



Indian Health Service
Closed Class - Proton Pump Inhibitors
IHS National Pharmacy and Therapeutics Committee
Last Reviewed: August 2007



Background:

In August 2007, the IHS National Pharmacy and Therapeutics Committee (NPTC) reviewed the Proton Pump Inhibitor class and voted to maintain omeprazole on the IHS National Core Formulary (NCF). Furthermore, the committee concluded that there was no clinical advantage to using one product over another and that maintaining the closing of the class to one product was appropriate.

Clinical Review:

Proton pump inhibitors act by irreversibly blocking the hydrogen/potassium ATPase system in gastric parietal cells, leading to a reduction in gastric acid of up to 90%. There were five available agents at the time of this review: omeprazole, lansoprazole, esomeprazole, rabeprazole, and pantoprazole. These agents are FDA-approved for the treatment of duodenal and gastric ulcers, gastroesophageal reflux, hypersecretory states and the prevention of upper GI bleed in critically-ill patients. Direct comparisons in DBRCTs have shown that the safety and comparability of PPIs are similar. As well, there are few clinically relevant differences in drug-drug interactions. In 2003, a randomized, open-label, comparative, 5-way cross over study was conducted, evaluating 24-hr intragastric pH. This study showed that the mean percentage of time with intragastric pH above 4.0 was significantly higher for esomeprazole compared to the other 4 agents. However, the study used higher dose of esomeprazole and lansoprazole compared to equipotent doses of the other three agents. As well, the medications were taken for only 5 days prior to measurement of intragastric pH. Other studies have shown more equivalent effect after 2 weeks of therapy.¹ A 2003 systematic review of direct comparative trials showed esomeprazole produced faster symptom relief of GERD compared to lansoprazole, which was faster than omeprazole. However, the author concluded, “Despite these differences, there are as yet insufficient data to establish the superiority of any one agent over all the others across all disease states treated with these agents.”² In a 2006 Drug Class Review conducted by the Oregon Evidenced-Based Practice Center, they concluded that in general, there is very little evidence that there are important differences in the effectiveness or safety of the five PPIs in the general population, or in relevant subgroups.³

Cost Avoidance Potential:

With a strong collaborative effort from all I/T/U facilities and enhanced compliance of omeprazole’s closed class status on the IHS National Core Formulary, the IHS has the potential to realize a significant amount of cost avoidance annually.

If you have any questions regarding this document, please contact the NPTC at nptc1@ihs.gov.

References:

1. Miner P. et.al. Gastric acid control with esomeprazole, lansoprazole, omeprazole, pantoprazole, and rabeprazole: A five-way crossover study. *Am J Gastroenterol* 2003 Dec; 98:2616-20.
2. Vakil N, Fennerty MB. Systematic Review: Direct comparative trial of the efficacy of proton pump inhibitors in the management of gastro-oesophageal reflux disease and peptic ulcer disease. *Aliment Pharmacol Ther* 2003; 18(6): 559-568
3. McDonagh MS, Carson S. Drug Class Review on Proton Pump Inhibitors. 2006 <http://www.ohsu.edu/ohsuedu/research/policycenter/DERP/about/final-products.cfm>