# Are Specialty Drug Prices Destroying Insurers and Hurting Consumers?

## A Number of Efforts Are Under Way to Reduce Price Pressure

**Stephen Barlas**

WellPoint, Inc., one of the biggest health care insurers in the U.S., started paying $350-a-month incentives to certain Midwestern oncologists in its network on July 1. What is going on here? All the talk lately has been about insurance companies tightening marketplace networks under the Patient Protection and Affordable Care Act (ACA) so they include physicians who accept the *lowest* possible reimbursement. What's more, WellPoint will start making those incentive payments to oncologists around the country by the end of the year.

**Stephen Barlas**

The high price of oncology drugs is the main reason—quality care is another—that WellPoint has inaugurated its new "pathways" program. The program is starting initially with pathways for breast, lung, and colorectal cancer. When an in-network physician follows the pathway, including prescribing authorized drugs, he or she gets a monthly payment from WellPoint of $350.

"The cost of new oncology drugs is high and going higher," explains Jennifer Malin, MD, head of oncology for WellPoint, "and that is one of reasons for this program. We want to encourage use of the latest therapy when it provides additional clinical benefit. If it just adds cost without benefit, we hope this program diminishes use of those therapies and encourages the uses of those that improve outcomes and quality of care."

Oncology therapies are one, if not the top, category of "specialty" drugs, which some argue are going to capsize the health care system because of their high cost. An article in the leukemia journal *Blood*, published in 2013, said that 11 of the 12 drugs approved by the Food and Drug Administration (FDA) in 2012 for various cancer indications were priced above $100,000 per year.[1] The FDA approved three new drugs in 2012 for chronic myeloid leukemia (CML)—all Bcr-Abl tyrosine kinase inhibitors. All were "priced at astronomical levels," the authors of that article wrote. Ponatinib (Iclusig, Ariad) costs $138,000 annually, omacetaxine (Synribo, Teva) costs $28,000 for induction and $14,000 for a maintenance course, and bosutinib (Bosulif, Pfizer) costs around $118,000 per year. Even the original drug in this class, imatinib (Gleevec, Novartis), which was launched in 2001 at a price of $30,000 per year, has undergone a huge price hike: In 2012, it cost $92,000 per year.

Treatments for arthritis, multiple sclerosis, and hepatitis C are also members of this mile-high price club. While comprising less than 1% of all U.S. prescriptions, specialty medications in 2013 for the first time accounted for more than a quarter (27%) of the country's total pharmacy spending. That is projected to grow to 50% in 2017, according to Express Scripts, the pharmacy benefits manager.

"We are talking about a tsunami of expensive medicines that could literally bankrupt the health care system," says John Rother, President and CEO of the National Coalition on Health Care (NCHC), which launched the "Campaign for Sustainable Rx Pricing" on May 28.

Worriers most often cite the $84,000 list price for a 12-week treatment with sofosbuvir (Sovaldi), Gilead Science's new drug for hepatitis C virus infection. But new oncology drugs are often introduced at Tiffany prices, too. Many formularies are adding trastuzumab emtansine (Kadcyla, Genentech) as a second-line treatment for patients with HER2-positive, unresectable, locally advanced or metastatic breast cancer. It can cost $9,000 a month, according to Dr. Malin. WellPoint added that expensive drug to its formulary as a way of encouraging drug industry innovation and improving patient outcomes.

### Impact of High-Priced Specialty Drugs

High-priced specialty drugs pose a number of potential dangers. The impact on patient financial solvency and medication adherence is a concern, although those fortunate enough to have health insurance typically have a cap on what they have to pay annually. In the new federal marketplace, ACA policies have a cap of $6,250. Individuals taking drugs on specialty tiers are likely to reach that cap. But drug expenses at that level can pose a hardship even for middle-income people. Of course the uninsured and those with individual policies outside the marketplace have either no caps or higher caps. There is no cap in Medicare Part D; once someone pays $4,550 (in 2014) for drugs, they then become eligible for co-payments and/or co-insurance above that level.

