Last fall's launch of a lower-priced monoclonal antibody to treat colorectal cancer raised the question: Has the biotech industry opened a price war? Not necessarily. Even if it were so, payers would view it with skepticism – despite all the talk about the cost of biologic drugs. So when a lower-cost product hits the market, if price isn't persuasive enough…

… WHAT DO PAYERS REALLY WANT TO SEE?

BY ED SILVERMAN

LEONARD SALTZ IS OPTIMISTIC, but not hopeful.

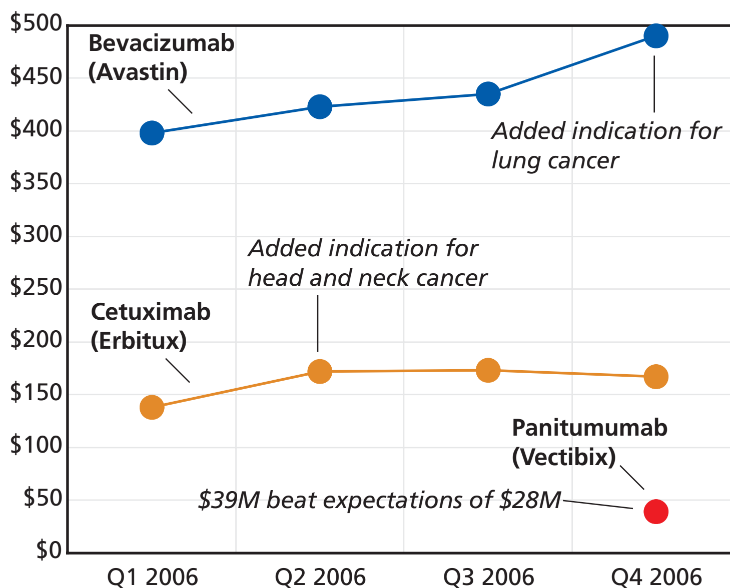
The decision by Amgen last fall to price its panitumumab (Vectibix) colon cancer treatment at a 20 percent discount to ImClone Systems' cetuximab (Erbitux) was certainly welcome news. As a colon cancer specialist who also chairs the pharmacy and therapeutics committee at Memorial Sloan-Kettering Cancer Center, in New York, Saltz is particularly sensitive to discussions about access to — and payment for — these drugs.

But the move by the Thousand Oaks, Calif., company hasn't convinced Saltz that biopharmaceutical companies have suddenly experienced an epiphany. As he sees it, Amgen's pricing strategy — which positions panitumumab at a monthly cost of about $8,000, compared with $10,000 for cetuximab — plays a marketing opportunity. As such, Saltz doesn't believe this automatically suggests that other manufacturers will follow suit.

"Time will tell, but the first question in my mind is whether Vectibix and Erbitux are equivalent. You know, is it a Coke-or-Pepsi kind of thing? If so, then people would hope price is a consideration," says Saltz. "But there are more data available for Erbitux than Vectibix, which is an issue. There are data showing Erbitux works better with chemotherapy than by itself, but studies haven't been done with Vectibix.

"The price of Erbitux was widely viewed as particularly egregious in the first place, and so that left a healthy amount of room to undercut it and still get a healthy profit margin," he continues. "Companies will evaluate the market and find pricing that will work best for their drugs. But was this a sign that companies are interested in lowering prices? That would be an overly optimistic interpretation."

Certainly, Amgen's pricing decision took many cancer specialists,



other manufacturers, and third-party payers by surprise. The company had signaled to Wall Street that a significant discount would be offered, but the world at large didn't expect a 20 percent difference. On the surface, Amgen's decision suggested a change was underway. For the most part, the approach to pharmaceutical pricing has been a game of leapfrog — if the market can bear X dollars, then it can pay a little more for the latest medication, especially if various claims can be touted.

For the moment, though, the panitumumab pricing gave everyone pause. Perhaps the mold was cracking just a little and other companies would consider similar actions. In the weeks following the panitumumab debut, panitumumab sales were strong enough that ImClone's cetuximab was losing market share, even though panitumumab may have lacked the kind of clinical outcomes data Saltz — not to mention payers — would like to see.

