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Biotech products for chronic conditions will be coming with regularity in the next few years, and these represent both a clinical opportunity and a financial challenge for health plans. So far, few payers have figured out how to make such treatments available without breaking the bank. The challenges ahead and strategies for handling them.

BY STEPHEN HERSKOVITZ

# PAYERS' DILEMMA: LOOMING COSTS FOR CHRONIC CONDITIONS

A storm is gathering for MCOs in the form of costly biotech therapies for chronic diseases. The same technologies that hold dramatic promise for people with hard-to-treat conditions threaten to wreak havoc on health plan budgets, overwhelm cost-containment strategies, and pit patient desires against economic realities.

No one denies that biologic agents represent a dramatic clinical advance to some patients, as these medications help patients with cancer, HIV/AIDS, and rheumatoid arthritis enjoy a quality of life unimaginable 20 years ago. By 2010, between 325 and 400 biotech drugs could reach the market, with the promise of better health outcomes. For payers, this surge represents a potentially ruinous economic perfect storm as new and expensive biologics find uses in more common disease states, thus reaching larger populations.

While many biologic products focus on oncology and HIV/AIDS, the technology now is being used to target familiar chronic conditions:

- Cardiovascular disease (e.g., cholesterol management; congestive heart failure)
- Diabetes (inhaled insulin; type 1 vaccine)

- Digestive disorders (GERD; Crohn's disease)
- Respiratory disorders (allergic rhinitis; asthma)

As manufacturers reach out to larger populations who must use prescribed medications for years, their wares present MCOs with a Gordian knot. Intertwining threads of consumer demand, political imperatives, burgeoning budgets, and medical ethics — each representing a daunting challenge individually — can become overwhelming when combined.

“The fundamental problem,” says Randy Vogenberg, RPh, PhD, “is that the current system is bad for biologics and bad for injectables.” Vogenberg, a senior vice president at AON Consulting, adds that “The big issue is that the system was built to deal with large quantities of oral medications. It didn't take into account the delivery method and the unit cost of biologics.”

MCOs know that biologics are potential budget busters, yet few plans have instituted comprehensive cost or utilization controls. It's not that health plans don't recognize the problem. Winston Wong, PharmD, director of pharmacy management at CareFirst Blue-Cross BlueShield, says, “Biologics and other injectables have been high on our radar screen for several

years." CareFirst represents more than 3.2 million members in the Mid-Atlantic.

In his work with MCOs, physician networks, and pharmaceutical, biotech, and medical device manufacturers, Melvin Stein has seen increased sensitivity to this issue on both sides of the negotiating table.

"The number one problem is the flood of new biologics. It's a major focus for payers; the cost of biologic administration is an additional problem," says Stein, the managing executive at Healthcare Executive Partners, a consulting firm in Horsham, Pa., and who is a former senior executive at Aetna U.S. Healthcare. "Those costs, because biologics are a medical benefit, have been buried for years. It's as if — all of a sudden — a year or so ago, everyone noticed the impact. And now everyone is asking how they should manage these costs."

The challenge of biologics is more than economic, Stein says. Medical ethics are being re-examined in light of tough decisions forced by the availability of biotech drugs. Is a nonessential treatment worth \$200,000 a year? On a more fundamental level, what is the purpose of insurance? How these questions are answered could lead to formalized rationing, which Americans have been loathe to accept. Nevertheless, with limited resources to pay for healthcare, access to biologics might have to be restricted.

"In some situations, it is difficult to come up with a sound reason, other than cost, not to use some products," Wong says. "In these situations, it is difficult to tell a patient to use a standard therapy." Medical ethics must address the other aspects of the evaluation process to ensure that reasonable, defensible, and medically appropriate decisions are made.

#### STRATEGIES IN THEIR INFANCY

Vogenberg says that employers are just beginning to look at the issue of the impact of bi-

ologics on their bottom lines. Currently, most plans rely on traditional cost-containment strategies, such as prior authorization, to control utilization of biologics and, by extension, the overall effects of specific products on the budget. The use of prior authorization is a default strategy, he says. The next stage is creating and implementing plan benefit designs that take biologic products into account. It can take up to 18 months to change plan designs, however, and with the product pipeline looking robust through 2010, there is a concern that employers and health plans could be playing catch up.



**Biologics force hard** questions about what is ethical in health-care. "If the right patient shows up with the right condition, how can he be denied coverage?" asks Mel Stein, of Healthcare Executive Partners.

Overall, he says, the portfolio of potentially marketable products "seems to be on track."

Vogenberg expects more plan designs in 2006 to include biotech riders or carve-outs and to target top-5 usage drugs in disease management programs. "For many employers, especially smaller

ones, the issue is too far away," he says. "Larger employers have a longer time horizon and are concerned about the growing use of biologics in more common diseases."

Together, union members and retirees compose a wild card that many companies are hoping Medicare will take out of their hands, Vogenberg says. He expects most employers to take advantage of the new Medicare Part D subsidy but adds that if the subsidy ends up being spent on a large enough number of biologics, the subsidy approach taken by employers could change.

