

5 THINGS EMPLOYERS WANT TO KNOW ABOUT BIOLOGICS

Frank Johnson is worried. According to the executive director of employee health and benefits for the state of Maine, there is a woeful lack of knowledge about biologics in the healthcare payer community today. “In talking with my peers, as well as our plan trustees — who are lay people — there seems to be a fundamental lack of understanding of the biotech industry, its growth, and its opportunities.” Not only that, says Johnson, but “There is less understanding in this area than in any other area of healthcare.”

It’s not news to anyone that employers and other purchasers are becoming more concerned about the cost of the health benefits they provide, particularly biologic therapies for such conditions as cancer, rheumatoid arthritis, multiple sclerosis, psoriasis, and Crohn’s disease. Many employers are hesitant to provide coverage for biologic treatments for some of these diseases, at least until employees try less expensive products first. And as agents of the

Can a determination of the value of biologics really be boiled down to a handful of issues? According to our sample of purchasers, the number of issues that really counts in the realm of biologics is just 5.

BY WILLIAM ATKINSON

employers, health plans have been known to make members jump through hoops before they can gain access to biologics.

But just how did today’s concerns come about? Until recently, biologics have been able to slip under the radar and manufacturers were not asked to demonstrate a value proposition. Two factors stand at the forefront of their exclusion.

First, in the early 1980s, when biotech products were first introduced, many payers felt that they would be a panacea — a way, finally, to treat patients with chronic, progressive, and even rare diseases. These early treatments delivered good value, even at high cost, because they addressed various cancers, hemophilia, and primary immune dis-

ease — high-cost diseases, to be sure, but because the patient populations who used biologic treatments often were small or extremely ill, the expense did not preclude their usage.

Second, most biologics were delivered by injection or intravenously, and, thus, usually covered under the payer’s medical benefit budget rather than the comparatively smaller pharmaceutical benefit budget.

Things have since changed. Increasingly, payers and purchasers seek proof that biopharmaceutical companies’ products deliver value commensurate with their costs.

But with the development of more biologics to treat more diseases that are widespread, like breast cancer, and the accompanying growth in usage and cost, payers now are scrutinizing these drugs more closely with an eye toward greater cost control.

Also, biologics have gradually moved from the medical expendi-



Employers in the NBGH want to know what works, says President Helen Darling. They also want to know that whatever works “is better than some other alternative.”

ture budget, where they accounted for only 1 to 2 percent of costs, to the pharmaceutical expenditure side, where they now account for up to 15 percent of costs.

The bottom line is that purchasers want to make sure that the biologics they pay for will keep diseases in check, prevent or mitigate even higher medical costs in the future, and result in improved productivity from their employees. The biotech industry's responsibility, they argue, becomes one of providing better information on the value of their agents in terms employers understand.

David Balekdjian, a partner with the Bruckner Group, in Wakefield, Mass., puts the history of biologics in perspective.

"Initially, when payers were looking at coverage and formulating decisions based on a healthcare value perspective, the focus was primarily on small-molecule therapies."

Since that time, Balekdjian says, there have been a lot of payer cost-saving gains in the utilization of traditional drug therapies. This, he says, has created momentum to intensify the focus on biologics, because biologics' spend totals and growth rates have been so high. Payers now, he adds, are using the same standards for evaluating biologics that they use to evaluate traditional drug therapies in most, but not all, disease areas, Balekdjian says.

SPECIFIC ISSUES TO ADDRESS

Whether such apples-to-apples comparisons are accurate or even appropriate may depend on the quality of the information employers have to work with. According to observers in the industry, there are five things biotech companies

need to communicate to employers vis à vis the value proposition of their products.

1 Prove the value

Astute manufacturers should focus more on the substance of their value proposition and less on the packaging of messages, suggests Balekdjian. That is, the focus shouldn't be on how to package the message more attractively, but rather on how to provide payers and purchasers with what they're seeking—compelling healthcare value propositions for all new therapies and substantially enhanced value propositions for existing therapies. To accomplish this, he says, companies must comprehensively, and from the earliest stages possible, incorporate purchasers' value concerns in the product development and clinical trial process.

"This is not as straightforward as it sounds," he cautions, "because it swims against established methodologies for how most manufacturers shepherd the development process."

Done properly, however, a company can bring to market a therapy that addresses a real need, Balekdjian says, with a value proposition that is meaningful to MCOs and their purchaser clients. Moreover, such a strategy can be leveraged for commercial success.

"You can take the exact same compound or protein, and, based on following two different development paths, end up at launch with a drug that payers love from one path, or one that payers reject from the other path," says Balekdjian. "In the Bruckner Group's experience, most manufacturers are still struggling to understand that this is possible."

Balekdjian's experience is that

payers are willing to work cooperatively during the development process with manufacturers that are genuinely trying to understand and address payers' healthcare value needs, although unfortunately, this is still all too rare. "I have been told over and over again by payers that they can tell fairly easily who is genuinely trying to work with them, versus who is trying to give the appearance of working with them while actually pursuing their own agenda," he says.

2 Offer valid comparisons

Helen Darling, president of the National Business Group on Health, emphasizes the importance of being able to compare biologics with traditional treatments.

"Our members, large employers, want to know not only what works, but also want to know that what works is clearly better than some other alternative. This is especially important if the biologic is much more expensive," she emphasizes. "The evidence has to be published in a peer-reviewed journal."

Peter Hayes agrees. Hayes, director of associate health and wellness for Portland, Maine-based Hannaford Bros., and governance committee member of Care Focused Purchasing, a coalition of more than 50 large employers and seven regional carriers building a data warehouse in the belief that healthcare costs can be controlled through high-quality care, uses three "filters" when looking at new medical treatments. The first of these focuses on comparison.