But even what some might assume to be reasonable out-of-pocket (OOP) costs can be a major disincentive to medication adherence. A Prime Therapeutics study found pharmacy plan members are more likely to abandon their new prescriptions as costs rise.[2] The study showed that abandonment rates became significantly higher for both multiple sclerosis (MS) and biologic anti-inflammatory (BAI) drugs when OOP costs reached $250. Furthermore, members whose OOP costs reached $2,000 or more were 24 times more likely to abandon new MS prescriptions and 19 times more likely to abandon new BAI prescriptions than members whose OOP costs were less than $100.

Health insurance premiums are particularly sensitive to prescription drug costs the insurer must pay the manufacturer. "Drug costs are a significant part of premiums," states Lori McLaughlin, a WellPoint spokeswoman. "Oncology drugs are

*Mr. Barlas, a freelance writer based in Washington, D.C., covers topics inside the Beltway.*

the largest piece of the oncology treatment pie—at 25% and the fastest growing."

To keep premiums in relative check and maintain their own solvency, health plans may ration care to keep high drug costs from overrunning their operations. The staff of the Oregon Health Plan (OHP), which is the state's health insurance plan for low-income residents, recently recommended that the plan deny routine coverage for Sovaldi. Covering the new drug for just a third of the OHP members with hepatitis C, about 7,000 people, would cost $168 million a year. In comparison, all pharmaceutical spending for the OHP's more than 600,000 members last year was $377 million.

WellPoint's Dr. Malin thinks limiting patient access is the wrong way to go. Asked whether the costs of drugs in the price range of Kadcyla might ultimately put the health care system under water, she responds, "About one-third of health care cost is waste. We have a long way to go in improving the efficiency of health care before we need to even talk about limiting access to a therapy that prolongs patients' lives."

John Castellani, President and CEO of Pharmaceutical Research and Manufacturers of America (PhRMA), thinks the benefits of some new, expensive drugs outweigh their costs. "It is penny-wise and pound-foolish to focus solely on the price of a new medicine while completely ignoring the value it provides to patients and the health care system broadly," he says, referencing the debate about the price of Sovaldi. "Curing hepatitis C not only dramatically improves patients' lives but has the potential to save the U.S. health care system as much as $9 billion per year by preventing expensive hospitalizations and avoiding thousands of liver transplants that routinely cost over $500,000 each."

## Reactions to Specialty Drug Prices

The impact of specialty drug costs on insurers, pharmacy benefit managers, P&T committees, physicians, employers, and patients is forcing all of them to consider actions to blunt the escalating price spiral. The FDA is speeding up approval of new specialty drugs, ostensibly leading to lower drug development costs, which should, theoretically, reduce prices. The American College of Cardiology is planning to rate the value of treatments based on the cost per quality-adjusted life-year (QALY)—a method used in Britain and by many health economists. Treatments costing less than about $50,000 per QALY would be rated as high value, while those costing more than $150,000 per QALY would be low value.[3] "We couldn't go on just ignoring costs," says Paul A. Heidenreich, MD, MS, Professor at the Veterans Affairs Palo Alto Health Care System and a Stanford Health Policy Associate.

There is no commonly accepted definition of a specialty drug. What sets the class apart, typically, is 1) they often require special handling by pharmacies and physicians; 2) their costs, which can range from $15,000 a year to as much as $750,000 a year; and 3) most have no close substitutes, rendering health plans' traditional efforts to control costs by encouraging generic substitution largely ineffective.

Brian Henry, spokesman for Express Scripts, states: "For us, specialty drugs are those medications that are used to treat complex diseases such as rheumatoid arthritis, HIV, hepatitis C, multiple sclerosis, and others. These patients require a high degree of specialized care, and the medications that treat those patients are considered specialty drugs."

The NCHC launched its "Campaign for Sustainable Rx Pricing" to spotlight what the group characterizes as "unsustainable and abusive" prices for some medicines.[4] Rother, its President and CEO, formerly headed lobbying for the senior citizen advocacy group AARP. The NCHC singled out specialty drugs, citing one estimate that by 2020 spending on such drugs will quadruple from $87 billion to more than $400 billion. This continued growth in spending will put significant upward pressure on premiums in the private marketplace as well as in public programs like Medicare. "Sovaldi is the canary in the coal mine, alerting all of us that disaster is coming unless something is done to prevent it," says Rother, whose group includes more than 80 organizations representing employers, purchasers, providers, and consumers.