Wong says CareFirst is using standardized reimbursement levels as a tool to help control utilization of non-self-administered bio-

logics. Currently, he says, physician reimbursement for biologics has been set at a “reasonable discount” off the average wholesale price — an attempt to make reimbursement more reflective of the actual acquisition cost of the medication. Prior to the implementation of this strategy, physicians were paid at either billed charges or at a slight discount off AWP. In some cases, Wong says, physicians purchased generics for injection and billed for the brand. Using national drug code (NDC) billing numbers would help with this issue, but there are significant barriers to that strategy.

Another issue Wong views as a barrier to good plan control over biologics is that some medications fall under the medical benefit, while others — usually self-administered injectables — fall under the pharmacy benefit. It is known at the point of sale that a patient is obtaining a biologic under the pharmacy benefit, but an accounting of therapies incurred under the medical benefit are more elusive. “We usually learn that a patient is on a specific drug 30 to 60 days after the patient has received the drug under the medical benefit,” Wong says.

“We can use prior authorization to monitor and minimize overuse of self-administered products,” he adds. CareFirst evaluates biotech and standard treatments in the same way. Each drug is evaluated on an individual merit basis, and not by category.

### CHRONIC THERAPY

In the past, most biologic products were geared to treating life-threatening conditions or disease states with smaller populations. New issues arise with the advent of products using biologic technology to treat high-impact diseases.

Omalizumab (Xolair) is a recent example of a biotech drug that was introduced to treat a chronic condition and that faced significant barriers among payers to its use. “Xolair is meant to treat asthma with an allergic component,” Wong says. “I understand the mech-

anism of action, but I haven’t seen it compared to inhaled steroid therapy (assuming the steroids are taken properly).” Currently, CareFirst treats omalizumab as a tier 3 drug requiring prior authorization and evidence of an allergy component present.

The omalizumab example — a drug that treats a common condition for which conventional therapies exist — is becoming less rare. Wong points to rheumatoid arthritis medications or a category such as multiple sclerosis as areas of concern. “We have these products on prior authorization,” he says, “and we try to lead patients to a cost-effective solution.”

In terms of other biotech products, Vogenberg says, “Due to complicated delivery modes, we have yet to see as wide an impact on a very large number of patients. Some biologic products have had a larger financial impact but on fewer patients, as they are embedded into procedures such as cardiovascular catheterization.”

In general, Wong expresses some frustration with biotech companies as marketers. “I want to see efficacy data comparing their drugs versus standard therapies that are usually much, much less expensive,” he says. His experience has been that many manufacturers skirt the issue and do not provide direct answers to direct questions — thus fueling payer skepticism about the value of a biotech product as well as doubts how well biotech companies understand payers’ needs.

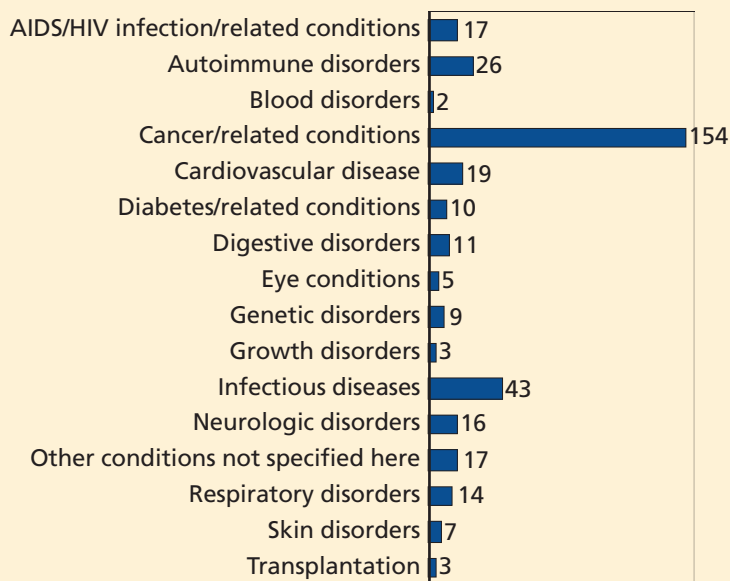
### COMPLICATING INFLUENCES

Several key factors present challenges to health plans attempting to get a handle on their present and potential biologics costs.

**Defining biotechnology.** Although it is acknowledged that, on the most superficial level, products produced from a bioengineered production process fall in the biotechnology sphere, some products seem ambiguous. Proton-pump inhibitors may be considered an example of an early biotechnology product because of their mechanism of action.

## Biotech in the Pipeline

According to the Pharmaceutical Research and Manufacturers of America (www.pfma.org), at least 324 new biotech drugs are in development.



SOURCE: "2004 SURVEY, MEDICINES IN DEVELOPMENT: BIOTECHNOLOGY," PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, WASHINGTON

Such definitions come into play because there may be an appropriately different set of expectations for biotech drugs; if the difference between biotech drugs and standard pharmacy products is not clear, then cost differentials may be harder to justify.

"Many payers may not really understand what 'biotech' means," says Vogenberg.

To me," says Wong, if a product is produced synthetically and costs more than \$1,000 per month, then it is probably a biotech product."

