Covering the Cost of the Cure
From Hepatitis C to Cancer, New Therapies Are Straining a System Plagued by Inefficiency

Peter Sonnenreich and Linda Geisler

As researchers devise ever-more-costly therapies for diseases, managed care experts warn that the struggle to pay the bills could threaten the sustainability of the nation’s inefficient health care system.

Sofosbuvir (Sovaldi, Gilead Sciences) is often cited as an example of the conflict that can arise between cures and costs. Before sofosbuvir, the focus was on value, explains Newell E. McElwee, PharmD, MSPH, an Associate Vice President in the Center for Observational and Real-World Evidence at Merck. “Sovaldi was an ‘aha’ moment for many of us in the pharmaceutical industry that we could have a drug that by all of the traditional ways of assessing value showed both clinical and economic value, and it would still not be used in all the patients that it could be used in because of budget impact and affordability issues.”

For curative therapies, such as Sovaldi, some programmed-death-1 oncology agents, or some newer gene therapies, Dr. McElwee identifies two distinct issues: 1) financing, and 2) overall budget impact and unsustainability of the health care system.

“It’s a financing issue because all of the costs come up front, but the benefits occur downstream,” Dr. McElwee explains. “That is very difficult in a fragmented health care system like we have in the U.S., where one payer pays for the drug cost, but when the patient transfers to another payer or to Medicaid or to Medicare later on, those payers who haven’t incurred any of the costs are now going to reap all the benefits.”

Dr. McElwee was among the speakers at the April 2016 Academy of Managed Care Pharmacy (AMCP) Managed Care and Specialty Pharmacy Annual Meeting in San Francisco. In interviews afterward, session leaders recounted themes that emerged from their discussions revolving around the cost and value of curative therapies.1

“That’s the tricky thing about evaluating cost of a curative therapy,” says John Watkins, PharmD, MPH, BCPS, Pharmacy Manager of Formulary Development at Premera Blue Cross, based in Washington state. “The value extends over the patient’s entire lifetime and involves a lot of assumptions because you’re projecting into the distant future.”

Evaluating the Costs
Take hepatitis C, for example. Dr. Watkins explains that “with relatively low-quality observational data and follow-up of no more than 10 years, projections are made as to what that patient will look like 20, 30 years down the road, assuming that their hepatitis was cured, but some of the effects of it may still have unknown long-term impacts.”

“The value-based pricing approach raises some questions as to what really is a fair price,” Dr. Watkins says. “Patients are struggling to pay the out-of-pocket cost, and this ‘financial toxicity’ is a challenge; we don’t think going forward that the traditional methods of monitoring provider prescription practices are going to be adequate to manage the growth of these new technologies, and so something else is going to be needed.”

“Obviously, if these are high-value treatments, we don’t want to limit access to good things,” Dr. Watkins adds. Also, he notes, “There is a limit to how much cost you can share with a member because that creates a barrier to access and adherence.”

Budget Impacts on an Unsustainable System
According to Dr. McElwee, “we need to focus not on how we assess the value of a drug for inclusion in the formulary, but how we think about the larger issue of overall budget impact and unsustainability of the health care system.” Two assumptions are important when thinking about that issue, he says: 1) the U.S. health care system is very inefficient, and 2) the need to balance innovation and affordability.

A 2012 Health Affairs article noted that a third or more of annual U.S. spending on health care may be wasteful—it could be eliminated without harming consumers or reducing quality of care.2 Dr. McElwee likens a discussion focusing on value for formulary with someone driving a 1970s SUV that gets five miles to the gallon who complains about gas prices. “It’s just incongruent to talk about value when you’ve got such an inefficient system,” says Dr. McElwee. “That inefficiency has to be addressed as part of the long-term solution.”

Balancing innovation and affordability is very difficult. A 2013 population survey showed that the public wants more investment in and faster access to new cancer treatments.3 This should be encouraged, Dr. McElwee says, but we still need “a financially stable and sustainable health care system.”

“How are we going to pay for the tidal wave of technologies that are coming soon and may offer major advances in terms of patient outcomes is the question,” says Dr. Watkins. “Value addresses the question of whether something is worth doing, whereas affordability raises the question of how we will pay for it, and this is a problem in the U.S. health care system.”

A Value-Based Formulary
Premera has devised “a value-based formulary, which tiers drugs based on their value or cost-effectiveness,” Dr. Watkins says. “We have specialty drugs that are on tier 1 and many that are in tier 2 because it’s not about the price of the drug, it’s about the value of it, and that value is really a ratio of the cost to that clinical benefit.” The results of Premera’s value-based formulary design, implementation, and first-year outcomes were published in the Journal of Managed Care and Specialty Pharmacy.4 The authors concluded that the value-based

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Ability to avoid cost is also considered a benefit. Any sort of toxicities and some of the indirect costs as well. "Much you would use some sort of other therapies to mitigate therapy, it could be the cost of a biomarker and cost of how outcomes," she adds, "and that cost could be the cost of quality of life, symptomatic relief, or even avoidance of toxicity."

