Communicating value to providers and payers

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As market access and medical communications strategy experts, Drs. Emma Medin and Jamie Kistler help companies communicate the value of cell and gene therapies (CGTs) to providers and payers. The complexity and novelty of CGTs—including proprietary manufacturing processes—require a comprehensive communication strategy to win healthcare providers' trust. Meanwhile, the one-time, front-loaded costs of these treatments have necessitated new payment models to win payer approval and be affordable. Medin and Kistler offer some best practices for telling a resonant value story.

Understand the patient's journey so you know where to add value

Kistler: Consult thought leaders from the start of development to get a clear picture of the disease and unmet needs. Input from national and cross-regional advisory boards with experts and community-level healthcare providers (HCPs) can precisely reveal what the journey looks like for patients and caregivers and where there may be gaps in HCP understanding. These insights inform how biopharmaceutical companies communicate about a novel CGT product from day one. Setting the scene for a new treatment—especially a transformative one—should happen long before the product launches. For example, there may be multiple treatments already available to patients; ensuring that there is a straightforward value narrative for a novel CGT product—one that resonates with payers and regulators as well as HCPs and patients—is critical. There may be important differences (beyond cost) that will affect how patients and providers choose between them. Sponsors can disseminate information on the patient journey and how a novel CGT addresses unmet needs through many different channels, including direct discussions between field medical teams and the HCPs treating patients, educational symposia programs, and peer-reviewed publications. But mapping out the who,

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what, why, how, and when early on in planning is critical for success:

- Who are the external audiences that need the information?
- What specific information does each audience need?
- Why do they need that information?
- How should that information be disseminated to each audience to ensure adequate reach and understanding?
- When is the appropriate time to disseminate the information?

Generate the evidence that payers want to see

Medin: In markets with value-based pricing and health technology assessment (HTA) agencies, comparative effectiveness data is essential; how does your treatment perform versus current clinical practice versus a placebo? Also, payers want to know how a product works in real life, outside the rarefied setting of a clinical trial. Does it work for the average person? Regulatory agencies often approve drugs for rare diseases on a set of evidence that payers will consider insufficient. If you have not gathered the evidence that HTA agencies are looking for, you will come up short in their assessments. Mitigate this risk with an evidence-generation plan. The one-time upfront costs of CGTs require new payment models, such as outcomes-based models, which need to be negotiated with payer agencies and prepared for from an evidence generation standpoint.

Tell an informed, evidence-based medical value story

Kistler: One of the most critical elements of a CGT communication strategy is an informed, evidence-based, and integrated scientific and value narrative about the product and disease state developed with input from a cross-functional team and, in some cases, external experts. For CGTs, this includes how you will communicate about early preclinical data, proprietary manufacturing data, and clinical data that is sometimes unique compared with standard pharmaceutical products, for example, cellular pharmacokinetic data and health economics and outcomes data as they become available. You have

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to establish why the new product is needed, why it's safe, how it can be viably scaled up, and how effective it is. The communication strategy is a lot like a score for an orchestra—except it must be conducted over several years as the product progresses. Consider all the different instrument sections and audiences. To gain HCPs' and other key audiences' trust, tell a consistent and integrated scientific and value story in all external communications (such as press releases, websites, educational symposia, disease awareness campaigns, publications, and congress activities).

Seize early opportunities for scientific advice

Medin: Invest in early scientific advice meetings. You can have a joint meeting with the European Network for Health Technology Assessment (EUnetHTA) and the EMA in the European Union. You can also apply for country-specific consultation meetings. For example, the U.K.'s National Institute for Health and Care Excellence (NICE), one of the most prestigious HTA agencies, is one of the HTA agencies you can submit to the earliest. Sponsors can submit data for review a full three months before their expected review by the Committee for Medicinal Products for Human Use (CHMP). Some sponsors are reluctant to seek advice like this because they are afraid they will receive advice they won't want to follow. Scientific advice is non-binding, but you should always consider it. These consultations are critical for sponsors to develop evidence-generation plans that can satisfy both regulators and payers and understand what can become hurdles for a successful launch.

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Be clear-eyed about clinical and commercial viability

Kistler: Even if you are a small biotech company whose strategy is to license or sell the CGT in your pipeline, you need a solid value story told consistently and well. Companies increasingly realize that charging astronomical prices for these exciting new therapies may not be a viable business plan, even with vast unmet needs. Developers, both small and large, need to articulate the value—or expected value—of their product and how it will be commercially viable. What is the competition in this therapeutic area? How robust is the efficacy data? What price point can win reimbursement? It takes strong integration between the scientific, clinical, and market access teams to answer these questions well.

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Engage with payers' challenges from day one

Medin: For a product administered once with a lifelong effect, such as gene therapy, you need to address the payer landscape very early in development. These products can create difficult issues on the payer side. Based on results to date, it is doubtful that you can launch a product without a managed-entry agreement. There are several payment models under development, such as annuity payment models, pay-for-performance models, risk pooling models, and licensing. But only a handful of gene therapies have gained market access as of yet. The reimbursement landscape is fluid now, and temporary solutions such as separate budgets for innovative treatments are in some markets. However, payment models will probably evolve to a standard.

How to build a compelling value story

- Establish value with consistent communication at every stage of development.
- Understand that an effective publication strategy for a CGT starts with preclinical data, includes clinical and manufacturing data, and continues with health economics data after launch.
- Give HTA agencies the data they want.
- Seize the opportunity offered by early scientific advice meetings, don't fear them.
- Realize that exciting science is not enough. A successful CGT product must meet safety and efficacy standards, fill an unmet need, and be commercially viable.

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