By early November, panitumumab had garnered 18 percent of the U.S. market for anti-EGFR (epidermal growth factor receptor) treatments. That was ahead of expectations, according to Eric Schmidt, managing director and senior research analyst at Cowen & Company, in New York, and who has forecast that panitumumab will continue to capture market share from cetuximab. Nonetheless, he doesn't view Amgen's pricing move as revolutionary. In part, that's because there still aren't many therapeutic categories in which there are rival biologics that are essentially equivalent and have supporting data that can be analyzed for outcomes.

"To be honest, I don't think it signals any sort of trend," says Schmidt. "This is one of the few head-to-head situations in the marketplace where it *is* like a battle between Coke and Pepsi — panitumumab has some modest advantage over cetuximab in convenience and safety, but the drugs are more similar than different. Currently, there just aren't that many situations where you have a 'me-too' biotech drug. There may be a few by 2008, but most are a year off.

"Now, there's no question that a 20 percent discount is sizeable," Schmidt continues, "and I do think that maybe you'll see other companies throw a bone to managed care. But in reality, it's a pretty small bone. I think we're still in a situation where companies will charge as much as they can."

Premera isn't assuming a particular drug is the better choice simply because it carries a 20 percent discount to its nearest rival.

PRICING AND UNIQUENESS

That's not necessarily the case, however, with every therapeutic category. Biologic therapies for psoriasis recently generated some headlines because sales of biologics have been flagging (see page 22), and the number of people using the medications isn't as great as manufacturers had hoped. A key reason is the expense, which is prompting third-party payers to employ step therapies and insist that patients try conventional therapies first.

Of course, the cost of biologic therapies is, in part, rooted in the understanding that developing one isn't a cheap proposition. The average cost to nurture a biotech from discovery to delivery is now approximately $1.2 billion, according to the Tufts Center for the Study of Drug Development. A new biologic drug takes, on average, 97.7 months to wind its way through clinical development and regulatory review — roughly 8 percent longer than the time required to do the same for traditional pharmaceuticals.

"I don't draw a connection between research-and-development costs and the price of a specific molecule," says Joseph DiMasi, PhD, director of economic analysis at the Tufts Center. "On the other hand, you have to remember that if costs are high but prices aren't commensurately high, then that will impede future innovation. That's not a justification or explanation, though, for any particular price. What you really need to look at is how the value of the medicine is perceived in the marketplace. And if there are similar medications on the market, then that can create some price competition. But with most biologics, there's more uniqueness."

Uniqueness is, indeed, an issue, and for various reasons. John Watkins, RPh, MPH, of Premera Blue Cross in Mountlake Terrace, Wash., notes that no two biologics are really alike. As a result, each produces its own set of challenges for third-party payers. The key to sorting it all out is data, so his pharmacy and therapeutics committee recently fast-tracked panitumumab as part of a class review of the anti-EGFR treatments.

"We've bumped this to the top of

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our priority list," says Watkins, who is Premera's pharmacy manager for formulary development and a clinical associate professor of pharmacy at the University of Washington, in Seattle. "We need to look at the economic modeling and cost effectiveness — which doesn't really tell me which treatment to choose, but helps me understand the return."

Not surprisingly, he isn't assuming panitumumab is the better choice just because it carries a 20 percent discount to its nearest rival. He wants to scrutinize the treatment for clinically novel or significant benefits. Failing that, he wants to see if the medications are equally effective. The highest value, he notes, doesn't necessarily correspond with the lowest price.

In his view, panitumumab didn't alter the larger discussion within managed care circles about biologics' value and pricing. And like many others in his position, Watkins sees the costs of medications moderating only when there are competitive treatments available in a given category. Nonetheless, he does believe panitumumab can serve as a useful example for third-party payers who constantly haggle and jawbone with manufacturers about pricing.

"It is significant, actually. With the exception of the growth hormone class, it's the first case I'm aware of in which a manufacturer has come out with a dramatically lower price," says Watkins. "So yes, we'll be talking with manufacturers about this and you can bet this class — the anti-EGFR treatments — will become an example to raise about pricing. The message will certainly go out to the manufacturers."

"A LEADERSHIP POSITION"

Amgen says it already understands that message.

