Succeeding in the Marketplace:
The Importance of Pricing, Reimbursement and Patient Access Strategies

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In today’s complex and competitive healthcare arena, receiving approval by the Food and Drug Administration (FDA) is just one of the many hurdles that a biopharmaceutical company must overcome to achieve commercial success for a new drug or medical device. A sponsor also must ensure that the new product is readily available to physicians and patients, that public and private insurance plans will cover its use for the approved indication and that reimbursement rates will be adequate to cover the cost of treatment. Without favorable decisions on coverage, coding and payment, even the best product will fail to thrive in the market.

More importantly, a product’s overall value—not just its safety, efficacy or cost—is becoming a key factor in determining whether it will attain optimal market results. “Pharmaceutical economics” and “evidence-based medicine” are the new mantras of the healthcare system, with most payers now requiring that novel products reduce treatment costs, improve medical outcomes or provide some other tangible benefit over current therapies if they are to receive favorable formulary placement and be approved for reimbursement.

Given the estimated $800 million cost to develop a new drug, no biopharmaceutical company can afford to bring a product to market only to have it fail because major healthcare payers will not afford favorable coverage or provide adequate payment for its use. To avoid such a devastating failure, sponsors must initiate strategic planning for patient access and reimbursement issues in the early stages of product development—before Phase II/III clinical trials. By analyzing current therapies and reimbursement practices, selecting the most appropriate initial indication and understanding the impact of evolving federal, state and private healthcare policies, a sponsor can adapt its product development strategies to these new realities and design pivotal trials that will demonstrate a product’s value to patients, physicians and payers. This helps to ensure that the product will not only reach the market, but reach its full potential.

Rising Costs Alter Environment
Biopharmaceutical companies bringing new products to
Reimbursement

The healthcare environment that has undergone profound changes in recent years due to soaring costs. According to a 2007 report by the Kaiser Family Foundation, healthcare spending topped $2 trillion in the United States in 2005—a 16 percent of the country's total economic activity. Even more troubling, healthcare's share of economic activity has more than doubled since 1970. Faced with dramatically escalating costs, all of the stakeholders in America's healthcare system—patients, hospitals, physicians, private insurance companies, employers and public healthcare insurers like Medicare and Medicaid—are intensely focused on the price of care.

While prescription pharmaceuticals account for just 10 percent of total healthcare expenditures, their rapid cost growth in the last decade—coupled with extensive public discussion about direct-to-consumer advertising and product recalls—has raised serious issues about the cost and value of new pharmaceutical products across the healthcare system. As a result, both private and public payers are asking biopharmaceutical companies to demonstrate that their new products provide measurable, meaningful advantages compared with the products already on the market if they want to receive favorable coverage and payment decisions.

Although cost-benefit analyses have been a part of formulary and reimbursement decisions for many years, the concept of "evidence-based" or "outcome-based" medicine places a much greater emphasis on the issue of product value, with payers demanding new levels of data to inform their decisions, such as:
- Comparisons of the new product to the current "gold standard" treatment or an acceptable surrogate—an approach sometimes referred to as "comparative effectiveness";
- Proof that the drug or device improves the delivery of care;
- Demonstrated value for the payer's specific patient groups;
- Positive internal or third-party technology assessments;
- Results supported by peer-reviewed clinical data or presentations at major scientific/professional conferences; and
- Analysis of the overall cost impact of the total treatment process, not just the cost of the product, and how it will affect the payer.

While these issues may not be as critical for a product that addresses a serious unmet medical need, cost and value have become the paramount criteria in most payer decisions about novel therapies. Unlike in the past, demonstrating the safety, efficacy and novelty of a new product is no longer sufficient to assure positive results from the key payers. Biopharmaceutical companies must account for this seismic shift in healthcare focus if they want their product development and commercialization strategies to be successful.

**Medicare: A Payer Requiring Value**

Major changes across the payer landscape are also affecting the pharmaceutical industry and its introduction of new products. Publicly funded healthcare programs—mainly Medicare, Medicaid and the State Children's Health Insurance Program (SCHIP)—now account for more than 45 percent of spending for U.S. healthcare. Medicare alone covers nearly 44 million American seniors, and with the advent of the Part D Program, Medicare is now providing beneficiaries with coverage of Health Care Professional (HCP) administered products and oral medications.

With the huge baby-boom population just beginning to reach the automatic enrollment age of 65, Medicare's size and cost will continue to increase in the years ahead. Medicare was once viewed as the Nation's indemnity health plan, one that would provide coverage and payment for virtually any FDA approved product. Significant changes in the leadership, mission and administration of the Centers for Medicare and Medicaid Services (CMS) now have Medicare acting as a payer that requires that value be provided when it pays for treatment.

This growth will lead to additional influence by Medicare on coverage and payment issues for pharmaceutical products and medical procedures. The Medicare program is already a major trendsetter in healthcare. Its coverage and reimbursement decisions often determine the policies that other insurers—public and private—will follow, and its leadership role in this area can be expected to be even greater in the future.

For biopharmaceutical companies, this trend means that a new product's Medicare strategy is more important than ever. While Medicare has historically not been viewed as being on the leading edge of healthcare policy innovation and evidence-based medicine, the program has been embracing this approach in recent years to more closely mirror private insurers' focus on value and outcomes. The result is that the program's administrators are increasingly evaluating new products for both their health and financial impact on covered patients. Any drug company with a product targeting older Americans must have a robust strategy that demonstrates value to Medicare and its beneficiaries to gain favorable coverage and payment decisions.

