

**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.

There are six proton pump inhibitors currently available on the U.S market. All PPIs are available in an oral dosage form; omeprazole and pantoprazole are available generically. Omeprazole is also the first over-the-counter PPI, which became available in June 2003. Esomeprazole and lansoprazole generic formulations have received tentative FDA approval in early 2008. Nexium® recently received approval for use in the treatment of symptomatic GERD and erosive esophagitis in pediatric patients 1 to 11 years of age. In November 2003, Prevacid® NapraPAC™ was approved because the use of a PPI has been demonstrated to accelerate the healing of gastric ulcers and to prevent ulcer recurrence in patients taking an NSAID chronically (discussed in NapraPAC monograph). Kapidex™ (dexlansoprazole), the most recently approved PPI, 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. The clinical significance of this is unknown. 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 H<sub>2</sub> 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	Kapidex™	Takeda	N
Esomeprazole	Nexium®	AstraZeneca	N
Lansoprazole	Prevacid® Prevacid® Solutab™	Takeda	N
Lansoprazole/Na proxen	Prevacid® NapraPAC™	Takeda	N
Omeprazole	Prilosec®, Prilosec OTC™	AstraZeneca	Y
Omeprazole/ Sodium Bicarbonate	Zegerid™	Santarus	N
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.