**Medical versus pharmacy expenses.** Traditionally, many biologics have been considered a medical cost. Concern focused more on professional and institutional fees than on medication costs. As biologics begin to move to the phar-

macy benefit, priorities shift and a drug's cost must be managed separately from the medical procedure.

Bringing biologics under cost-containment strategies will necessitate greater cooperation between medical and pharmacy departments. Medical and pharmacy priorities differ and their information technology systems capture different types of data.

**J-codes versus NDC.** Shifting biologics to the pharmacy benefit necessitates another transition — from the traditional method of labeling biologic injectables based on medical procedures (J-code) to a more pharmacy-based methodology (NDC). The NDC allows payers to know more precisely what drugs and doses were used during a procedure and to scale payment ac-

ordingly. There is a problem, however: The process of switching claims-processing systems from the J-code (which has 6 digits) to the NDC (which has 11) is extremely expensive — so much so that the federal government, which originally mandated use of NDC under the Health Insurance Portability and Accountability Act, reversed itself and allowed plans to continue using J-codes.

Wong says his plan still uses J-codes and that it would cost Care-First millions of dollars to change claims processing systems to accommodate the NDC.

**Medical ethics.** Aside from cost and utilization considerations, this is perhaps the most significant issue that payers face when thinking about the impact of biologics. It may yet be difficult to measure the clinical advantage of a biologic over standard treatments, but it will be extraordinarily difficult for plans to deny treatment — especially for oncology or HIV products. To avoid charges of arbitrary rationing and to ensure that the best care is delivered to the right people at the right time, plans will need to spend time discussing the ethical dilemmas they face.

"If the right patient shows up with the right condition, how can he be denied coverage?" asks Stein.

### THE VALUE PROPOSITION

At the core of the debate around biotech drugs and their use in larger populations with chronic care situations is the question of value: Is the biologic worth it? Is the higher additional cost for a biologic offset by significantly better patient outcomes or by permitting a plan to avoid other, longer-term costs?

Wong wonders if many biologics are significant enough advances over current therapies to warrant expenditures that are often tens or hundreds of times higher. “We have not seen a lot of data showing the effect of these drugs on final clinical outcomes for patients,” he says.

Stein says that’s why biotechnology companies need to reorient their approach. Traditionally, he says, biotech products were sold on their clinical benefit; now they also must make a clear economic case.

“Margins are going to be squeezed across the board,” says, Louis M. Sherwood, MD, a colleague of Stein at Healthcare Executive Partners.

“It is difficult to understand the cost structure of biologics, and they will be lumped under the same blanket as pharmaceuticals. There isn’t an endless pool of money in the system, and we can’t keep shifting the costs.”

Wong says he understands and can accept that biologics may cost more than standard treatments, and he concedes that it can be difficult to tell a patient to use a standard treatment rather than a biologic product because of cost. He says, however, that it is legitimate to question the cost-value relationship of the drugs. What’s needed, he adds, is evidence to support treatment decisions. “The problem is that when I ask for data [on the] clinical outcome of the patient, I do not get a response.”

Vogenberg concurs: “What does this drug bring to the table?” The biotech companies need to demonstrate significant value to support their pricing structure. “There is a

danger, I suppose, that biotech companies could lose their halos.”

If indeed biotech companies are perceived as scientific entities versus marketing entities, what happens, Vogenberg wonders, when more and more consumer influence is factored in? “Direct-to-consumer advertising, coupled with rapidly emerging consumer-directed health plans, will raise the ante,” he says. Aside from an MCO, employer, or

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government payer asking the value question, consumers will ask whether a biologic drug is worth it.”

Finally, Wong adds, long-term safety issues should be considered. “It must be understood that biologic agents are designed, engineered, and manufactured to alter specific natural biological processes. Quite often, while we look for the effects of these agents on the specific biologic pathway of focus, we do not adequately know the effects upon other processes.” Such unknowns can be beneficial and result in broader indications, such emerging uses of TNF inhibitors. “However, in some cases the unknown has led to harmful effects, such as seen with [natalizumab]. We know very little about these biologic modifiers.”

### SELLING A PARTNERSHIP

Stein says that in today’s world, biotech companies need to work to

build a strong rationale for a product’s use with payers. “First, they need to let payers know what is in the pipeline and to work more in partnership with payers,” he says.

Second, Stein and his colleagues believe that it is critical that biotech companies use technology and data to make their case. They advocate the proactive use of pharmacoeconomics — using the health plan’s own data based on a powerful, well-designed algorithm — to help demonstrate cost offsets. For instance, the biotech company may want or need to demonstrate how, through the use of one or more of its products, the plan is avoiding other healthcare

costs within its membership.

“Biotech companies need to understand the connection between the clinical and business worlds,” says Vogenberg. Part of the challenge “is that biotech doesn’t understand the market from a payer’s perspective.” To succeed, Vogenberg says, biotechs need to create value propositions that work for employers and for government payers. “They need to ask questions as if they were the employer: ‘Do I need to pay for this product through my plan coverage? What does it mean to me as an employer?’”

“It is important,” says Wong, “for them to stay scientific *and* to understand how to be cost-conscious.”

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