

SPECIALTY PHARMACY NEWS

News and Strategies for Managing High-Cost Biotech, Infusible and Injectable Products

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As Specialty Drug Costs Continue to Rise, Patients Are Still Filling Scripts — for Now

Specialty drug prices continued to rise last year, according to a recent report. And even through the economic downturn, patients for the most part have continued to fill prescriptions for these expensive medications, many of which treat chronic and life-threatening conditions. But if prices continue to rise and the financial pressure on health plans continues to increase, these patients may find it hard to continue filling prescriptions, say several sources.

According to the *AARP Watchdog Report: Trends in Manufacturer Prices of Prescription Drugs Used by Medicare Beneficiaries 2008 Year-End Update*, the average annual increase for the 144 most commonly used specialty therapies was 9.3% in 2008 — almost two-and-a-half times the general inflation rate of 3.8% (*SPN 5/09, p. 8*). Prices of brand nonspecialty drugs increased 8.7% during that time, while generic nonspecialty drugs decreased 10.6%.

With specialty drugs “popping up as the top drugs in terms of cost,” plan sponsors “are starting to ask some targeted questions” about them, says Sean Brandle, national Rx practice leader at The Segal Company. “Only a small amount of the population is on them, but plan sponsors are spending a lot on them.”

When people can't afford these drugs, that “exacerbates an already-bad situation,” says David Knowlton, president and CEO of the New Jersey Health Care Quality Institute and a board member of the nonprofit HealthWell Foundation. More people are using specialty drugs, he contends, in large part due to the aging of the baby boomers and the fact that more of these drugs are hitting the marketplace. But “health plans can't pay more in claims than they take in on premiums.” Because health plans are “in the midst of contract periods, they can't change” what they charge their members midstream. However, newer contracts will likely reflect the financial pressure that plans are under, he says.

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Companies May Be Worried About Reform

The uptick may be “in anticipation of reduced margins going forward,” says Craig Kephart, president and CEO of Centric Health Resources, Inc., a health services company focused on rare, orphan and chronic disorders. With a new presidential administration and health care having been a hot topic since last year, manufacturers may believe their profit “margins may be severely impacted,” so they are attempting to “maximize their margins while they can....Comparative effectiveness is scary to a lot of people,” who wonder whether the government will use it to help patients and physicians make better treatment decisions or as a cost-effectiveness tool. He points to the recent CMS decision to deny coverage of CT colonographies — so-called virtual colonoscopies — to beneficiaries as a possible “harbinger” of things to come (see story, p. 3). Although “there is some logic” to the decision, “at the end of the day,” the decision “is an economic one,” he says. With health reform, “there is only so much money we have to accomplish the goals set down by the administration and others. Cost control has to be a major component,” he adds.

“Don’t get me wrong — I think comparative effectiveness is necessary,” says Kephart. “All the health plans and physicians I’ve talked to want that data” in order to “use it as another tool in the decision-making process.” Nevertheless, he says, “there are only so many dollars. We can’t have Cadillac health care for everybody with no way to pay for it....You’ve got to figure at some point someone’s going to say that we need to put some price controls on this.”

And with all the attention on legislation to create an approval pathway for biosimilars, the prospect of facing competition from these drugs “has got to play into the psyche of anyone who is a [specialty drug] manufacturer,” Kephart says. “Their original business plan never conceived of” biosimilar competition. Manufacturers “are worried about their return on investment,” agrees Knowlton. Having this competition “affects their metric to determine return on investment.”

Beckie Fenrick, Pharm.D., director of clinical pharmacy at Blue Cross and Blue Shield of Florida, tells *SPN* that although “we have historically seen growth in the

utilization of specialty drugs,” the plan’s 12-month data through March 2009 shows specialty prescriptions are “flat.” But she adds that the plan has not looked into why this may be the case. “We did see an increase in costs, but it was not as steep as it has been historically,” she says. “There is a tempering for some reason.” She says that “there probably are some economic factors” behind this, but since the plan has implemented a new specialty management strategy, this may be a factor as well.

“On the managed care side, there is very definitely an understanding of the economy overall and the ability of people to pay for their medications,” says Steven Avey, vice president of managed care for PBM Partners Rx Management LLC. He points to the recently released *2009 Biotechnology Monitor & Survey: Marketplace Policies, Practices, & Perspectives*, which shows that health plan respondents expect their members to pick up about 12% of the cost of a biologic under the pharmacy benefit. Avey, who is also a member of the publication’s editorial board, contrasts this with a nonbiologic drug, perhaps for high blood pressure, for which the member generally will cover 25% to 30% of the cost. He adds that the 12% might be a bit high, as members of Partners Rx health plan clients pay about 4% of the total costs of biologics.

Some plans are adding another tier to their drug formulary for specialty drugs, but are still limiting members’ cost-share amounts somewhat. “With specialty, there is a lot of movement about putting these drugs on a fourth tier,” says Avey. In 2008, 55% of the commercial plans that participated in the survey said they had member out-of-pocket spending limits for biologics covered under the medical benefit, and 38% applied such limits to specialty drugs adjudicated under the pharmacy benefit.

