity of cold storage requirements.

CGTs often need to be stored and transported at ultra-frozen temperatures (-60° C or lower) – with many requiring cryo-frozen storage (-80° C) using liquid nitrogen. Given the high value of these therapies, monitoring and maintaining temperature control at every point in the supply chain after the therapy is manufactured is essential. As part of your value chain planning, determining the temperature at which your therapy will need to be stored will be critical because cryo-frozen technology and processes are vastly different from ultra-frozen. It is also important to consider how your therapy's commercial requirements and SOPs may differ from clinical requirements leading up to approval. Partnerships with value-chain suppliers will be important and should be engaged 24 months prior to launch or earlier to allow adequate time for planning and testing. Be sure to fully research potential partners to assess their experience, cold-storage facilities and technology for maintaining and monitoring strict temperature requirements.

3) Value chain planning requires a strong understanding of how different distribution models impact reimbursement.

Reimbursement models can also impact value chain planning. Today, CGTs are often reimbursed through either a medical benefit "buy-and-bill" model or through a specialty pharmacy. Under the buy-and-bill model, the treatment center purchases the therapy from the manufacturer, typically working through a specialty distributor to handle the logistics. While the buy-and-bill model enables providers to potentially collect more revenue (because they bill for the product plus the administration of the therapy), it also comes with greater financial risk. The treatment center must front the high cost of the therapy, then wait for payer reimbursement, which may take weeks or months due to complex payer dynamics. As treatment centers take on more CGT products, the financial burden grows, creating a stacking effect that may be unsustainable over time, particularly for smaller sites of care such as community hospitals and clinics.

Under the specialty pharmacy model, the treatment center purchases the therapy through the pharmacy and the pharmacy bills the payer directly. The treatment center only bills the payer for the cost of the ancillary services related to patient care, thus avoiding the need to carry the cost of CGTs on their books. While this model may have different revenue implications for the treatment center, it also lowers their financial risk.

When developing your value chain strategy, it is important to remember that not all sites of care will have the same needs when it comes to reimbursement. Providing both a buy-and-bill option and a specialty pharmacy option empowers your treatment centers to select the model that is best for them. It will also help to ensure that you are not inadvertently limiting the size of your treatment network. As you evaluate these options, it is important to consider partners who offer specialty distribution, 3PL and specialty pharmacy capabilities, and who have the expertise and integrated services to support both models.

4) Your value chain strategy should be designed to address the unique challenges of each patient's journey.

The journey for patients who receive CGTs involves a series of highly coordinated, often complicated and individualized steps – starting with their initial referral, and flowing through to pre-treatment evaluation, pre-authorization, cell collection and dosing preparation, all the way to site-of-care administration, post-treatment monitoring and long-term follow up. Each of these touchpoints requires seamless value chain planning across clinical, logistical and regulatory domains. But it's also essential to remember that for patients and caregivers, each of these touchpoints can be physically and mentally exhausting, particularly for those dealing with advanced stage or life-threatening conditions. That's why your value chain strategy must carefully consider what kind of care coordination, access support, financial assistance, education, and emotional and psychosocial support patients may need to ensure they can access your therapy in a timely manner and can have an optimal experience. Having these types of customized patient support services in place at launch, to provide personalized patient support through every step, may be especially helpful in accelerating early uptake.

5) Effective value chain planning requires partnerships that can scale right along with your therapy.

CGTs have the potential to move rapidly from limited clinical use to broader commercial deployment – which means developers need partners that understand the complexity of the ecosystem and can scale in reach, capacity and capabilities. Identifying and engaging with the right value chain partners early in your commercial planning is key to avoiding bottlenecks in manufacturing, logistics, site-of-care enablement and patient services that can cause delays, missed revenue and compromised patient care. To reach more patients, it is crucial to identify and eliminate barriers to maximize access.

Successful value chain planning for innovative CGT treatments requires developers to think, plan, collaborate, innovate and troubleshoot in new ways. It also requires developers to start early, and reach out to experienced partners, like InspiroGene, who can help bridge the gap between CGT innovation and reality. In the next installment in this series, I'll explore one of the most significant obstacles to expanding CGT access: reimbursement.

Author's note: Joe DePinto is Head of Cell, Gene and Advanced Therapy at McKesson, where he leads InspiroGene, the company's dedicated business focused solely on supporting the commercialization of cell and gene therapies (CGTs). At InspiroGene, we offer flexible, sustainable solutions to help manufacturers, payers, and providers navigate the complex CGT commercialization landscape. As an enduring ally, we're dedicated to transforming patient care and driving better health outcomes. Learn more about the InspiroGene advantage at **InspiroGene.com**.