



PHOTO: JUPITER IMAGES

Drug firms should begin developing pricing, reimbursement and access strategies prior to launch. **Kevin Barnett** examines how addressing payer-related strategies early will help products succeed and provides guidance to managers who find themselves ‘behind the eight-ball’

Obviously, payers are becoming increasingly important in determining the commercial success or failure of pharmaceutical and biotech products. However, managers of development-stage products often begin to address payer-related strategic considerations later than they should, treating the pricing and reimbursement strategy as an afterthought. This is a high-risk “game” of chance that can easily be avoided. New product planners should develop a basic understanding of a product’s likely reimbursement environment—and requirements for the product’s value proposition—as early as Phase II of clinical development. Then, more in-depth strategic work should take place as the product moves toward launch.

This article outlines key considerations for managers of pre-launch products in developing effective pricing, reimbursement, and access strategies. It explains why managers should begin addressing payer-related strategies early to help their products succeed. In addition, it provides some guidance to managers who may find themselves “behind the eight-ball,” with less than a year to go before launch, with little in the way of pricing, access, and reimbursement strategy.

The rising influence of payers

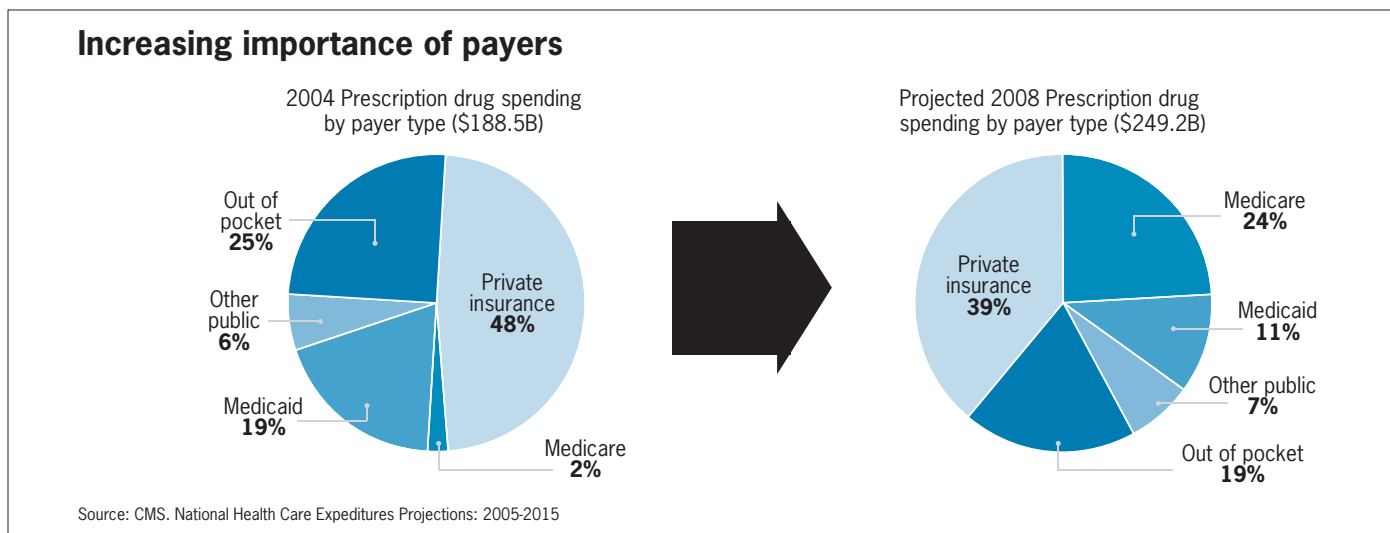
According to the Centers for Medicare and Medicaid Services (CMS), private and government payers were expected to manage 84% of prescription drug expenditures during 2008. That percentage will not decline as time goes on, and payers are becoming increasingly important to the commercial success of products. Marketers who don’t take payers’ needs and objectives into account when developing new products can endanger a product’s odds of commercial success.

