COSTLY CARE

Expensive Cancer Drugs With Modest Benefit Ignite Debate Over Solutions

By Gunjan Sinha

Like many oncologists, Don Dizon, M.D., doesn’t like to candy-coat bad news. “I try to be realistic about what we can accomplish with treatment,” said Dizon, who specializes in treating gynecological cancers at Women and Infants Hospital of Rhode Island.

But it’s in what he tells his patients afterward that Dizon may stray from the norm. Dizon also discusses with his patients the cost of drugs and the fact that their particular insurance may not cover them. Patients then meet with a hospital-appointed nurse manager, who not only explains chemotherapy to them but also helps them navigate the morass of health insurance coverage in the U.S. The nurse manager is responsible for figuring out whether a prescribed course of therapy will be covered by a patient’s insurance. And if it isn’t, that patient is sent to a hospital-appointed financial counselor who then explains that if insurance won’t pay, the patient is responsible for all costs.

Welcome to the new world of cancer care. As pharmaceutical companies charge ever-higher prices for new drugs, American health care insurers have responded by tightening their belts. Many are denying payment for treatments that aren’t backed by clinical evidence. Others are asking patients to share a portion of the costs. Consequently, oncologists can no longer focus only on prescribing the best therapy; they must also consider the price tag. Moreover, hospitals and other facilities that treat cancer have had to hire additional staff to navigate the stony path of reimbursement.

“Things have changed a lot,” said AnneMarie Bradley, a nurse manager at Women and Infants Hospital who has worked there for 22 years. She used to help to treat about 10 patients a week. But when she first started, she explained, there were few outpatient chemotherapy regimens. But insurance began refusing to pay for patients to be admitted to the hospital because that required too many ancillary people. So doctors began giving most chemotherapy on an outpatient basis, she said. Since then, Bradley has also seen insurance companies and Medicare refuse to cover certain chemotherapeutic drugs because they deemed them too expensive or of unproven benefit; she has also seen patient copayments skyrocket and her time eaten up by the bureaucracy of trying to fight for coverage. She often must help doctors draft letters that cite data to support a particular course of treatment. “It takes a lot of work getting all that coordinated,” she lamented.

As for patient copayments, many can’t afford to pay them. New cancer drugs can cost $50,000 a year or more. Twenty percent of that—a typical copayment—is well beyond what many people can afford, Bradley said. And even though many pharmaceutical companies have support programs that help patients pay for drugs, not everyone qualifies. If a patient owns a home, for example, he or she probably will not qualify for aid, even if the patient has little income.

To be fair, the high cost of health care has been a political hot button for more than 20 years. But the fact that patients are being hit with such high out-of-pocket costs is driving the debate about cost more than it ever has before, Weeks said.

Costs Drive Change

Bradley has experienced first hand how rising costs have changed the practice of oncology. In 1992, for example, she began working in the hospital’s chemotherapy outpatient unit. Back then she helped to treat about 10 patients a week. Today she helps to treat 30–40 patients a day.

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Making Health Care Cost-effective

Policy experts have long debated how Americans can get a better value from their health dollars. The debate has been restricted largely to academic circles because proposed solutions have been politically unpopular, experts said. But the high cost of health care is back on the agenda, and politicians have been looking abroad for pointers.

Former Senator Tom Daschle and his coauthors, for example, speak at length...
about “value” in their new book, Critical: What We Can Do About the Health-Care Crisis. One proposal that many experts, including Daschle, support is a health care system that makes value assessments when approving coverage for treatments. More specifically, they propose the creation of a federal health care board responsible for recommending coverage for drugs on the basis of cost–benefit analyses.

This model already exists in Great Britain, where the National Institute for Clinical Excellence (NICE) evaluates data on new drugs and their cost. NICE then issues decisions on whether to make new drugs available through Britain’s National Health Service. Earlier this year, NICE issued a draft guidance recommending that the National Health Service not pay for the cancer drugs sunitinib, bevacizumab, sorafenib, and temsirolimus. Patients who wish to buy the drugs privately, however, may do so.

According to NICE, the drugs were too expensive for the marginal benefit that they provide. Sunitinib, a drug to treat kidney cancer, for example, costs about £24,000 ($45,000) a year and prolongs life for an average of 5–6 months. The high cost with limited benefit would mean that the health service would be less able to afford more cost-effective drugs for other illnesses, the agency said. NICE plans to issue a final decision on the drugs in January 2009.

The idea of using cost–benefit analyses in health care isn’t unique to Great Britain. Not only do other countries use it in various aspects of health care policy, but health officials in the U.S. have applied cost-effectiveness analyses to study several health care problems since the 1960s, said Peter Neumann, Sc.D., director of the Center for the Evaluation of Value and Risk in Health at Tufts Medical Center. But the medical community has been reluctant to embrace cost-effectiveness analyses in practice for various reasons, with many arguing that financial considerations have no place in the clinic.

“If a drug saves a life, we don’t want to deny that drug,” Weeks said.

