Coordinating your reimbursement and regulatory strategies for a successful product launch

Dentons

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Ensuring appropriate third-party reimbursement for a new pharmaceutical or medical product involves an intricate interplay of considerations. There is no doubt that government and private payers have been under increasing pressure to control spending across the patient management continuum. not surprisingly, there has also been rising tension between, on the one hand, providers, caregivers and other patient advocates and, on the other, the payers, who are financially accountable to a variety of stakeholders and constituencies. A consequence of this growing divide is that reimbursement rate debates have grown ever more rancorous; fraught exchanges between those who “do” and those who “have”—with those in “need” too often left out of the conversation.

Drug pricing is arguably one of the most complex and least understood aspects of the healthcare reform debate. What Is a fair price anyway? And who gets to decide? Payers have created a variety of evidence-based approaches in an attempt to understanding a drug or medical technology's intrinsic value. Beginning in the 1980s, the Blue Cross Blue Shield Association began to coordinate evidence reviews via its Technology Evaluation and Coverage (TEC) group. TEC's assessments continue to be used for coverage decisions and represent a window into private-payer considerations of product value. Today, almost every major payer either has a unit similar to TEC, or utilizes TEC findings in its making reimbursement decisions.

The 1990s witnessed the emergence of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC), which was jointly launched by the Centers for Medicare & Medicaid Services and the Academy of Managed Care Pharmacy (AMCP). Soon, the AMCP Dossier, a pre-specified format for submission of clinical and economic evidence in support of formulary consideration, was required by every formulary committee for purposes of formulary adoption.

The operation of these entities, and their decision-making rubrics, provides further insight around drug and technology valuation. Importantly, all of these organizations share common aims and regularly collaborate on issues surrounding reimbursement policies. The evidence requirements are intended for use by manufacturers of pharmaceuticals, biologics and vaccines who are responding to an unsolicited request from a health care system (in the United States) to support reimbursement and/or formulary placement of a new product, new indication or new formulation of an existing product.

The impact of these entities has not only driven access to cutting-edge drugs and technologies for patients but also impacted corporate valuations. The business media regularly reports on the results of TEC Assessments and AMCP Dossiers in a manner similar to coverage of clinical trial results. Whether a new product would be covered widely and priced appropriately has become as compelling an investment concern as whether Phase III clinical trial endpoints were met. This additional layer of pressure on innovation makes the work that is necessary to achieve payer adoption and appropriate pricing all the more critical.

Taking these trends into consideration, there are some clear directions that emerge with respect to how appropriate pricing is best arrived at. Overall, companies seeking to bring new products to market must carefully consider a deliberate strategy for achieving an appropriate price.

1. **Begin early, and include pricing in go/no go decisions**. As clinical information emerges about a product in development, so should information be derived and analyzed about sector and product pricing trends. Payers tend to review pricing according to therapeutic or disease categories. Often pricing for drugs and products used in specific medical specialties (e.g., oncology) receive particular scrutiny and recalibration. Utilization is also a key variable in understanding future pricing. Those responsible for product development should possess a working knowledge of factors associated with pricing in order to inform their decisions about continued development and balancing investment risk and return.

2. **Specialty medical society advocacy**. Payers turn to medical specialists for guidance about clinical effectiveness. Just as important, these clinicians are regularly asked for comparative information concerning new vs. on-market products by pharmacy staff and other stakeholders. Most specialty societies now operate product- and formulary-related review panels or committees. These groups often publish best practice bulletins and clinical guidelines in specialty journals and publications. An effective pricing strategy includes adopting approaches to offer clinicians opportunities to make critical product comparisons in the context of professional society functions. This will result in a well-informed clinical perspective and position.

3. **Evidence-based analytics**. The most effective approach to price determination is an evidence-based valuation of the drug or product. Pharmacoeconomic[1] analysis for product valuation has matured over the last two decades. This science-based decision methodology utilizes patient outcomes to determine the cost-effectiveness of product options. Early cost-effectiveness studies can be used to make informed decisions about product development and risk. These studies can also be utilized in clinical trials by including economic endpoints in trial design. In the end, this information will objectively inform payers about value and pricing.

4. **Publication plan that includes pharmacoeconomic findings**. The evidence reviewed by payers for pricing determinations is largely in peer-reviewed publications. It is important to include studies that outline quantitative findings concerning product cost-effectiveness in coordination with clinical

findings. A series of such publications will prove invaluable in providing payers with justification for making informed pricing decisions.

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