

Rx Inform

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IN THIS ISSUE:

Generic Protonix is Approved by FDA



Effective immediately, generic Protonix [pantoprazole]—a proton pump inhibitor (PPI) medication used to treat gastroesophageal reflux disease (GERD)—has been approved for distribution by the FDA, and pharmacies can now obtain the generic equivalent from wholesalers. As soon as Medispan has national drug code (NDC) and pricing information, pantoprazole will be available for dispensing and reimbursement for all Innoviant plan sponsors and their members.

Innoviant will continue to watch for developments as pantoprazole is being launched “at risk” of infringing on the brand patent. This means that the generic may only be available for a limited time if Wyeth (brand manufacturer of Protonix) chooses to pay Teva (generic manufacturer of pantoprazole) a settlement to pull the generic and delay its full launch.

As part of the FDA’s standard approval process for generic equivalents, Teva has been granted a 180-day exclusivity period for pantoprazole and has priced its product at only 10 percent below the price of Protonix based on Average Wholesale Price (AWP).

The generic product is available to members at the generic co-payment amount as established by their plan sponsors. For plans that include a brand penalty as part of their plan design, members will pay *only* the brand co-payment for Protonix during the exclusivity period; the penalty cost of the difference in price between Protonix and the generic pantoprazole will not be applied until pricing changes significantly. A price drop is anticipated once multiple generic manufacturers begin offering pantoprazole, which is expected in about six months.

The Innoviant Pharmacy and Therapeutics Committee will closely monitor the situation and make preferred product adjustment recommendations for the PPI class as more information on generic availability and pricing becomes available.

If you have questions, please contact your Innoviant account manager at 866-800-4321.

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