According to Hayes, the real value that needs to be created for any decision maker is credible research that answers the question:

“For the investments we are making in the full range of medical procedures, drugs, and so on, what do biologics buy in terms of quality of life?”

It is difficult to determine what should and should not be included in a health plan to achieve desired outcomes if clinical studies don't exist to point out the best investment among the available alternatives, says Hayes. “If there are four or five different modalities to treat a particular illness, how do we make the most efficient decision on the one with the best outcome?”

Hayes notes there's no scarcity of research in the U.S. marketplace showing that certain drugs work. What is missing in the United States, but common in Europe, is a thorough analysis of the clinical efficiencies of the different drug modalities and treatments that are available, versus the health outcomes that result from the investments. “In other words, Drug A and B may both give good outcomes, but the question is which is more efficient?” Hayes explains. For example, he says, injectables tend to be expensive. If the research shows that these are the best way to treat an illness, they should be covered. But if they simply replace other, less-expensive therapies that may not be as convenient but still deliver satisfactory outcomes, then additional discipline needs to be brought to the decision-making process.

3 *Emphasize efficiency*

The second filter Hayes uses relates to efficiency: “Injectables are being promoted by some pharmacy benefit managers. When do you force members to go through a sup-

ply house, and how does that integrate into local healthcare?”

For example, Hayes says, a member may first go to a physician who prescribes the injectable and then arranges to have the product shipped to his or her office, and then the member goes back to the physician for administration of the injection. “This may not be the most efficient delivery system,” Hayes observes. “I struggle with this.”

4 *Show positive employee impact*

The third filter Hayes uses involves assessing the impact of a treatment — both personally and professionally — on employees. “As I've said, if the procedure for taking a drug is lengthy, time-consuming, and complex, what does it do to a person's absenteeism and productivity?” he queries. There is compelling evidence, Hayes says, that a minimally invasive procedure versus an open surgical procedure will reduce disability duration by as many as 30 to 40 days. If the procedure costs a little more, but a person's pain, suffering, and disability time period can be shortened, Hayes considers this a strong positive that needs to be factored into the decision-making process.

Frank Johnson, in Maine, agrees. “The biotech industry should be able to demonstrate to senior management and plan trustees the opportunities that exist for a reasonably good return on investment,” he states. It doesn't have to be an immediate return on investment, Johnson says. “People are willing to accept the premise — and sometimes take the risk — that it may be several years before you see a downturn in claims related to certain illnesses as a result of taking a more aggressive

posture on the technologies.”

According to Johnson, if some pilot programs are demonstrating positive preliminary results, this can provide his plan with enough information to proceed with its own pilot program for a given segment of its population.

5 *Properly target population size*

NBGH's Darling raises a final point to be addressed: To what extent is the marketing of biologics and services related to them appropriately targeted to the people who truly need them?

“Employers were concerned in the past about drugs approved for a very small percent of the population, such as Vioxx,” Darling points out by way of example. Over time, though, there was additional promotion and much wider prescription well beyond the original approval category. Employers soon found themselves under greater pressure to cover it. Twelve years later, evidence began to mount that many people may have experienced negative consequences from use of the drug.

“If you look back and ask the question of whether Vioxx was used only by those people for whom it was the most suitable,” she says, “the answer was increasingly ‘no,’ and that was one of the reasons the problems occurred.”

Experiences like this make employers wary. That, she says, reinforces their desire for assurances that biologics are being used by medically appropriate populations.

A HEALTH PLAN PERSPECTIVE

Charles Mihalik, PharmD, RPh, director of pharmacy services for Indianapolis-based M-Plan, believes that new biotech products are valu-



PHOTOGRAPH BY GLENN TRIEST

Payers and purchasers should focus on the true overall value of treatments, not just the initial cost, says Stephen Lash, PharmD, pharmacy director for value-based healthcare at Genentech. "It is also important to look at the simplicity of the treatments and the long-term safety profiles."

able and necessary. "Biologics also can be stepping stones to more effective and more cost-effective drugs in the future," he says. "As such, we want to support them, and I think our employers may want to support them, as well."

According to Mihalik, the biotech industry has a responsibility to "get the studies out." If they don't, he says, then the employers, who are the ultimate payers, may decide not to pay for what is currently available. "If this ends up

happening, then who will pay for the continued development that can lead to these more effective drugs?"

Based on what Mihalik has seen and heard from several large employer groups, few studies have addressed the quality outcomes that the employers are most interested in, such as length of time off work and productivity. "In other words, employers are investing a lot more money in their employees for these biotech drugs, but they don't nec-

essarily know what value they are receiving," he says.

Another concern, says Mihalik, is that MCOs have not seen many studies that compare cost-effectiveness of biologic therapies, or at least the value being received, with that of older, more traditional products. "We aren't receiving information to suggest that we are getting a lot of value for the extra money we are spending."

Smaller employer groups are worried that biologic treatment regimens can cost more than what some of their employees earn in a year, says Mihalik. "This causes smaller group premiums to go up substantially, to the extent that insurance becomes unaffordable or of lesser value, even in instances where just a few members have these expensive disease states."

BIOLOGICS INDUSTRY PERSPECTIVE

It's obvious that payers want more information to make informed decisions about the value of biologics. It's also clear that they are looking to the biotech industry to provide this information.

At least one biotech insider believes it is the responsibility of the payer community, not the manufacturers, to gather and analyze the information. Stephen Lash, PharmD, pharmacy director for value-based healthcare at Genentech, begins his argument by noting the advantages of biologics, and suggests that payers should focus on the true overall

