InspiroGene™
By McKesson

Joe DePinto
Head of Cell, Gene and Advanced Therapies, McKesson

Article 2:

Commercializing your first cell or gene therapy (CGT): Developing your market access strategy

As discussed in article 1 in this series, the complex, patient-centric nature of cell and gene therapies (CGTs) presents biopharma companies with complicated commercialization challenges, particularly for those embarking on the journey for the first time.

Here, I share steps for creating a strong market access strategy to ensure that once your CGT earns regulatory approval, it will be accessible at the right time and place, for the patients who need it.

Step 1: Establish Your Market Access Strategy

Market access is not a standalone function. Building and executing an effective market access strategy typically requires input from an interdisciplinary team, working together to ensure commercial readiness. If your resources are constrained, you can also consider working with a market access consultant or starting by hiring a Chief Commercial Officer or a Vice President of Market Access that has broad expertise. Considering the complexities of the CGT space, the earlier a senior commercial leader is hired the better. Ideally, you'll want your market access strategy to be informed by the following functional areas:

- **Clinical Development,** to ensure alignment between trial endpoints and the specific efficacy and other data that guides payers' reimbursement decisions.
- **Regulatory Affairs,** to coordinate with regulatory agencies, help shape and navigate complex approval processes, align data generation with health authority expectations, and anticipate and plan for potential regulatory hurdles.
- **Manufacturing, Supply Chain and Technology Operations,** to address challenges related to cold chain logistics, distribution channels, delivery timelines and scalability.
- **Health Economics & Outcomes Research (HEOR),** to develop evidence that demonstrates the value, efficacy, real-world outcomes, patient-reported outcomes, cost-effectiveness and other benefits of your therapy. This data can be used to justify pricing, formulary inclusion and reimbursement decisions, which in turn can play a crucial role in supporting payer negotiations.
- **Pricing, Contracting & Payer Groups,** to develop innovative pricing models and payment agreements; collaborate with payers, providers, advocacy groups and regulators; and build consensus on how to price and pay for your therapy.
- **Marketing and Sales Strategy,** to shape your therapy's value proposition and integrate access strategies into its go-to-market plans.

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Decisions made by each of these functional experts on your team will shape the strategy. So it's also important to understand, and expect, that your market access strategy must be iterative, adaptable, and informed by cross-functional input.

Step 2: Define the Target Product Profile

Creating optimal access to your therapy starts with understanding where your therapy will be positioned in the market, beginning with your target product profile (TPP). Your TPP defines key characteristics of your therapy, including indication and patient population, dosing and administration, pricing and reimbursement potential, and an overview of how your product is differentiated within its broader competitive landscape. As part of your TPP development, it may also be helpful to run both "base-case" TPP scenarios, which would be realistic projections based on current assumptions; and "best case" TPP scenarios, characterized by ideal projections based on the outcomes of the pivotal clinical trial. This helps ensure that your team can develop flexible pricing, reimbursement and access strategies that can accommodate your therapy's full range of potential clinical and economic outcome possibilities.

Step 3: Carefully Select and Prioritize Clinical Trial Sites

The sites selected for clinical trials often become your therapy's first commercial treatment centers. That's why it's important to strategically identify where your patient population is located, and how to effectively reach them. Your early selection of high-performing sites, characterized by robust patient populations that align with your target patient profile, engaged investigators and strong infrastructure, will ensure a smoother transition to commercialization. Selecting too many sites with low patient accrual rates can slow trial progress and dilute early adoption efforts. Once your product receives approval and adoption is growing, your team should map out additional sites for expansion to ensure optimal patient access. With the increase in clinical activity and competition in the CGT space, it is important to understand what else treatment centers are studying, as academic medical centers will often move patients to the next clinical trial once one study ends, rather than onto a commercial product.

Step 4: Engage Key Stakeholders and Partners Early

Because CGTs are so complex, your successful market access strategy will be dependent on support from many different stakeholders, who should ideally be engaged early in the commercialization process. For example, you'll want to build relationships with key opinion leaders and patient advocacy groups to inform them about the benefits of your cell and gene therapy and update them on your latest data. You'll also need to select and build relationships with experienced external partners who support your therapy's commercialization journey, including distributors, value chain partners and marketing agencies. Unlike traditional therapies, CGTs can't follow established pricing and coverage pathways – they require the development of innovative payment models. That's why it's also essential to engage payers as early as possible – so you can understand their expectations, anticipate and address their concerns, and have the time needed to develop novel reimbursement strategies that are tailored to meet their evolving requirements.

Keep an eye out for the next articles in this series, where I'll explore the important role that supply chain and reimbursement planning has on the commercialization success of CGT therapies.

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**.