“The one place where you can’t be making these sorts of [financial] decisions is when you are in a room with a patient,” echoed Eric Winer, M.D., director of the Breast Oncology Center at the Dana-Farber Cancer Institute. “In that setting, my job is to be my patient’s advocate and to use all the tools available to me.”

Expensive Drugs, Modest Benefit

But there are some clear cases in which cost-effectiveness analyses of drugs might help guide oncologists, experts said. Take bevacizumab, for example. Both the European Medicines Agency and the U.S. Food and Drug Administration approved the drug to treat metastatic breast cancer in 2007 and 2008, respectively, despite data showing that although bevacizumab shrunk tumors or prevented them from growing, it did not help women live longer. Moreover, the drug caused substantial side effects, and even some deaths. The drug costs up to $4,000 per treatment.

“If this the best way to spend our health care money?” asked Ian Tannock, M.D., Ph.D., an oncologist and scientist at the Princess Margaret Hospital in Toronto. “I don’t think so.”

Like Great Britain, Canada also has advisory boards that make clinical recommendations and issue guidelines on cancer treatment. Oncologists must follow the guidelines to ensure that the cost of the therapy that they prescribe is covered. Bevacizumab isn’t available in Canada for breast cancer patients because the data don’t support its use, Tannock said. He isn’t missing the drug either. “I don’t have any particular wish to use it, given its cost and its lack of efficacy in terms of real endpoints that benefit women with metastatic breast cancer,” he said, although he does support more clinical trials to further investigate the drug.

Another case: aromatase inhibitors to treat breast cancer. For postmenopausal women with estrogen receptor–positive breast cancer, tamoxifen is a well-established first-line therapy. But many oncologists prescribe aromatase inhibitors instead on the basis of data showing that this class of drugs improves disease-free survival compared with tamoxifen. Current research, however, shows no difference in overall survival, says Tannock, and aromatase inhibitors come with serious side effects such as osteoporosis and elevated cholesterol levels. Moreover, the class of drugs cost about eight times more than tamoxifen.

At least six studies have tried to justify using aromatase inhibitors over tamoxifen despite their higher price tag by concluding that aromatase inhibitors are cost-effective. “But I am very, very suspicious of their results,” Tannock said. All the reports base their results on the prediction that improvement in relapse-free survival will ultimately translate into improvement in overall survival, he explained, “and that hasn’t happened.” Moreover, some of the analyses that examined trials of aromatase inhibitors to see whether the drugs improve quality of life fail to include joint pain as a serious side effect, although there are now several other studies showing that this is a major reason that women stop taking the medication, he added.

Change Unlikely

Most U.S. experts interviewed said that they would welcome some type of control on how oncologists prescribe therapy. The question of how that control should be implemented remains up for debate, however. “If there were a national decision by a guideline panel that Avastin [bevacizumab] was not an appropriate
drug because the cost cannot be justified by the benefit, then I’d abide by that,” Winer said.

Others favor a change in how regulatory agencies approve drugs. “I would rather see us focus on the levels of evidence before allowing a drug to be on the market for large populations of people that may not benefit them,” said Ellen Stovall, president of the National Coalition for Cancer Survivorship. “I want us to stop paying for what doesn’t work and pay for what does.” If a drug is truly effective, insurers have no qualms about paying for it, she added, because the benefits outweigh the costs. For an example, she pointed to imatinib, which costs on average about $2,700 a month.

But many are skeptical that the U.S. will use cost-effectiveness analyses on a large scale. Experts have been predicting that increasing costs would translate into using these types of analyses, Neumann said, “but although there are some exceptions, it generally has not happened, and I don’t see it happening anytime soon.”

Americans have been unwilling to say no to high-priced drugs. “We don’t explicitly say you can’t have a drug, but what we are saying is that if you want an expensive drug, you might have to pay for it,” Neumann added. In fact, Medicare has explicitly stated that it does not use cost-effectiveness analyses in its coverage assessments, even though it is not legislatively precluded from doing so, as many mistakenly believe.

What especially troubles oncologists about this business-as-usual scenario is that cancer drugs may become an exclusive item—something affordable only to those with the means or the connections to finagle the system. Or even worse, patients may ration their own drugs, a prospect that Winer finds “terrifying.”

“We need to have a societal debate about this,” Stovall said. “How much pain in the pocketbook are we willing to tolerate? If we don’t deal with these issues, Medicare is going to go broke and then won’t cover drugs for anyone.”

In the meantime, more oncologists appear to be adopting Dizon’s approach of discussing costs with patients. A 2007 study published in the Journal of Clinical Oncology found that 42% of oncologists surveyed had discussed the cost of treatment with their patients. And the numbers will probably rise because the American Society of Clinical Oncology is developing a set of tools and resources to help doctors better communicate the cost of treatment to their patients that should be ready by year’s end.

Being up front about costs with patients might certainly prevent health care providers from going bankrupt. It won’t, however, provide a long-term solution. “I don’t really know what we should do about the problem,” Winer said, “but I do know we should be talking about it. One thing we can’t do is just ignore it.”

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