Value Purchasing Programs Make Plodding Progress

Drug Manufacturers Question Some Pay-for-Performance Methodologies

Stephen Barlas

In mid-July, Michael Nardone, Director of the Disabled and Elderly Health Programs Group at the Centers for Medicare and Medicaid Services (CMS), sent letters to state Medicaid programs and drug manufacturers encouraging them to consider value-based purchasing agreements for pharmaceuticals.[1] Those agreements present a significant opportunity for CMS and the states to reduce huge, escalating drug costs for some of the specialty pharmaceuticals that have recently come on the market for conditions such as hepatitis C.

Value-based purchasing (VBP) contracts can include provisions that lower the cost of a medication if it doesn't provide the kinds of health benefits the manufacturer says it will based on the clinical trial results. Such agreements are called "pay for performance," and they are, so far, rare. A more typical value-based contract requires the drug company to lower the cost of the drug when the insurer agrees to put that drug on a lower formulary tier than its competitors. The insurer pays that lower price regardless of whether the drug works as promised, whether it costs $10 or $10,000 per month. Neither the federal government nor the private sector has a universally accepted definition of VBP for pharmaceuticals.

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Nardone's encouragement is unlikely to move either state Medicaid programs or drug manufacturers to dip their toes in the VBP waters. "Best price continues to be an obstacle to VBP arrangements for drug manufacturers," explains Alan Kirschenbaum, an attorney with Hyman, Phelps & McNamara, who wrote about the Nardone letters on the law firm's Food and Drug Administration (FDA) blog. The best-price provisions of the Medicaid drug rebate program require brand-name drug manufacturers to give Medicaid the lowest price they offer in the rest of the drug marketplace. The recent CMS notice provides best-price relief for a VBP agreement as long as it is a supplemental Medicaid rebate program approved by CMS. "This relief is quite limited," Kirschenbaum states.

Matt Salo, Executive Director of the National Association of Medicaid Directors, notes that many states are interested in VBP in the prescription drug space. "It seems to be the only area where they aren't actually doing it, however, meaning that many states are well under way with VBP efforts in primary care, hospital payments, mental health, etc.," he explains.

Private insurers are only slightly more aggressive. Harvard Pilgrim Health Care has signed three contracts in the past year, the latest in July, with pay-for-performance attributes tied to health outcomes.

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Escalating Drug Prices Seed Interest in VBP

The FDA continues to provide ammunition for the "value of pharmaceuticals" debate by approving new, very expensive specialty drugs with benefits and adverse effects that haven't quite been pinned down. The agency approved Roche's new bladder cancer drug atezolizumab (Tecentriq) in May. The immunotherapy product will cost about $12,500 a month despite a clinical trial showing that the medication shrank tumors in only 14.8% of the 310 participating patients.[2]

Does that drug's "value" justify P&T committees putting Tecentriq on insurance company formularies? The answer is unclear, and the question about the value of high-priced pharmaceuticals—whether for cancer, hepatitis C, diabetes, or any other disease—continues to occupy a premier place among current drug industry controversies.

Drug prices irritate consumers, health plans, and policy-makers, and not just the prices of specialty drugs. More than two-thirds of the 20 largest pharmaceutical companies said that price increases boosted sales revenue for some or most of their biggest products in the first quarter of 2016, according to a *Wall Street Journal* (*WSJ*) review of corporate filings and conference-call transcripts. "The upshot is that in a period of low inflation and sluggish economic growth, drug makers' power to raise prices still exceeds most other industries," the July *WSJ* story stated. "And though it's long been common for companies to gradually raise prices on drugs after launching them, the magnitude and frequency of the increases have grown in recent years."[3]

That's not how it works in every business. "You can't take the price of the iPhone ... up 10% a year," Geoffrey Porges, a Leerink Partners LLC biotech analyst, said in the *WSJ* article.[3]

Pay for Performance

Complaints about initial prices and price hikes are stoking the emergence of the value price movement, whose highest form is pay for performance (PFP). But pharmaceutical manufacturers are touchy about some aspects of the value/PFP equations that various organizations are perfecting. The National Pharmaceutical Council, made up of drug manufacturers, has questioned the value case methodologies used by the Institute for Clinical and Economic Review (ICER).