**Understanding State-Based Programs**

Changes to state Medicaid programs have also impacted how biopharmaceutical companies approach obtaining product coverage. Preferred Drug Lists (PDL) and supplemental rebates require that
companies carefully analyze their market segments that will be covered by Medicaid programs.

Understanding the administration of these state-based programs can be particularly daunting for smaller or foreign-based pharmaceutical companies that lack the personnel or experience to deal with multiple agencies and the myriad of rules governing these programs. Such companies may benefit from outside resources with specialized expertise in evaluating the requirements of these programs and preparing the right value message to meet those needs. Even the most experienced pharmaceutical companies face the challenge of formulating appropriate coverage and pricing strategies as state-administered programs continue to evolve.

Private payers and their key customers—employers—are leading the way in the value-based treatment movement. Because most of these companies are profit-driven, they are strongly focused on the cost of new therapies and how they will impact total treatment costs for a particular condition or group of patients. New products or treatment regimens that could have a significant impact on insurance premiums paid by employers and their employees are also of major concern to these payers.

The other important change in this segment of the payer market is consolidation. Although private payers account for more than 40 percent of healthcare expenditures, more than two-thirds of that total is paid by just a few large insurers. Biopharmaceutical companies with new products must thoroughly understand the requirements of these major companies and formulate strong value propositions for the patient populations they cover, because the formulary and pricing decisions of this small group of payers will play a vital role in determining the accessibility and utilization of any new product.

**Challenge of Evidence-Based Medicine**

With the continuing evolution of evidence-based medicine across the healthcare environment, pharmaceutical companies must adapt their patient access and reimbursement strategies to succeed in this new world. However, the goal of these strategies remains unchanged: to achieve optimal patient access with few restrictions, under the appropriate coding, with a payment rate that covers the cost of the treatment. To reach that goal today, a company must present solid scientific evidence that demonstrates why its product should be covered for a particular indication at a favorable reimbursement rate. It is the “why” that defines the product’s value.

Payers are looking for therapies that provide improved outcomes compared with current treatments, both from the treatment and financial point of view. Does the product allow the patient to be treated in a more cost-efficient setting, such as outpatient vs. inpatient, with the same outcome? Do patients experience fewer side effects requiring less use of supportive care agents, have shorter hospital stays, or need fewer follow-up visits?

It is important for the pharmaceutical company to look at the broad picture of the complete treatment process—the cost of the drug, the ease of administration, the treatment setting, the time it takes for a patient to return to normal activities, the quality of life following the treatment—to make the most appropriate case for the value of a new therapy.

To make that case, a company must have real-world data derived from well-controlled clinical trials. That is why the strategic planning process for coverage and payment issues must take place before pivotal Phase III clinical trials begin. The strategy should include a “product value proposition” for the new therapy that takes into account the current standard treatments, and how payers view the value of those treatments. The clinical development program should be aligned with the value proposition and designed to produce clinical endpoints that will support the case for optimal patient access and reimbursement. The study protocol might include approaches such as:

- Comparing the new therapy against the current standard of care, rather than a placebo;
- Including validated and generally accepted quality-of-life markers in the trial; and
- Having investigators track the incidence of unscheduled follow-ups, improved management of chronic conditions, or other indicators of improved outcomes.

The key factor is to determine as early as possible in the development process the information needed to support the value proposition, then design clinical trials that will produce meaningful outcomes data for the targeted payers, patients and healthcare providers.

**Other Best Strategies**

Other best practices to consider when planning patient access and payment strategies include:

- Know your target market
  - Understand how each payer views the value equation;
  - Identify the stakeholders, and their financial risks and incentives;
  - Evaluate the impact of prevailing co-payment and co-insurance obligations on the market success of the product;
- Review coverage and payment policies of major payers in the targeted market; and
Reimbursement

- Examine existing codes for the targeted therapeutic area, and determine if your product will be adequately supported by current codes.

Assess current standards of care
- Identify the current standard therapy in the target market, the complete costs (both direct and indirect) of existing therapies;
- Investigate the perceptions of payers and providers about efficacy and cost of the current therapies;
- Determine if your product is likely to change the standard of care or replace current therapies;
- Review how any competitive products are classified, as well as the commercial tactics of those products, such as the use of contracts, rebates or discounts, and how they ultimately impact government price reporting and profitability; and
- Understand the treatment setting where your product will be used and all the associated reimbursement issues (inpatient, outpatient, home health, etc.).

Align regulatory and reimbursement strategies
- Ensure that clinical endpoints have stand-alone market value;
- Collect cost and pharmacoeconomic information in trials; and
- Collect evidence to support proposed coverage and payment strategies.

Conclusion
While the healthcare environment in the United States is constantly evolving, it is clear that evidence-based medicine and the concept of product value will continue to grow in importance as key elements in patient access and reimbursement decisions. Although pharmacoeconomics are not yet a requirement for regulatory filings in the United States, in contrast to some filings in other markets, the message for the biopharmaceutical industry is that a strong value proposition is essential for every new product. By including coverage, pricing and payment strategies early in the development process, a company with a potential new product will be better prepared to demonstrate its product’s value to key payers, help maximize its commercial success and ultimately benefit patients through improved access to therapy.