Medication Policy Manual

Policy No: dru039

Topic: esomeprazole-containing medications:
- Nexium®
- esomeprazole strontium

Date of Origin: May 2001

Committee Approval Date: October 9, 2015

Next Review Date: October 2016

Effective Date: November 1, 2015

IMPORTANT REMINDER

This Medical Policy has been developed through consideration of medical necessity, generally accepted standards of medical practice, and review of medical literature and government approval status.

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control.

The purpose of medical policy is to provide a guide to coverage. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care.

Description

Esomeprazole (Nexium® or esomeprazole strontium) is a proton pump inhibitor (PPI) that decreases acid production in the stomach. This policy applies only to orally-administered esomeprazole-containing products.

Note: Policy criteria for Vimovo® (esomeprazole/ naproxen) can be found in DRU 447.
Policy/Criteria

I. Most contracts require prior authorization approval of esomeprazole prior to coverage. Esomeprazole may be considered medically necessary when treatment with each of the following medications has been ineffective, contraindicated, or not tolerated:
   A. Omeprazole.
   AND
   B. Pantoprazole.
   AND
   C. Dexlansoprazole (Dexilant®).

   Ineffective treatment is defined as gastric-peptic symptoms (such as heartburn) not resolved after ten consecutive days of treatment.

II. Administration and Authorization Period
   A. OmedaRx considers oral esomeprazole to be a self-administered medication.
   B. Authorization may be reviewed at least annually to confirm that current medical necessity criteria are met and that the medication is effective.

Position Statement
- All PPIs are considered therapeutically interchangeable in the treatment of gastroesophageal reflux disease (GERD), erosive esophagitis (EE), gastric duodenal ulcers, and eradication of H. pylori. [46,47]

- Comparative evidence among the PPI class is not useful. Common short-comings of these trials include: study design (power) that shows similarity of PPIs rather than superiority, PPI doses that are not equivalent, and use of gastric pH as an endpoint rather than a clinical endpoints (e.g. esophageal healing rates).

- Because there are no proven differences in efficacy or safety between proton pump inhibitors, the least costly PPI (such as omeprazole) is often the best value.

- Of the branded PPIs, dexlansoprazole (Dexilant) provides the best value and may be an option for patients when a generic lower-cost PPI is not effective, contraindicated, or not tolerated.

- Lansoprazole, esomeprazole (Nexium), and rabeprazole may give a more rapid onset of acid suppression correlating to earlier symptom relief. However, it is not known if the more "rapid onset" makes a clinically significant impact in reducing the number of physician office visits or preventing dosage increases or drug switches. [29-33]

- The clinical guidelines provide recommendations for the use of PPIs in dyspepsia/GERD with the intent of promoting appropriate dosing and length of therapy. Guidelines do not distinguish between PPI products, but recommends that "the least expensive appropriate PPI should be used". [29, 48-50]
- There is no conclusive evidence of differences in safety between PPIs. Potential drug interaction profiles are varied, due to different metabolic pathways. However, the clinical significance of the drug interactions, in most cases, is unknown.

- Omeprazole (generic Prilosec) and esomeprazole (Nexium Rx or 24HR OTC) contain the same active ingredient, but in different amounts. A 20-mg capsule of esomeprazole delivers the same amount of esomeprazole as a 40-mg capsule of omeprazole.

**Clinical Efficacy**

- Scientific literature does not consistently demonstrate the superiority of one PPI over another:
  *
  * Various PPIs given once daily produced similar healing rates in patients with gastric and duodenal ulcers and ulcerative or erosive GERD. [46,47]
  *
  * Comparative trials demonstrate only modest gains in EE healing rates with esomeprazole (93-96%) compared to lansoprazole (89%), [4-5, 38] pantoprazole (92%), [42] and omeprazole (84-87%). [1-2, 35]
  *
  * Other head-to-head trials have demonstrated similar efficacy for esomeprazole (Nexium) when compared to omeprazole, [3-4] lansoprazole [34], and pantoprazole. [36-37, 43]
  *
  * In patients with moderate to severe EE, observed healing rates were similar with esomeprazole and lansoprazole at the 8-week endpoint. [41]

- Proton pump inhibitors may be given to patients who are receiving non-steroidal antiinflammatory drugs for chronic pain and inflammation to decrease the risk of developing gastric ulcers.

**Safety**

- Adverse effects and safety profile among the PPIs are similar, with no advantage of one over the other. [13-18, 46,47]

- Potent inhibitors of CYP 2C19 (e.g. omeprazole, esomeprazole, cimetidine) should be avoided in combination with clopidogrel (Plavix) because they can reduce the effectiveness of clopidogrel. There is not sufficient information at this time to make specific recommendations regarding coadministration of clopidogrel and other PPIs. [45]

**Dosing considerations**

- Nexium 24HR OTC contains 20 mg of esomeprazole magnesium, equivalent to 20 mg esomeprazole contained in prescription-strength esomeprazole magnesium (Nexium).

- Prilosec OTC contains 20.6 mg of omeprazole magnesium, equivalent to 20 mg omeprazole contained in prescription-strength omeprazole (generic Prilosec). [36]
Cross References

- rabeprazole-containing medications, AcipHex®, AcipHex® Sprinkle™, Medication Policy Manual, dru101
- Dexilant®, dexlansoprazole, Medication Policy Manual, dru174

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References


44. Dexilant™ (dexlansoprazole) delayed-release capsules Product Information. Takeda Pharmaceuticals America, Inc.: Deerfield, IL; December 2014.