ICER's framework forms the conceptual basis for some of the recent PFP contracts signed by Harvard Pilgrim, which is the leading insurer, and one of the very few, to pursue PFP contracts. In November 2015, Amgen agreed to provide Harvard Pilgrim with two PFP rebates if its evolocumab (Repatha), one of the two new proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors, failed to meet two separate thresholds.[4] In June 2016, Harvard Pilgrim signed two more PFP deals. In one it obtained a discount from Novartis if its new

sacubitril/valsartan (Entresto) treatment for congestive heart failure does not yield a specified drop in hospitalizations.[5] In the other, Harvard Pilgrim agreed to accept a lower rebate from Eli Lilly if its dulaglutide (Trulicity) diabetes drug lowers hemoglobin A1c (HbA_{1c}) levels—a common way to track the disease—better than rival medicines.[6] Harvard Pilgrim essentially started the drive toward PFP contracts last year with the Amgen/Repatha deal.

Asked whether Harvard Pilgrim had results on the impact of the PFP contract with Amgen, spokeswoman Joan Fallon was unable to provide any information.

Congress and Obama Administration Slow to React

There has been a push from consumer, pharmacy, and other professional groups for more transparency over drug data. That includes pressure for making more robust information publicly available from clinical trials, as well as insight into the pricing of drugs. The Academy of Managed Care Pharmacy (AMCP) in June released a set of recommendations that would allow biopharmaceutical companies to share health care economic information (HCEI) more easily with entities that make formulary and coverage decisions. The recommendations address restrictions in the sharing of product information that does not appear on the drug label, a prohibition that hinders decision-makers from accessing HCEI on new therapies.[7]

"Effective communication of HCEI is more important than ever, as biopharmaceuticals entering the market today are highly complex and often very expensive," says AMCP Chief Executive Officer Susan A. Cantrell, RPh. "With the U.S. health care system increasingly focused on the concept of providing value, it is essential that pharmaceutical product value is accurately measured and disseminated."

The AMCP is trying to push the FDA to clarify Section 114 of the 1997 Food and Drug Administration Modernization Act. Section 114 serves as a regulatory safe harbor for the dissemination of HCEI to formulary decision-makers, such as P&T committees. Its language is murky, and its lack of clarity has impeded the transfer of useful information from drug companies to insurers, pharmacy benefit managers (PBMs), and P&T committees.

It is not just the AMCP that is leaning on the FDA. So are drug manufacturers. Their Medical Information Working Group (MIWG) has submitted two citizen petitions to the FDA, in 2011 and 2013, asking the agency to clarify what kind of information it can provide to P&T committees when those committees come to the drug companies asking for what could be classified as HCEI. The MIWG is composed of companies such as Allergen, Bayer Healthcare, Eli Lilly, Johnson & Johnson, and GlaxoSmithKline, among others. The companies are just as anxious to be allowed to provide more information on off-label uses of approved drugs, which has been a sore spot for them, as opposed to fuller information on indications of a drug as approved.

Alan Bennett, Senior Counsel at Ropes & Gray LLP, who represents the MIWG, says the FDA's delay in addressing those petitions has to do with "a lack of full understanding of how the payer market works, which it has been grappling with, and with the underlying policy issues, including the applicability of the First Amendment. I suspect those are the real reasons for delay, rather than a lack of resources. But the agency did promise a speedy resolution more than two years ago, and it clearly is time for them to act."

More Data for Insurers, Everywhere But Drugs

While the FDA has been hesitant to mandate greater flow of HCEI and while clinical trial data often remain hard to access—whether because of FDA impediments or not—data about other health services is becoming more transparent, thanks to Congress. The Patient Protection and Affordable Care Act (PPACA) created a VBP program for hospitals serving Medicare patients, and the Medicare Access and CHIP Reauthorization Act (MACRA) that Congress passed in 2015 established somewhat of the same thing for physicians' pay from Medicare. The hospital program has been around for a few years and adjusts hospitals' payments based on their performance on four domains that reflect hospital quality: the clinical process of care domain, the patient experience of care domain, the outcome domain, and the efficiency domain. Congress created the Merit-Based Incentive Payment System (MIPS) for physicians and a second program called Alternative Payment Models (APMs) under the MACRA. Congress has ignored the Medicare Part D drug, Medicaid, and PPACA programs when it comes to injecting any value methodologies into the drug payment schedules and standards.

