

Medication Policy Manual

Policy No: dru174

Topic: Kapidex™, dexlansoprazole

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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

Dexlansoprazole (Kapidex™) is an orally administered proton pump inhibitor (PPI) that decreases acid production in the stomach.

Policy/Criteria

- I. Most contracts require prior authorization approval of dexlansoprazole prior to coverage. Dexlansoprazole may be considered medically necessary when treatment with omeprazole has been ineffective, contraindicated, or not tolerated.

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

II. Administration and Authorization Period

- A. Regence considers oral dexlansoprazole 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*.^[3-4, 7-28, 40]
- 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).
- Of the branded PPIs, lansoprazole (Prevacid) provides the best value and may be an option for patients when omeprazole is not effective, contraindicated, or not tolerated.
- Omeprazole (Prilosec) and esomeprazole (Nexium) contain the same active ingredient, but in different amounts. A 20-mg capsule of Nexium delivers the same amount of esomeprazole as a 40-mg capsule of omeprazole.
- Lansoprazole (Prevacid[®]), esomeprazole (Nexium[®]), and rabeprazole (Aciphex[®]) 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 offices visits or preventing dosage increases or drug switches.^[29-33]
- The National Institute for Clinical Excellence (NICE) provides recommendations for the use of PPIs in dyspepsia/GERD with the intent of promoting appropriate dosing and length of therapy. NICE does not distinguish between PPI products, but recommends that "the least expensive appropriate PPI should be used".^[29]

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. ^[3-4, 7-28, 34]
 - * Comparative trials demonstrate only modest gains in EE healing rates with esomeprazole (Nexium; 93-96%) compared to lansoprazole (Prevacid; 89%), ^[4-5, 38] pantoprazole (Protonix; 92%), ^[42] and omeprazole (Prilosec; 84-87%). ^[1-2, 35]
 - * Other head-to-head trials have demonstrated similar efficacy for esomeprazole (Nexium) when compared to omeprazole (Prilosec), ^[3-4] lansoprazole (Prevacid) ^[34], and pantoprazole (Protonix). ^[36-37, 44]
 - * In patients with moderate to severe EE, observed healing rates were similar with esomeprazole (Nexium[®]) and lansoprazole (Prevacid[®]) at the 8 week endpoint. ^[41]
- Likewise, dexlansoprazole, the newest PPI, has not been shown to be superior to other PPIs.
 - * Dexlansoprazole 60 mg and lansoprazole 30 mg demonstrated similar esophageal healing rates over an 8-week treatment period. No additional benefit was demonstrated with a 90-mg dose of dexlansoprazole. ^[45]
 - * Dexlansoprazole 30 mg was superior to placebo in maintaining esophageal healing over six months and in controlling non-erosive GERD symptoms over 4 weeks. No additional benefit was demonstrated with a 60-mg dose of dexlansoprazole for these conditions. ^[45]
 - * The “dual delayed-release” system used with dexlansoprazole has not been proven to be clinically superior to the delayed-release delivery used with other PPI products.

Safety

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

Dosing considerations

- Prilosec OTC contains 20.6 mg of omeprazole magnesium, equivalent to 20 mg omeprazole contained in prescription omeprazole (Prilosec[®]). ^[36]

- A 30-mg capsule of lansoprazole (Prevacid) delivers 15 mg of dexlansoprazole (Kapidex), the biologically active isomer of lansoprazole.

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Cross References
Aciphex [®] , rabeprazole sodium dru101
Nexium [®] , esomeprazole dru039
Prevacid [®] , lansoprazole dru098
Protonix [®] , pantoprazole dru102

Codes	Number	Description
N/A		