
DRUG BENEFIT NEWS

First Generic Protonix Hits the Market; Plans, PBMs Expect Modest Savings at First

In a short-lived move, Teva Pharmaceutical Industries late last month launched the first generic version of Wyeth Pharmaceuticals' blockbuster heartburn drug Protonix (pantoprazole) in 20- and 40-mg strengths. While Teva managed to ship the drug for only two days before being stopped by a Wyeth lawsuit, industry observers say roughly six months worth of generic Protonix is now in the distribution channel, enough to have an impact on health plan and PBM spending.

While significant savings are not expected in the short term, one health plan pharmacy executive says the arrival of generic Protonix could allow plans to move the remaining brand proton pump inhibitors (PPIs) to the third formulary tier, which has the highest copayments.

Protonix, which has annual U.S. sales of roughly \$2.5 billion, is one of several brand drugs that compete in the PPI category, which is also used to treat gastrointestinal ailments. The class already has other generic and over-the-counter options, including AstraZeneca's Prilosec OTC (omeprazole). The category also contains the country's No. 2 selling drug, AstraZeneca's Nexium (esomeprazole magnesium), which generated U.S. sales of \$5.1 billion in 2006, according to IMS Health. In addition, the overall PPI category ranked second in U.S. pharmaceutical spending at \$13.6 billion in 2006, according to the latest IMS figures.

Wyeth said its marketing exclusivity on Protonix extends until January 2011 as the result of pediatric testing on the drug. On Dec. 24, Wyeth said it would pursue a patent infringement claim for lost profits and other damages against Teva. The same day, Teva said that it had agreed to stop shipping the drug for 30 days, and had begun settlement discussions with Wyeth.

'Not Earth Shattering'

Until details of any agreement are announced, some health plans and industry observers are taking a wait-and-see stance toward potential savings of generic Protonix.

"On a scale of one to 10, it's about a six," Mesfin Tegenu, president of PerformRx, which is AmeriHealth Mercy's PBM division, says of Teva's generic Protonix release. "The real event was the release of Prilosec OTC," which the FDA approved in June 2003. Prilosec OTC "gave managed care a low-cost PPI option for the first time," and has had a "significant effect" on reducing PPI drug spend, he tells *DBN*.

The release of generic Protonix, meanwhile, "simply gives managed care another generic step option to consider before allowing the use of the remaining brand product," Tegenu says. "Important, but not earth shattering."

Terry Shea, Pharm.D., director of pharmacy services for BlueCross BlueShield of Tennessee, says the release of generic Protonix "has the potential to be a major event for payers."

"We expect the addition of another generic... would reduce the spend significantly for this therapeutic class," says Shea, who notes that PPIs are among the plan's top five drug classes by spending. He also says that the Tennessee Blues' customers are increasingly interested in benefit designs that reduce the benefit for brand drugs when there are multiple generic choices in a therapeutic class.

Tegenu says he suspects that Teva's agreement to suspend shipment was more form than substance. "This gives Teva at least 30 days to negotiate with Wyeth for a money settlement, or potentially an early generic release at some point in the future," Tegenu says. "We certainly won't know for a month or two what the outcome is."

Meanwhile, he adds, PerformRx's sources do not seem to be having any trouble getting stock of either strength of the Teva product. "Nor are we being told of any quantity limits put in place when ordering" he adds. "The pricing on the product at this time is not significant enough to get us very excited one way or the other."

A 90-tablet supply of 20-mg strength Protonix sells for \$353.61, while a 90-capsule supply of 20-mg strength generic Prilosec sells for \$63.97 on drugstore.com.

Other industry observers agree that generic Protonix price savings will be incremental at first. **Eric Auger, partner at pharmaceutical consulting firm Putnam Associates**, says it's still unclear whether Teva's efforts will lead the way to multisource competition in the near term. "If they're the only ones to enter, we don't expect the pricing of the generic product would go low enough to lead to significant savings for payers," he says in an interview.

The PPI category already is highly competitive, Auger explains. "Prices are not differentiated that much. You have a lot of situations where not all products are on formulary, so there is competitive rivalry for formulary position," he says.

In fact, a single-sourced generic could actually have a negative impact on the bottom line. A single-sourced

generic is placed on the drug formulary's first tier, which has the lowest copays, Auger notes. "So the plan won't be recouping as much of the cost of the product from the patient contribution," he says. "And on the other side, [the Rx payer] really won't be getting that much of a discount from the pharmacy for filling the generic product in the short term." It's only after multiple generics enter the market following a six-month exclusivity period that prices dramatically fall.

Nexium Sales Are Likely to Remain Strong

With the arrival of a second generic PPI, plans could move the remainder of the brand PPIs — Prevacid, Nexium and Aciphex — to the third tier, which has the highest copay, Tegenu says. If a health plan wants to keep one brand product on tier two, "then whoever gets out there and contracts aggressively may get that spot," he says. "So this competition for the one spot on tier two could have some positive financial effects."

But Auger says that even if Teva's move leads to multisourced competition on generic Protonix earlier than expected, he still wouldn't expect to see a major drop in the market share of Nexium right away.

"Nexium is one of the most heavily promoted drugs, period," he says. "There are some [plans] who are willing to put hard restrictions on Nexium, and in so doing are able to move share to a lower-priced product or products where they have better contracts. But there are still a lot of plans out there that don't want to tangle with Nexium," he continues. "Patients want it. It's a high-demand product, particularly in the [Medicare] Part D environment where patients make the decision on what plans they're going to choose. Nexium is one of the drugs they look for on the formulary when making that decision."

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