Seeking Value as Cancer Drug Costs Soar

Oncologists and their patients look closer at the cost-effectiveness of expensive therapies

As the next generation of cancer drugs arrives, how many U.S. patients will be able to afford them?

That’s a major question at UnitedHealthcare, which insures more than 40 million U.S. residents for their medical expenses.

“The cost of established cancer drugs is increasing by 7% to 10% a year,” says Lee Newcomer, MD, senior vice president of oncology services at the Minnetonka, MN, company.

“Additionally, if a new-generation agent at $100,000 a year replaces old agents at $7,000, you can imagine the kinds of inflation rates we’re seeing.”

While it’s difficult to get a handle on the accelerating cost of drugs, some oncologists point out that the 13 cancer drugs approved by the U.S. Food and Drug Administration (FDA) in 2012 all cost more than $5,900 per month.

Such pricing is strongly driven by federal and state drug policies, comments Scott Ramsey, MD, PhD, a health economist and oncologist who directs the Hutchinson Institute for Cancer Outcomes Research at Fred Hutchinson Cancer Research Center in Seattle, WA.

One cost driver is that the Centers for Medicare and Medicaid Services, which cover about half the nation’s spending on cancer treatments, do not negotiate cancer drug prices with manufacturers. A related issue is that oncologists typically draw a substantial portion of their income from reimbursements for drugs at Medicare’s average-sales-price-plus-6% rate, Ramsey says. (The 6% rate has been cut to 4.2% this year under the federal budget sequestration clampdown.) A higher price tag for a drug thus increases the income to oncologists when they prescribe it under the price-plus reimbursement system, creating a strong incentive for companies to set high prices.

Another major factor is that “most states now have mandatory coverage rules for new approved oncologic drugs; insurance companies are forced to cover them no matter what,” Ramsey adds.

Given the effect of these state rules on insurers, “we’re not allowed to make a value decision,” Newcomer emphasizes.

“There is no price regulation at all, and insurers don’t have any negotiating ability. The only way we can make this work is to pass the cost on to patients as higher premiums and copays.”

“In turn, drug expenses are a major contributor to the high risks and large resources inherent in drug development, investors want good paybacks for the drug candidates that do succeed. Additionally, the push into personalized medicine that targets ever-more-specific subpopulations of cancer patients may further boost drug prices, because prices generally rise for products that offer particularly high benefits for well-defined small groups.

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“We price our medicines in consideration of the value they bring to patients and society,” says Novartis. “Other important contributing factors include the significant investment in research, the scientific innovation the product represents, the growing cost of operating at the highest standards, the level of unmet medical need, and the clinical value that the drug delivers to patients. We work together with government healthcare systems, charities, and other payers to build successful cost-sharing models.”

CONTAINING COSTS

Although oncologists can’t control drug pricing, they can optimize drug use.

As a first step, “we need to get smarter and smarter about who needs which medicine,” comments Amy Abernethy, MD, PhD, associate professor of medicine and director of the cancer care research program at Duke University School of Medicine. “We need to work hard to make sure that companion diagnostic assays are available to us,” she says, although their development and use often face tough scientific, regulatory, and economic challenges.

Secondly, Abernethy says, it’s important to assess when not to give drugs. “When do we continue with successive lines of therapy in a person whose disease has progressed or recurred?” she asks. “Unless we sit down with patients and really understand what they want, often we just keep prescribing. And until we force ourselves to have the hard conversations as a community, it’s hard to have that conversation in the room with patients.”

Moreover, as treatment options grow ever more complex, decision support systems “will have to tell you at the point of care, here’s the smartest solution for this patient right now, and here’s what it will cost,” she predicts.

The FDA and the Centers for Medicare and Medicaid Services don’t systematically gather data for cost-effectiveness studies, but insurers such as UnitedHealthcare do. Similarly, the American Society for Clinical Oncology’s CancerLinQ project eventually will include billing data that can be plugged into cost-effectiveness analyses, notes Abernethy, who chairs the CancerLinQ advisory board.

LOOKING FOR GOOD VALUES

As the U.S. healthcare system struggles to broaden coverage and focus away from fee-based payments to outcome-based payments with the implementation of the Affordable Care Act, it needs to address issues such as cost-effectiveness for cancer therapies, oncologists say.

With new melanoma treatments, for example, “the science is exquisite, the potential is audacious, and the costs are remarkably high,” says Abernethy. “The other side of that story is, how do we derive value? As a society, we’ll have to start to figure how we can get our heads around the issues of costs.”

Going forward, manufacturers will need to price drugs more directly on their value, says Bruce Booth, PhD, life sciences partner at Atlas Venture in Cambridge, MA. “If a drug provides a real clinical benefit, it should command premium pricing,” he says. “Adding a month or two of life extension isn’t clinically meaningful and shouldn’t command those premium prices.”

“Purchasers, particularly the federal government, need to look at the value the drug is providing, and to be able to negotiate based on the value, which would give the manufacturers the right incentives for pricing,” says Ramsey. “I’m frankly a little bit pessimistic that this will change soon.”

He and Newcomer agree, however, that cancer drug costs offer just one dramatic example of soaring healthcare costs that can’t continue in the long run.

More generally, Newcomer points to one economic model suggesting that unless the United States alters its course, by 2018 the total of out-of-pocket expenses and healthcare premiums for a family will be equal to about half of all U.S. household income, which is simply not sustainable (Ann Fam Med 2012;10:156–62).

“Drastic change is coming,” says Newcomer. “What that looks like is anyone’s guess, but what’s clear is that the status quo just can’t be maintained.”

As one effect, “developers will need to have as much emphasis on making new drugs affordable as they do on making new drugs available,” he adds.

“We’re developing novel agents with novel mechanisms each year, and these drugs are expensive to develop and to produce,” says Duke’s Zafar. “But I wonder about the margin between the expense of drug production and the marketing price. We really have to consider whether that model is sustainable going forward, particularly since our healthcare costs are rising faster than in any other country in the world.”

“From the start of drug development to large post-marketing studies, cost will have to be considered every step of the way,” Zafar emphasizes. “We’ll all have to learn the language of cost and cost-effectiveness to understand how it impacts our industry, our healthcare system, and, most importantly, our patients.”—Eric Bender

NICE ALTERNATIVES

In covering cancer drug costs, the U.S. approach stands in stark contrast to that of many other developed nations (Blood 2013;121:4439–42).

In the UK, the National Health Service’s National Institute for Health and Care Excellence (NICE) negotiates pricing for some new drugs with manufacturers, which explains why the chronic myeloid leukemia kinase inhibitors dasatinib, imatinib, and nilotinib cost about a third what they do in the United States.

In addition, NICE flatly rejects drugs deemed to offer insufficient benefit for the price.

The UK continues to push on drug pricing, with NICE scheduled to implement a blueprint for “value-based” pricing of new drugs in 2014. In June, the UK’s Department of Health announced that it would seek to cut pricing on many existing branded drugs by 10% to 20%.

For more news on cancer research, visit Cancer Discovery online at http://CDnews.aacrjournals.org.