Andy Slavitt, Acting Administrator of the CMS, took a feint in that direction in November 2015 when he sent letters to Gilead Sciences,[8] AbbVie, Johnson & Johnson, and Merck, asking for information on VBP arrangements, if any, that are being offered to payers and state Medicaid agencies, and asking what the companies are doing to make their medications more affordable. Those letters referenced the companies' hepatitis C vaccines. The CMS public affairs office says the companies did respond but that those letters are not publicly available.

Kirschenbaum explains why the Nardone letters aren't likely to persuade state Medicaid plans or drug manufacturers to explore potential VBP contracts more aggressively. The recent CMS notice provides best-price relief for a VBP agreement as long as it is a supplemental Medicaid rebate program approved by the CMS. "It would only apply if the manufacturer paid supplemental rebates to the state, so it probably would not apply, for example, to VBP rebates paid by the manufacturer directly to a Medicaid MCO [managed care organization]," explains Kirschenbaum. "It also requires CMS approval and provides no best-price relief for VBP arrangements with commercial payers or with Medicare."

To some extent, the CMS is constrained by law, which explains growing pressure by certain groups on Congress. This spring saw the rollout of the Campaign for Sustainable Rx Pricing (CSRP). It is made up of multiple organizations representing doctors, nurses, hospitals, insurers, and consumers. "We need to pay for what works, not so much for what's marginally beneficial," said John Rother, President of the campaign and Chief Executive Officer of the National Coalition on Health Care. "The most expensive treatment is not always the best."

CSRP held a well-attended event on Capitol Hill on July 12 to brief staff on the campaign's recommendations. Rother admits that nothing will happen in Congress this year and that so far no Democrat or Republican has voiced an intention to push legislation in 2017 in the new Congress. "But on the political left there is support for Medicare to negotiate drug prices and on the right support for turning Medicare into a private industry program," he says. "There is a lot of room in the middle."

Value Contracts Signed But Sealed

Private insurers often take their lead from Medicare when it comes to payment reforms. But when it comes to drugs, the private sector has plunged in on its own, though on a very limited scale. Harvard Pilgrim's contract with Novartis for its new heart failure drug, Entresto, gives Harvard Pilgrim a discount if Entresto does not provide a given level of reduction in hospitalizations for heart failure. In clinical trials, Entresto showed a 20% reduction in the relative risk of death from cardiovascular causes or hospitalization for worsening heart failure compared with an angiotensin-converting enzyme inhibitor.[5]

Within a day after announcing the contract for Entresto, Harvard Pilgrim announced that it had signed a value-based contract with Eli Lilly for its type-2 diabetes drug Trulicity. The arrangement gives Trulicity preferred status on Harvard Pilgrim's formulary and means that Harvard Pilgrim will pay a lower net cost to Lilly if fewer of its members reach a preferred endpoint (HbA_{1c} less than 8%) compared with individuals taking other glucagon-like peptide-1 (GLP-1) receptor agonists, and a higher net cost if patients taking Trulicity do better than patients taking competing drugs. According to Harvard Pilgrim Chief Medical Officer Michael Sherman, MD, MBA:[6]

> Harvard Pilgrim is excited about its ability to show leadership in creating innovative contracts that pay not for pills but for patient outcomes. What is particularly attractive about this agreement is that the outcomes compare Lilly's drug to competitor offerings versus arbitrary endpoints. We believe that working with pharmaceutical companies that are willing to engage in these kinds of innovative, outcomes-based contracts will bring value to the members we serve.

One might expect the nation's leading PBMs to follow in the footsteps of their customers with regard to developing PFP drug purchasing contracts. Express Scripts has been vocal about its efforts in that regard, although the company has not gone as far as Harvard Pilgrim. Over the past few years, it has developed its Hepatitis Cure Value (HCV) Program and the Cholesterol Care Value (CCV) Program. Its latest offering in that vein is its Oncology Care Value (OCV) Program, which launched in 2016.

Express Scripts' OCV Program will take a multifaceted approach to align the cost of treatment with its outcomes, according to the company. That will be done by leveraging the specialization of Express Scripts' Oncology Therapeutic Resource Center (TRC) through exclusive dispensing of all oncology medications via the Accredo specialty pharmacy.[9] The company has used erlotinib (Tarceva, Roche) as an example of how the program works. Tarceva provides, on average, an additional five months of life for lung cancer patients compared with standard care. The same drug provides, on average, an additional 12 days of life for pancreatic cancer patients.[10] But Express Scripts declines to detail how that comparison affects the way it pays Roche for Tarceva.