Another way to manage specialty drugs, Avey says, is to have a defined benefit, where members pay a certain amount — maybe \$60 or \$70 — for a prescription. And then all members pay these “deductibles,” which result in offsets to cover the costs of the more expensive biologics. “I love this approach,” says Avey, noting that it doesn’t “penalize” members with biologic prescriptions like other benefit designs do. Last year, 47% of commercial plan respondents said they applied deductibles to

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biologic drug use under the medical benefit, with 44% applying it to these drugs under the pharmacy benefit.

Avey illustrates the problem with copayments through the following example: If a member is prescribed a drug that costs \$1,000 per prescription, there will probably be a \$100 or \$150 copay for specialty drugs. "So I have a \$150 additional copay that I earned from that member," he says. "But the problem is that there are such few numbers of prescriptions" for specialty drugs that "I might be gaining \$150 but on only 15 prescriptions." His PBM wanted to find out what the impact on savings would be for a plan that places a \$50 deductible on brand-name drugs. "We determined this would save the plan in the ballpark of 18%," he says. But if "you raise the copay to an arbitrary level of \$200, you save the plan in the ballpark of 3%." According to Avey, "it makes more sense to spread [the costs] out. People didn't ask to get cancer or rheumatoid arthritis; they got them through no fault of their own. We don't need to penalize them."

Health plans "need to help patients get the care they need, not drive them away with copayments," agrees Knowlton.

In the survey, the majority of commercial/group plans and PBMs polled reported a 6% to 15% growth in the utilization of specialty drugs. Those same groups reported that biologic expenditures had mean percentages of 13% to 14% for the total pharmacy benefit budget. For Partners Rx, says Avey, 1% of the prescriptions are for biologics, but these drugs represent 10% of its drug spend. If the

utilization goes up even 2% or 3%, that means "a dramatic increase in drug spend if [the trend] holds true across the board," he says. "There is so much emphasis on how to pay for these, especially when you look at the pipeline," which holds hundreds of specialty therapies. "A conversation about deductibles is good," he contends.

How Long Can Unemployed Afford Specialty Rx's?

According to Kephart, at least for now, "patients are still getting their [specialty] prescriptions." Other trends that he notes are "the number of people on COBRA is increasing, the length of time to pay off patient responsibility is getting longer, and the number of people seeking assistance from patient-assistance programs and copayment-assistance programs is starting to tick up." Wondering how long people can afford COBRA if they are unemployed, he adds that it is "reasonable to expect an uptick in the number of uninsureds with these conditions... In our niche, we're kind of at the beginning of what will be impacts" of the economic downturn. "Patient concern is much higher than it used to be."

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More information about the specialty pharmacy market — vendors, products and payer strategies — is available in the new Specialty Pharmacy: Stakeholders, Strategies and Markets 2009. Go to the MarketPlace at www.AISHealth.com, or call AIS at (800) 521-4323.

NEW FDA SPECIALTY DRUG APPROVALS

♦ On May 7, the FDA approved mycophenolate mofetil for the prevention of organ rejection in patients receiving kidney, heart or liver transplants. The Mylan Inc. therapy is a generic version of Roche's CellCept. The FDA approved 500 mg tablets and 250 mg capsules. Mylan lists the average wholesale price for 120 of the 250 mg capsules as \$396.24 and the AWP for 200 of the 500 mg tablets as \$792.59. Drugstore.com lists the price for 100 of the 250 mg capsules of CellCept as \$402.40 and the price for 100 of the 500 mg tablets as \$787.64. Visit www.mylan.com.

♦ On May 13, the FDA granted another indication to UCB, Inc.'s Cimzia (certolizumab pegol) in patients with moderately to severely active rheumatoid arthritis. The therapy now is available in a prefilled syringe. Sprycel, which is also approved for the treatment of Crohn's disease (SPN 5/08, p. 7), may be administered every two weeks or four weeks after an initial dosing period. PrescriptionGiant.com lists the price for one 200 mg/ml kit as \$1,578.82. Visit www.cimzia.com.

♦ On May 19, the FDA granted another indication to Astellas Pharma US, Inc.'s Prograf (tacrolimus) used in conjunction with mycophenolate mofetil

for the prevention of organ rejection in kidney transplant recipients. The therapy is also indicated for preventing organ rejection in liver and heart transplant recipients. Drugstore.com lists the price for 120 0.5 mg capsules as \$245.99, 120 of the 1 mg capsules as \$485.90 and 180 of the 5 mg capsules as \$3,791.47. Visit www.astellastransplant.com.

♦ On May 27, the FDA granted full approval to Sprycel (dasatinib) for the treatment of chronic myeloid leukemia (CML) in all phases after resistance or intolerance to prior therapy including Gleevec (imatinib mesylate). The FDA originally approved the oral Bristol-Myers Squibb Co. therapy under the accelerated approval regulations for new drugs for serious or life-threatening illnesses. The updated drug label also has a new recommended starting dosage of 140 mg of Sprycel once daily for accelerated, myeloid blast and lymphoid blast phases. A spokesperson for Bristol-Myers Squibb says that for patients with chronic-phase CML, the wholesale list price for Sprycel at the indicated dose of 100 mg once daily is approximately \$6,000 per 30-day month. For patients with accelerated- and blast-phase CML, the wholesale list price for Sprycel at the indicated dose of 140 mg is also approximately \$6,000 per 30-day month. Visit www.sprycel.com.