The NCHC did not respond to a request to produce a list of specialty drugs other than Sovaldi with prices the group finds "abusive."

## Sovaldi, the Poster Child

The poster child for alleged specialty drug price excess is Sovaldi. Gilead Sciences calls the hepatitis C drug "a finite cure" and justifies its cost based on avoided treatment costs, resulting in long-term savings by health plans and patients. The company has not produced data to back it up. Cara Miller, a Gilead spokeswoman, says, "Despite its clear potential to improve significantly on previous treatment approaches, Sovaldi was priced such that the total regimen cost is comparable to the previous standard-of-care regimen for genotype 1 patients with hepatitis C." Gilead uses a fact sheet that compares the Sovaldi price to that of boceprevir (Victrelis, Merck) and telaprevir (Incivek, Vertex). Those two hepatitis C treatments, each combined with two other drugs (as is Sovaldi), cost approximately the same as Sovaldi but are taken over a period of 48 weeks, not 12 like Sovaldi.

Miller did not produce any data relating the price of Sovaldi to Gilead's research and development, marketing, and other costs. Even if Gilead produced convincing data, it would not get at perhaps the broader issue: What good is saving long-term costs if patients, physicians, and insurers are forced to suffer in the short term because of excessive specialty drug costs?

"Never before has a drug been priced this high to treat a patient population this large, and the resulting costs will be unsustainable for our country," says Steve Miller, MD, Chief Medical Officer at Express Scripts. "The current pricing mentality around innovative products is unprecedented and unreasonable."

However, even some critics of drug pricing think Sovaldi doesn't deserve the target that has been slapped on its back. Rena Conti, PhD, Assistant Professor of Health Policy and Economics at the University of Chicago, is one of them. She just completed a study of the launch pricing of 56 oncology drugs that came onto the market between 1996 and 2013.[5] What she found is that the price of those new drugs was set at 5% to 7% above the price of the last new drug launched, even when the newer drug does not afford patients any benefit in terms of extending a patient's life. She says the price of the newest drug has nothing to do with the costs the drug

company expended developing the drug. "The money they make on a new drug simply goes into launching the next new drug," Dr. Conti states.

But she says Sovaldi's price is justified because it provides very significant benefits over previous hepatitis C treatments. "This drug is part of a cure. Gilead is not overcharging," she adds. "Sovaldi saves peoples' lives, increases their quality of life, and will also save the system the cost of dialysis, treating liver cirrhosis, and liver transplants." Moreover, very few consumers are buying the drug at the $84,000 sticker price because of the deep discounts available through the Veterans Administration, the 340B program, and the Medicaid program.

Richard Schilsky, MD, Chief Medical Officer for the American Society of Clinical Oncologists (ASCO), also thinks that the price of a drug such as Sovaldi, which promises a "cure," has to be considered differently than the price of a cancer drug, similarly priced, that offers a cancer patient another four weeks of life. "Most produce only a small benefit; none of them are curing anybody, that is the critical distinction," he emphasizes.

## The Lure of High-Priced Drugs

The fact that Sovaldi pulled in a reported $2.3 billion in sales in its first few months on the market has not been lost on other drug companies, not that they weren't already aware of the revenue potential of blockbuster specialty drugs. In June, Merck & Co. announced it would buy Idenix Pharmaceuticals for $3.85 billion in an effort to speed development of new hepatitis C drugs. The payoff for Merck could come from a triple therapy that may cure patients with all genotypes or strains of the hepatitis C virus in as little as four to six weeks, its research chief, Roger Perlmutter, said in an interview with Reuters.

Idenix has three drugs in development to treat hepatitis C, most notably a pill in early-stage trials called IDX21437. Like Sovaldi, it is a nucleotide inhibitor that blocks a protein needed by the hepatitis C virus to replicate. Merck hopes to combine IDX21437 with its two high-profile experimental oral treatments, a protease inhibitor called MK-5172 and an NS5A inhibitor called MK-8742 that together received a "breakthrough therapy" designation from the FDA.