The reimbursement environment is also getting tougher. Shifts over the next few years will have major effects on the competitive dynamics for many products. For example, a number of big changes are being debated now, including further adjustments to Medicare, changes in the role and scope of comparative effectiveness research, the development of an approval pathway for generic biologics, and other important issues.

In addition, payers are becoming generally more aggressive in their management of products, even in areas that have not been aggressively managed until now, such as oncology. Managers must stay abreast of these changes and be proactive in preparing their products for commercial success.

In today’s world, payers’ needs and objectives are just as important to a product’s commercial success as those of physicians and patients. For example, physicians may find dosing convenience to be a positive differentiator. Payers, however, will not place value

PLAN EARLY OR PAY THE PRICE



on convenience unless it can be tied to benefits in outcomes.

Therefore, product managers who count on securing a certain percentage of the market based on the convenience attribute may be sorely disappointed when the product fails because of poor access and reimbursement. Instead, managers must understand the needs of payers early. They should gather the insights they need to help guide clinical development, which will enable them to collect data on endpoints that are more relevant to payers.

Ideally, during phase II of development, management:

- Understand how payers manage products in the class (or therapeutic area), and how their attitudes might change by the time the new product is launched;
- Understand payers' needs, objectives, requirements, and evaluation criteria for the class (or similar therapeutic area);
- Begin to formulate a value proposition for payers;
- Incorporate endpoints into phase III studies that could support that value proposition; and
- Collect the data that will be needed later when dealing with payers.

Without early planning, manufacturers can find themselves "up the creek" six months prior to launch with a dubious value proposition for payers, as well as pricing and contracting strategies that are built on that flawed foundation. This can seriously endanger access and profitability. Early planning is especially important for products that are not substantially differentiated or first-in-class. It is tougher to distinguish those products from existing therapies, and payers are likely to be more skeptical when making formulary decisions regarding them.

Pillars of a pricing, reimbursement and access strategy

The burden of proof for any value proposition is likely to be high, or else significant price concessions will be required. Managers may have an easier time differentiating a first-in-class therapy, but they are not immune from the dangers of procrastination. Developing an effective value proposition for payers is only part of the challenge. Managers should begin thinking about a pricing and contracting strategy well before the launch is imminent.

Pillar One: Value Proposition

A payer value proposition is a compelling story used to commu-

nicate the clinical and economic attributes of a product relative to its competitors. It demonstrates the necessity for payers to provide access to that product.

To develop an effective value proposition, a manufacturer must answer several questions:

- How are substitute products reimbursed?
- What are payers' perceptions of those products?
- How familiar are payer decision makers with third-party guidelines for management of the disease in question?
- To what degree do these guidelines influence payer decision making?
- What trends are likely to have the greatest impact on reimbursement for the product?
- What are payers' perspectives, objectives, and assessment criteria for a new product of the type in question?
- What should the product's clinical and economic positioning to payers be?
- How would that position complement the product's value proposition to physicians and patients?
- How can health economics and outcomes research help support the product's value proposition?

To answer these questions, managers must review the market environment and develop their own hypotheses regarding payer needs and objectives.

While doing that, managers should work to identify unmet needs that their products might be able to fulfill. To do this, managers will likely rely on a combination of their own knowledge, secondary research, and primary research with payer decision makers and influencers.

By speaking with payers, managers can test their value proposition to see if it is appropriate. Based on the feedback they get, managers can identify weak points, refine their value proposition, and identify the additional data they'll need to support it.

By beginning to address the payer value proposition earlier in clinical development, managers will be able to include endpoints in phase III trials that can be used to substantiate it. A relevant and well-supported value proposition will give managers much more leverage when developing their pricing and contracting strategies for a product.

Pillar Two: Pricing

To develop an effective pricing strategy, managers must answer some important questions to guide their efforts:

- What are the primary goals of our pricing strategy? Do we want to penetrate the market, achieve the optimal balance between share and margin or convert users from a predecessor product?
- How might price affect access and reimbursement?
- How will price and formulary status affect physician prescribing, patient use and compliance?
- From the perspectives of payers, physicians and patients, how substitutable are other treatment options?
- Will there be multiple indications to follow launch? If so, what are the implications of launching with certain indications first? What constraints might this place on feasible pricing strategies?