ASCO defines value as health outcomes that can benefit survival, Dr. Chang says. ASCO underlies the ASCO framework, Dr. Chang says. ASCO centered system organized around what patients need." This organized around what physicians do and toward a patient-centered system. "We must move away from a supply-driven health care system from the practitioner standpoint," Dr. Chang says. "The five-year survival rate for patients with chronic myeloid leukemia before we had Gleevec was 31%; after introduction of Gleevec, it's 89%." She notes that since the introduction of Gleevec in 2001, "the cost has also increased threefold."

The affordability of new treatments is a dilemma for cancer patients, Dr. Chang says. "Somebody eventually has to pay for it, and its out-of-pocket costs are more alarming from a managed care standpoint and have brought a lot of attention to our oncologists—that patients with a higher out-of-pocket cost are more likely to not adhere to drugs and great cancer drugs, such as Gleevec."

At April's AMCP meeting, Dr. Chang compared two methodologies for assessing the value of cancer drugs: the American Society of Clinical Oncology (ASCO) Value Framework and the National Comprehensive Cancer Network (NCCN) Evidence Blocks. ASCO's Value Task Force seeks to identify factors that are driving up the cost of cancer care, says Dr. Chang. "Hopefully, we can move toward delivering highest-quality cancer care with the lowest cost."

Earlier value-based pharmacy benefit designs "just lowered copay for high-value drugs or eliminated them entirely," Dr. Watkins says. "The flipside is to raise the copay tier of things that are low value, or maybe things that by themselves have reasonable value but there is something else that is just as good and is lower priced." In addition, "part of the same general stream in value-based pricing is usually an attempt to try to deal with evidence gaps, where we're not sure of what the value is actually going to be, and so provide the way that payers don't pay if the treatment doesn't do what it's supposed to do."

Assessing the Value of Cancer Care

The value discussion is also under way in the oncology community, says Jennifer T. Chang, PharmD, MPH, Supervisor of Regional Drug Information Services at Kaiser Permanente in California. It has gained importance because of affordability of an expensive and valuable cancer drug, such as imatinib (Gleevec, Novartis Oncology). "Gleevec is one of the most valuable drugs from the practitioner standpoint," Dr. Chang says. "The five-year survival rate for patients with chronic myeloid leukemia before we had Gleevec was 31%; after introduction of Gleevec, it's 89%."

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ASCO relies heavily on prospective randomized trials comparing a new treatment with the standard of care, Dr. Chang says. ASCO "looked at the clinical benefit from the perspective of more advanced cancer versus the type of cancers that are curative," she adds. "For each endpoint, they assign a score of 1, 2, 3, 4, or 5 based on the percent improvement of the newer therapy compared to standard regimen." ASCO also considers the drug acquisition cost and out-of-pocket patient cost. An updated version of the ASCO Value Framework was published in May in the Journal of Clinical Oncology. The affordability of new treatments is a dilemma for cancer patients, Dr. Chang says. "Somebody eventually has to pay for it, and its out-of-pocket costs are more alarming from a managed care standpoint and have brought a lot of attention to our oncologists—that patients with a higher out-of-pocket cost are more likely to not adhere to drugs and great cancer drugs, such as Gleevec."

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NCCN Evidence Blocks

"The NCCN guidelines use a step-by-step algorithm in terms of how to treat certain cancers based on different types of treatment options," Dr. Chang says. They assign each treatment option a recommendation based on the consensus of experts from 27 U.S. NCCN member institutions. The NCCN evaluates and scores five evidence blocks on a scale of 1 through 5, with 1 the least favorable and 5 the most favorable. The five elements are: efficacy of the regimen/agent, toxicity of the regimen/agent, quality of evidence, consistency of evidence, and affordability of a drug regimen/agent.

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Unlike NCCN, ASCO did not address quality and consistency of evidence, Dr. Chang says; "ASCO only considered the best evidence, which is the comparative prospective randomized trial."

Use of Value Assessment Tools in Practice

Use of these tools is "definitely something that pharmacy and therapeutics committees can consider looking at," Dr. Chang says. At Kaiser, "this is part of our formulary evidence review process when we're looking at a new drug to determine its role in therapy." She notes that "application of these different methodologies requires someone with the expertise and understanding of oncology evidence to really make these tools useful."

Other Challenges and Solutions

Participants cited a number of other issues and potential solutions after April’s AMCP conference:

Elimination of Low-Value Services

Since 2012, health care providers have been implementing Choosing Wisely, a campaign developed by the American Board of Internal Medicine Foundation to reduce overuse and waste.
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Medical societies were asked to identify five low-value things to avoid. The responses have included imaging procedures, tests, and treatments. “Part of the challenge we have with efficiency is that we do a pretty good job of making sure we get high-value things coming into the system,” says Dr. McElwee, but “we do a terrible job of getting low-value things out of the system.”

The Limits of Health Care Interventions

Is it possible to make changes outside the health care ecosystem to address affordability? Studies show that clinical care contributes only about 10% or 20% to improved health care and that patient outcomes are mostly attributable to factors outside the medical system, such as food, shelter, and behaviors.12 “This is an example of how hard it’s going to be to address these issues of system inefficiency outside of the pharmacy space,” Dr. McElwee says.

The Stalled National Agenda

Legislatively, public health leaders predict that little is going to happen in an election year. Still, health care system improvements may include 340B reform, more value-based insurance design, and possibly addressing generic-drug price increases.13

REFERENCES