

Indiana Medicaid Therapeutics Committee Therapeutic Class Review Summary

Therapeutic Class:

Proton Pump Inhibitors

Overview:

The first proton pump inhibitor (PPI) was approved for clinical use in 1989. This class of agents suppresses gastric acid production via inhibition of the proton pump at the secretory surface of the parietal cell. FDA indications include duodenal/gastric ulcer, gastroesophageal reflux disease (GERD), erosive esophagitis, Zollinger-Ellison syndrome, risk reduction of NSAID-associated gastric ulcers, prevention of upper G.I. bleeding in critically ill patients, and *H. pylori* eradication when used in combination with clarithromycin and amoxicillin.

Six proton pump inhibitors are currently available on the U.S market. All PPIs are available in an oral dosage form; however, only lansoprazole, omeprazole, and pantoprazole are available generically. Omeprazole was the first over-the-counter PPI, which became available in June 2003. An OTC formulation of Prevacid[®] has also received FDA approval, and has been available since November 2009. Nexium[®] was recently approved for use in the treatment of symptomatic GERD and erosive esophagitis in pediatric patients 1 to 11 years of age. Protonix[®] also recently received a new indication and is now approved for the short-term treatment of erosive esophagitis associated with GERD in pediatric patients ages five years and older. Kapidex[™] (dexlansoprazole), the most recently approved PPI, is now being marketed under the name Dexilant[™], due to reports of dispensing errors with Casodex[™] and Kadian[®]. Dexilant[™] is the R-isomer of lansoprazole with a dual delayed release concentration-time profile that has two distinct peaks: the first occurs 1-2 hours after administration and the second within 4-5 hours. However, the clinical significance of this is unknown.

Esomeprazole, in combination with naproxen, has recently received FDA approval, and is being marketed under the name Vimovo[™]. This product is indicated for the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.

PPIs are generally well tolerated. The most common side effects in short-term studies were gastrointestinal related reactions. Studies suggest that PPIs are more effective than placebo and H₂ blockers in some instances. However, within this class, there are no differences in terms of efficacy and safety.

Generic Name	Brand Name	Manufacturer	Generic Available
Dexlansoprazole	Dexilant™ (formerly Kapidex™)	Takeda	N
Esomeprazole	Nexium®	AstraZeneca	N
Lansoprazole	Prevacid® Prevacid® Solutab™ Prevacid® 24Hr (OTC)	Takeda	Y N N
Omeprazole	Prilosec®, Prilosec OTC™	AstraZeneca	Y
Omeprazole/ Sodium Bicarbonate	Zegerid OTC	Schering-Plough, Par	Y (Rx formulation)
Pantoprazole	Protonix®	Wyeth Pharmaceuticals, Inc	Y
Rabeprazole	Aciphex™	Eisai (Janssen)	N

Summary:

Proton Pump Inhibitors are safe and effective medications. Selection of the preferred agent should be based upon safety and cost.