In preparing for the panitumumab launch, Amgen emphasized concern for patients and affordability. As part of its pre-launch campaign, Amgen developed a patient-assistance program that provides panitumumab at no cost to uninsured patients with household adjusted gross incomes of up to $75,000 annually. For those who aren't eligible, another feature limits patient copayment spending.

"We really hope to take a leadership position and push the industry to take a responsible position. Industry needs to recognize the financial burden on patients," says Joshua Ofman, MD, Amgen's vice president of reimbursement and payment policy for the global coverage, reimbursement, and health economics unit. "We wanted to be attuned to market dynamics — reimbursement policies, physician demand, and competition — but at a price that still allows us to fund incremental and continued research in cancer."

Ofman demurred when asked whether Amgen would take the same approach to pricing with forthcoming biologics the company may develop for other illnesses, although he did distinguish between biologics for cancer and other conditions.

"Clinical circumstances vary greatly — different cancer therapies, for instance, are used in different tu-

mors at different doses. So we look individually at each medication. There isn't a one-size-fits-all situation to apply."

Of course, manufacturers realize that insurers don't want to be accused of effectively denying treatments to patients because of cost, especially when a patient has cancer and a particular therapy can extend life or mitigate suffering. In this way, Amgen argues that it's trying to make it easy for MCOs to give its medication a hard look. Although, as Premera's Watkins is quick to note, any decision won't be made based on price.

"For the third-party payer, they're in a difficult situation," says Max Jacobs, a biotech analyst at Mehta Partners, an investment boutique in New York. "When it comes to a cancer product, they can't really say no. The Vectibix price gives insurers an incentive to pay for it, but if Erbitux is working well, they will still pay for it as well.

"There really just aren't enough data to compare the two drugs. We need head-to-head trials."

C. Douglas Monroe, RPh, who works with biotechnology drugs for drug information services at Kaiser Permanente, would seem to echo that position.

"Both Vectibix and Erbitux are vying to become first-line treatments, but those trials have not been completed and published. That could slow the decision making and the uptake because the oncologists look to data. Our clinicians may know about the pricing, but that only makes a difference when two drugs are considered equivalent. There may be clinical applications where they prove to be equivalent and others where they do not."

PRICE AS ADVANTAGE

The lack of data, for now, means that the discounted pricing on panitumumab isn't creating a shift in managed care thinking or action in the form of payment policies, says Rebecca Shanahan, who at the time of this writing was general manager of Orlando-based Aetna Specialty Pharmacy. For instance, 73 percent of cetuximab spending is still taking place in physician offices — the traditional buy-and-bill scenario. Only 25 percent of spending occurs in hospitals.

"So far, it hasn't been a watershed event," says Shanahan. "Vectibix has been out for only a short time and is still being evaluated in the marketplace on both efficacy and cost. We need more information before we make any decisions regarding formulary preference. So it makes for a lot of complexity. In our case, both Erbitux and Vectibix are covered by a medical benefit. So if the diagnosis meets the criteria, we don't have a preference. Not as of now.

"But this does show that manufacturers are beginning to think about price as an advantage — and the cost impact on patients. This is having an effect on their strategy," she continues. "You've got to be at a tipping point. What payers are looking for is something in oncology to move everybody to a continuum-of-care approach that advantages quality, cost, and outcomes. This is neither disappointing nor alarming. It's just another event that drives the dialogue."

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>
> — REBECCA SHANAHAN

For now, says another expert, Amgen's pricing move is a blip on the radar screen.

"The industry mantra is to avoid price competition and promote product differentiation. And for insurers, the mantra is vice versa," says James Robinson, PhD, Kaiser Permanente Distinguished Professor of Health Economics at the University of California–Berkeley. "This is an encouraging sign, yes, that a product is launched at a lower price. But I think it's a straw in the wind. Remember that a 10- to 20 percent discount is modest.

"This will have to play out over a number of years. What about biologic follow-ons? Who's capable of manufacturing those? Big companies? If so, why would they price a product lower than the product they're following?

"The biotech industry is absolutely famished for revenue," he continues. "The industry wants to squeeze so much out of any product that actually gets to market, so it doesn't want price competition. Even in this latest oncology case, the manufacturer will seek to promote the product's purportedly unique clinical characteristics and allow its lower price to play a secondary role in driving sales." **BH**

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