A PBM CALLS THE PLAYS

Managed care and PBMs are calling the shots on coverage. Before you make final decisions on marketing and pricing, make sure you know what matters to them. **Everett Neville** shares six moves pharma can make to enhance patient access

Today, the commercial success of a drug is largely driven by access to patients, and controlling that access are entities such as managed-care plans and pharmacy benefit managers (PBMs). Rising healthcare costs, a sluggish economy, and healthcare reform have led to consolidation among health plans and PBMs and more aggressive formulary and benefit controls.

Clients are designing controlled-level benefits—in which plan sponsors steer members toward preferred medications through financial incentives and step therapy, or decline to cover non-formulary drugs altogether. We have seen an increase of plan sponsors placing limitations on non-preferred drugs. Today we apply 28 rules for the average client, up from 19 just two years ago.

With this shift, people in pharma often ask, "What do we need to do to be successful?" Here's my advice:

Build better drugs

Develop new medications with truly better efficacy or outcomes. This is hard to do, of course, but when you have a drug that offers a significant advantage over the current therapies, you stand a much better chance of commercial success. We need cures for the incurable and better treatments for the treatable.

Last year, the FDA approved 39 new branded drugs, including two diagnostic agents. Of those, only 23 were unique new therapies, and 14 were "me too" drugs, accomplishing the same outcome or a minimal improvement compared to existing medications in the same therapy classes.

Assess the competitive environment

Be honest about the relative value of your drug. I have yet to have someone tell me we should add a drug to our formulary because it is no better than the drugs we already have. But in fact, that is often the reality. Understand what matters to the decision makers, and ask yourself if you make a difference in those criteria.

Manufacturers have targeted areas where more drug therapies are needed, but gaps in therapy still exist. Alzheimer's and Parkinson's diseases lack disease-modifying therapies; lupus and rare enzyme deficiencies lack safe and effective treatments; and obesity-related diseases lack safe therapies with significant and sustained efficacy.

Find your therapeutic role

Understand how your drug will fit in therapy. A drug may not replace the frontrunner but will have value for second-line therapy. As a payer, while we want novel and improved treatments, we also want to see second and third agents brought to market. Given the cost to develop, it is inevitable that pharma will want to recoup that cost. It benefits payers by bringing down the cost of therapy. Be aware that if you are the second or even fifth agent to market, your success will be tied to your pricing and discounting strategies.

Give good data

Show us data that are useful. How well your drug compares to placebo doesn't do much for you anymore. Real-world outcomes data are hard to come by, but we are suspicious of proxy measures

Pharmacists at work: Nowadays, they're taking a long, hard look at the new drugs the industry is developing

and assumptions about the cost burden of a disease that are not based on actual incurred medical costs.

Demonstrate improvements in outcomes or new outcomes that are meaningful to patients. We are less moved by whether your drug increases bone density or shrinks a tumor than if, by doing so, it keeps patients out of the hospital, or otherwise enhances their life.

Bring us in early

Start working with the payer community well before the expected launch of your product. Before you make decisions on marketing and pricing, seek feedback on what are the value points for the payer, the likely place in therapy and how we can expect to see it priced.

Recently, a drugmaker came out with an oral agent for multiple sclerosis. But the manufacturer hadn't prepared managed care or PBMs for the release, and it was seen as costlier without offering new outcomes. Many plan sponsors restricted access to this new drug.

But managed care and PBMs are likely to favorably receive a certain new oral agent for rheumatoid arthritis. The manufacturers worked closely with payers for a year prior to its release, positioning the medication as a second-tier line therapy and pricing it accordingly.

Work with us, not around us

Attempts to work around the system usually backfire. For example, DTC advertising—encouraging patients to pressure their physicians' script-writing, often to the detriment of the payer— drove the adoption of both prior authorization and step therapy. Similarly, the use and abuse of co-pay cards has begun a backlash of closed formulary classes and limitations on non-preferred drugs. Co-pay cards negate the impact of the health decision science we have applied to encourage patients to choose the drugs, pharmacy and health behaviors for optimum outcomes. Payers respond even more negatively when co-pay cards are introduced to undermine generic competition. In effect, these cards introduce waste into the system.

Think urban renewal

Pharma exists in a healthy tension with PBMs and managed care. Steve Miller, MD, chief medical officer at Express Scripts, compares the role of the PBM to that of urban renewal. "Our job is to retire or repurpose the old products to make room for the new and exciting products," says Miller. "We lower the cost—through generics, for example—of the old so that resources are freed up to pay for and hence fund the development of the new therapies."

The road to successful marketing of pharmaceuticals has passed through physicians and then patients and is now entering the territory of payer influence. Those able to let go of old pathways and pioneer new ones will have the most success. ■

Everett Neville is VP, pharma strategy & contract, Express Scripts.