The breakthrough therapy designation was created as part of the 2012 FDA Safety and Innovation Act. The FDA has called it "a virtual overnight success." As of May 5, 2014, the agency had received 186 requests for the breakthrough therapy designation and had granted 48. Six drugs had been approved, including a late-stage lung cancer drug that won approval four months ahead of its goal date using evidence from a trial with 163 patients. Breakthrough therapy designation provides all of the benefits of fast track designation plus intensive guidance on an efficient drug development program, beginning as early as phase 1, and the commitment from the FDA's review staff, including senior managers, to work closely together throughout the drug development and review process.

Of course, a shorter FDA approval time for breakthrough drugs won't necessarily be reflected in a lower drug price. Once the FDA approves a drug like Sovaldi, for example, the Medicare program generally approves it for use, price be damned. And once Medicare covers a drug, commercial insurers are sure to follow.

## Combating High Drug Prices

Insurers are increasingly looking for new ways to improve quality and blunt the cost of new, expensive specialty drugs, especially oncology drugs. Oncology—just like other medical areas—has problems with quality as well as costs. Up to one in three people treated with chemotherapy do not receive a treatment plan that is consistent with current medical evidence and best practices, according to studies cited by WellPoint, for example (Wu 2012,[6] Bilimoria 2009,[7] Neuss 2013[8]). Ninety percent of the use of white blood cell growth factors, which boost the immune system during cancer treatment, is not consistent with national guidelines. Many people who do not need these drugs receive them and others who should get them do not (Potosky 2011[9]).

WellPoint will expand its pathways program to cover a total of 12 cancers by the end of the year, and their use will be offered in additional geographic areas. Within breast cancer, for example, there are 24 different pathways, depending on the condition of the patient. Each of those 24 describes a treatment regimen that has the best clinical results, the fewest side effects, and the lowest cost, and is appropriate for 80% to 90% of patients with that kind of breast cancer. When an in-network physician follows that pathway, including prescribing the authorized drugs, he or she gets a monthly payment from WellPoint of $350. That is meant to compensate the oncologist for income he or she might have received by prescribing a higher-priced drug than the one authorized in the pathway.

In the current payment system, office-based oncologists who deliver chemotherapy are paid, for their "profit," a percentage of the cost of the chemotherapy agent, which they purchase. For Medicare, that is 6%. Commercial insurers use different percentages. So the more an oncologist spends on drugs, the more he or she earns. WellPoint is hoping to provide an incentive to oncologists to prescribe less expensive but equally effective drugs—or in some cases, no additional drugs.

"I think oncologists will adopt the WellPoint pathways without much pushback as long as they offer contemporary treatment options and allow physicians some leeway for the patients whose conditions don't match up with a particular pathway," states ASCO's Dr. Schilsky.

## ASCO's Pay Reform Suggestion

ASCO has developed a payment reform initiative[10] that would reduce the number of current procedural terminology (CPT) codes oncologists would bill, reduce the emphasis on traditional evaluation and management codes, and substitute five new payments, ostensibly meant to compensate oncologists better for services they provide now but don't get paid for, such as telephone calls, email, education, and counseling. The five payments would be: new patient, treatment, active monitoring, transition, and clinical trial—some once, some monthly. The current reimbursement system for drugs that oncologists purchase for office infusion would not change. But there would be less of an incentive to buy higher-priced drugs if the oncologist were getting compensated through the new five CPT codes for telephone calls and the like.

There is no question that some new, expensive specialty drugs are a real clinical advance, though it is not clear in each instance whether the price is set at what the market will bear

or what the company needs to make a reasonable profit. That question needs to be answered. But so do other important questions, such as: How can the U.S. reform its health care system to better account for justified higher drug prices?

