oscar

Clinical Guideline

Oscar Clinical Guideline: Proton Pump Inhibitors - Dexlansoprazole, Esomeprazole and Rabeprazole (PG047, Ver. 7)

Proton Pump Inhibitors - Dexlansoprazole, Esomeprazole and Rabeprazole

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Proton pump inhibitors (PPIs) are a class of drugs that are primarily used to reduce the production of gastric acid in the stomach. They function by irreversibly binding to and inhibiting the hydrogen-potassium ATPase (also known as the proton pump), an enzyme found on the gastric parietal cells that is responsible for the final step in the production of gastric acid.

Table 1: Formulary Proton Pump Inhibitors

Preferred	Prior authorization (PA) Required
Lansoprazole capsules (15mg, 30mg)	Dexlansoprazole capsules (30mg, 60mg)
Omeprazole capsules (10mg, 20mg, 40mg)	Esomeprazole capsules (20mg, 40mg)
Pantoprazole sodium tablets (20mg, 40mg)	Rabeprazole sodium tablets (20mg)

PPIs are commonly prescribed for a variety of conditions that involve excess stomach acid. These include gastroesophageal reflux disease (GERD), Zollinger-Ellison syndrome, peptic ulcer disease, and to manage dyspepsia. They are also used as a part of triple or quadruple therapy for the eradication of Helicobacter pylori, a bacterium that can cause stomach ulcers and gastric cancer.

PPIs have also demonstrated efficacy as gastroprotective agents in patients at increased gastrointestinal (GI) risk during anti-platelet therapy. This includes patients who are over 65 years of age, those on concurrent steroid/anticoagulant therapy, those with a history of peptic ulcers, and those with certain comorbidities such as heart failure, renal impairment, stroke, diabetes, ongoing malignancy, and smokers. These patients are at an increased risk for adverse GI events such as gastroduodenal ulcerations/erosions, overt and occult bleeding, and in rare cases, perforation.

The dosing of PPIs is often patient-specific and depends on the condition being treated. For example, in the management of GERD, PPI therapy may involve up to twice-daily dosing for 8-12 weeks. However, the ideal duration of PPI therapy is not well-established, and prolonged treatment may be required in some cases.

Definitions

"Gastroesophageal reflux disease (GERD)" is a condition that develops when the reflux of stomach contents causes troublesome symptoms and/or complications.

"Peptic Ulcer Disease" is a defect in the gastric or duodenal wall that extends through the muscularis mucosa into the deeper layers of the wall.

"Zollinger-Ellison syndrome" is a condition in which gastrointestinal or pancreatic tumors cause an increased secretion of gastric acid.

Medical Necessity Criteria for Authorization

The Plan considers <u>dexlansoprazole</u>, <u>esomeprazole capsules or rabeprazole tablets</u> medically necessary when the following criteria is met:

- 1. The member is unable to use, or has adequately tried and failed TWO (2) of the following preferred medications for a minimum of **ONE** (1) month:
 - a. lansoprazole; or
 - b. omeprazole; or

c. pantoprazole.

If the above prior authorization criteria is met, the requested medication will be approved for 12 months.

References

- 1. Aciphex Delayed-Release tablets (rabeprazole) [prescribing information]. Wixom, MI: Waylis Therapeutics LLC; July 2023.
- 2. Aciphex Delayed-Release tablets (rabeprazole) [prescribing information]. Woodcliff Lake, NJ: Eisai Inc; March 2022.
- 3. Aciphex Sprinkle capsules (rabeprazole) [prescribing information]. Englewood, CO: Aytu Therapeutics; December 2020.
- 4. Aciphex tablets (rabeprazole) [prescribing information]. Woodcliff Lake, NJ: Eisai Inc; November 2020.
- 5. Dexilant (dexlansoprazole) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America Inc; July 2023.
- 6. Katz, P. O., Dunbar, K. B., Schnoll-Sussman, F. H., Greer, K. B., Yadlapati, R., & Spechler, S. J. (2022). ACG clinical guideline for the diagnosis and management of gastroesophageal reflux disease. The American journal of gastroenterology, 117(1), 27-56.
- 7. Katz PO, Gerson LB, and Vela MF. Diagnosis and Management of Gastroesophageal Reflux. Am J Gastroenterology. 2013; 108:308–328.
- 8. Nexium (esomeprazole magnesium) [prescribing information]. Wilmington, DE: AstraZeneca; July 2023.
- 9. Nexium (esomeprazole magnesium) [prescribing information]. Wilmington, DE: AstraZeneca; March 2022.
- 10. Sandhu DS and Fass R. Current Trends in the Management of Gastroesophageal Reflux Disease. Gut Liver. 2018 Jan 15;12(1):7-16.
- 11. Wolfe MM. Proton pump inhibitors: Overview of use and adverse effects in the treatment of acid related disorders. UpToDate.com. Available at: https://www.uptodate.com/contents/proton-pump-inhibitors-overview-of-use-and-adverse-effects-in-the-treatment-of-acid-related-disorders?search=proton%20pump%20inhibitors&source=search_result&selectedTitle=2~135&u sage_type=default&display_rank=2#patient_information. Updated April 09, 2020. Accessed July 13, 2020.
- 12. Yadlapati, R., Gyawali, C. P., Pandolfino, J. E., Chang, K., Kahrilas, P. J., Katz, P. O., ... & Wani, S. (2022). AGA Clinical Practice Update on the Personalized Approach to the Evaluation and Management of GERD: Expert Review. Clinical Gastroenterology and Hepatology, 20(5), 984-994

Clinical Guideline Revision / History Information

Original Date: 08/06/2020

Reviewed/Revised: 06/24/2021, 12/01/2021, 06/23/2022, 06/29/2023, 9/21/2023, 12/19/2024