In developing a pricing strategy, managers should first assess the impact of price on access and reimbursement. For one product, pricing may have a massive effect on how payers manage it. For others, pricing may have a much smaller impact. It all depends on the product’s attributes, its competitive environment, and the relevance and strength of its value proposition.

Next, managers must assess how price will affect utilization. For many products, formulary positioning can have a significant effect on physician prescribing. Out-of-pocket costs for patients can also have a major influence on patient initiation and adherence. The level of impact of price on utilization depends on the condition the product is intended to treat, how well it works relative to therapeutic alternatives, and what other relevant attributes it brings to the table.

Finally, managers must conduct modeling and analysis to understand the likely demand response to variable pricing, formulary access levels, and market conditions. Using the results, they can develop final pricing recommendations.

Pillar Three: Contracting

Setting the right “list” price is very important, but developing an effective contracting strategy is equally so. A good contracting strategy will address questions in four areas:

- When: Is contracting necessary at launch, and are there specific market events that might necessitate it?
- How: What are the best ways to structure contracts?
- How much: What are the appropriate rebate levels?
- With whom: Which channels and customers will be critical to success and should be the focus of contracting efforts?

To properly manage the process, managers must answer some important questions:

- How is the payer environment likely to evolve?
- How should our contracting approach vary across payer segments such as commercial managed care, Medicare, Medicaid, hospitals, long-term care, Veterans Administration/ Department of Defense and specialty pharmacies?
- What innovative contracting approaches might we consider?
- In each segment, what is the cost of contracting (expected required rebate levels)?
- In each segment, what are the expected benefits of contracting (expected share gain)?
- How might contracting in one channel affect contracting in another channel (spillover)?

- What key trigger events could affect implementation of our defined contracting strategies?
- How can we effectively segment and prioritize channels and accounts to ensure that we deploy our resources appropriately?

To develop an effective contracting strategy, managers must determine which customer channels and accounts will be most important to the success of their product. This is critical to help the company focus on the right customers and employ the right strategies with various accounts.

When segmenting and prioritizing payer customers, managers typically weigh a number of criteria related to each payer, including but not limited to the number of covered lives, the prescription volume at stake, the account’s ability and willingness to control product utilization and the composition of the plan’s book of business (e.g., Medicare vs. commercial).

When formulating their strategy, managers must consider a wide range of contracting options from their own perspectives, as well as those of payers. Some examples are straight rebates, performance-based rebates, risk sharing and class capitation.

Throughout the contracting process, it is vital to weigh the cost of contracting against the benefits—the incremental business gained because of the improved access. Manufacturers that contract effectively will avoid throwing money away by giving rebates to payers who cannot affect utilization.

Behind the eight ball

Ideally, managers would begin developing the payer strategy for a new product sometime in mid- to late-phase II of clinical development. Certainly, it is not advisable to develop a fully fledged reimbursement and access strategy at that stage. Instead, new product planners should work to understand the product’s likely competitive environment at launch; identify potential unmet needs from the perspectives of payers, physicians and patients; gather feedback on potential endpoints and outcomes to be included in studies; develop draft value propositions focused on their core audiences (including payers); and then conduct some early testing of those value propositions.

Unfortunately, that doesn’t always happen in the real world. In many cases, managers do not address the payer situation for a new product until it is less than a year to launch. The biggest issues in these cases often include a lack of data to support the payer value proposition and/or a flawed value proposition.

When that happens, managers must determine how serious the situation really is. They will need to assess the state of the current payer strategy, including the value proposition, pricing and contracting components.

Second, they must identify the gaps or weaknesses, prioritizing them from most to least significant. It is also important to assess the feasibility of correcting the gaps and weaknesses. Some may be too big to fix, while others may be relatively easy.

The final steps involve simply getting moving: Tackle the high-priority weaknesses that can be fixed, then move down the list from there. With careful and early planning, however, managers can avoid these precarious scenarios and position their products for a successful launch, solid uptake and optimum profitability. ■

Kevin Barnett is SVP at Campbell Alliance