For example, hospitals are buying up community cancer centers and physician office practices, with the result that chemotherapy is shifting to hospital outpatient centers, where hospitals can charge both insurers and patients more and earn higher profits. A study by the Moran Company published in August 2013[11] found that Medicare beneficiaries getting chemotherapy treatment in hospital settings received 9% to 12% more chemotherapy treatments, using more-costly medications, resulting in per-beneficiary costs that were 25% to 47% higher compared with those treated in community oncology practices. Not only are Part A billing rates for chemotherapy higher than Part B, which is what office doctors can charge, but the hospitals can also buy chemotherapy drugs in some instances at large 340B discounts.

So insurers pay more for oncology treatment, putting upward pressure on premiums and co-payments just as Medicare is paying more for hepatitis C patients who are now taking Sovaldi. Georgetown University and the Kaiser Family Foundation estimated that increased cost at $6.5 billion for 2015. Medicare coverage of just this one drug would raise overall Medicare Part D drug spending by as much as 8%, according to Democrats on the U.S. House of Representatives Energy and Commerce Committee, who back legislation to allow Medicare to get Part D drug discounts the way that Medicaid does.[12]

But drug discounts are not silver bullets. Even price concessions of 30% won't alleviate all the financial pressure on insurers—be they Medicare, Medicaid, or ACA-qualified health plans—when having to pay for drugs with list prices of $84,000 and more. Broader policy approaches are needed.

## REFERENCES


1. The price of drugs for chronic myeloid leukemia (CML) is a reflection of the unsustainable prices of cancer drugs: from the perspective of a large group of CML experts. *Blood* 2013;121(22):4439–4442.
2. Starner CI, Bowen K, Yang Qiu Y, et al. Association of specialty drug prescription abandonment with increasing member out-of-pocket expense. Prime Therapeutics. April 2014. Available at: http://tinyurl.com/StarnerEtAl. Accessed June 24, 2014.
3. Anderson JL, Heidenreich PA, Barnett PG, et al. ACC/AHA statement on cost/value methodology in clinical practice guidelines and performance measures: a report of the American College of Cardiology/American Heart Association Task Force on Performance Measures and Task Force on Practice Guidelines. *J Am Coll Cardiol* 2014;63(21):2304–2322. Available at: http://content.onlinejacc.org/article.aspx?articleid=1853961. Accessed June 24, 2014.
4. Campaign for Sustainable Rx Pricing. National Coalition on Health Care. Available at: http://www.csrxp.org. Accessed June 24, 2014.
5. Howard DH, Conti RM. Are new drugs more expensive than old ones? Trends in the benefit-adjusted launch prices of anticancer drugs, 1995-2013. Presentation at the 2014 American Society of Clinical Oncology Annual Meeting, May 2014. Abstract published in *J Clin Oncol* 2014;32:5s (suppl; abstr 6525).
6. Wu XC, Lund MJ, Kimmick GG, et al. Influence of race, insurance, socioeconomic status, and hospital type on receipt of guideline-concordant adjuvant systemic therapy for locoregional breast cancers. *J Clin Oncol* 2012;30(2):142–150.
7. Bilimoria KY, Bentrem DJ, Lillemoe KD, et al. Assessment of pancreatic cancer care in the United States based on formally developed quality indicators. *J Natl Cancer Inst* 2009;101(12):848–859.
8. Neuss MN, Malin JL, Chan S, et al. Measuring the improving quality of outpatient care in medical oncology practices in the United States. *J Clin Oncol* 2013;31(11):1471–1477.
9. Potosky AL, Malin JL, Kim B, et al. Use of colony-stimulating factors with chemotherapy: opportunities for cost savings and improved outcomes. *J Natl Cancer Inst* 2011;103(12):979–982.
10. Consolidated payments for oncology care. American Society of Clinical Oncology. May 2014. Available at: http://tinyurl.com/ReformASCO. Accessed June 24, 2014.
11. Cost differences in cancer care across settings. The Moran Company. August 2013. Available at: http://blog.communityoncology.org/userfiles/76/Moran_Cost_Site_Differences_Study_P2(2).pdf. Accessed June 24, 2014.
12. Ranking members Waxman and Degette call for hearings on Medicare Part D impact of high costs of Sovaldi. Committee on Energy & Commerce (Democrats), U.S. House of Representatives. June 19, 2014. Available at: http://tinyurl.com/SovaldiHearings. Accessed June 24, 2014. ■