Manufacturers Question Some PFP Methodologies

It may be that insurers and PBMs have been slow to embrace PFP because of concern about perceived shortcomings of the methodology used by ICER. The organization looks at the factors underlying value, such as the quality of clinical data supporting the therapy's use, the magnitude of its treatment effects, the likelihood of severe adverse events, and the product's costs, ancillary benefits, cost-effectiveness, and effects on the health care system. The ICER methodology has two components: the value of the medicine and its budget implications, leading to a determination of what the price per patient should be based on—a concept called cost per quality-adjusted life-year (QALY).

ICER's inclusion of a "budget impact" factor has become an irritant to drug manufacturers. It was a flash point at a May 22 symposium during the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) 21st Annual International Meeting. National Pharmaceutical Council (NPC) President Dan Leonard criticized ICER's inclusion of budget impact analyses (BIAs) as part of the value consideration. The NPC has been vocal that BIAs, if used by payers as an integral part of a value assessment for making coverage and reimbursement decisions, could restrict the use of life-saving treatments for patients. A BIA is only a measure of resource use, not a measure of value, Leonard noted. It can inform end users about what they are paying, but not about what they are paying *for*—value. The way they are used collectively could have a considerable impact on society, such as discouraging innovation in highly prevalent diseases, he said.

Dan Ollendorf, ICER's Chief Scientific Officer, acknowledges that the BIA component of the ICER analysis did suggest a somewhat lower value-based price for Amgen's Repatha, one of the two new PCSK9 inhibitors (the other being alirocumab [Praluent, Sanofi-Aventis/Regeneron]). ICER's controversial draft report on the pricing of the two PCSK9 inhibitors was published in September 2015.[11]

In the wake of the ICER draft, Harvard Pilgrim signed the Repatha contract with Amgen in November 2015 that was hailed as the first significant PFP deal in the drug industry. The contract provides the health plan with an enhanced discount if the reduction in low-density lipoprotein-cholesterol levels for Harvard Pilgrim members is less than what was observed during clinical trials. The agreement also provides for additional discounts if utilization of the drug exceeds certain levels. As Harvard Pilgrim's preferred PCSK9, Repatha is offered to members at a lower cost share. Repatha costs $14,100 and Praluent $14,600, respectively, for a year's supply. The ICER's draft analysis suggested that these prices would need to be discounted by 46% to 62% just to meet commonly cited cost-effectiveness thresholds, and would need to drop even further (to $2,177, an 85% discount) based on the anticipated budget impact.[11]

Because Harvard Pilgrim's contract with Amgen is proprietary, there is no proof that the ICER analysis, with regard to BIA or long-term patient value, had any impact on pricing. But the complaints by the NPC's Leonard in May about ICER's use of BIA sound a bit hollow given the 10 analyses of various drugs and one medical device that ICER has done since Repatha/Praluent. The BIA portion of the organization's analysis has resulted in a significant reduction only once since then, for the Cardiomems medical device (St. Jude Medical), according to Ollendorf. The drugs studied subsequently included Entresto, mepolizumab (Nucala, GlaxoSmithKline), insulin degludec injection (Tresiba, Novo Nordisk), and six different drug regimens for multiple myeloma. However, in most of these cases ICER arrived at lower prices than the list price based on the long-term care value of the drugs and device.

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"The problem in most of these situations was misalignment of prices with value to the patient," Ollendorf states.

Still, ICER is sensitive to concerns and is working to improve its methodology. In July, it opened a national call for suggestions on how to improve its value assessment framework. The organization intends to update the methods that underpin its evidence reports.

Regardless of how the ICER changes play out, it is clear that Congress needs to step in if value-based pricing with regard to pharmaceuticals is to become *de rigueur.* Medicare, Medicaid, and PPACA marketplace plans often lead the way for private sector health plans, and those federal programs just aren't set up to allow pay for performance. The Medicaid drug rebate system is a mess, for example. It is way out of date. Congress has injected quality and outcomes into hospital and physician payment. So why not drugs?

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