

Dexlansoprazole (Dexilant)

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.

Dexlansoprazole (Dexilant)	1
Summary	1
Definitions	2
Clinical Indications	2
Medical Necessity Criteria for Clinical Review	2
General Medical Necessity Criteria	2
References	3
Appendix A	4
Clinical Guideline Revision / History Information	4

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.

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 those 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 individuals 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 often 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.

“[s]” indicates state mandates may apply.

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

Clinical Indications

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

The Plan considers ~~dexlansoprazole (Dexilant)~~ 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:^[s]
 - a. Esomeprazole (Nexium); *or*
 - b. Lansoprazole (Prevacid); *or*
 - c. Omeprazole (Prilosec); *or*
 - d. Pantoprazole (Protonix); *or*
 - e. Rabeprazole (Aciphex).

If the above prior authorization criteria is met, the requested medication will be approved for up to 36 months.^[s]

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. Prevacid (lansoprazole delayed release capsules) [prescribing information]. Lexington, MA: Takeda Pharmaceuticals America, Inc. August 2023.
10. Prilosec (omeprazole magnesium) [prescribing information]. Zug, Switzerland: Covis Pharma. July 2023
11. Protonix (pantoprazole sodium delayed release tablets) [prescribing information] Konstanz, Germany: Wyeth Pharmaceuticals LLC. July 2023.
12. Sandhu DS and Fass R. Current Trends in the Management of Gastroesophageal Reflux Disease. *Gut Liver*. 2018 Jan 15;12(1):7-16.
13. Slater BJ, Collings A, Dirks R, et al. Multi-society consensus conference and guideline on the treatment of gastroesophageal reflux disease (GERD). *Surg Endosc*. 2023 Feb;37(2):781-806. doi: 10.1007/s00464-022-09817-3. Epub 2022 Dec 18.
14. Weusten BLAM, Bisschops R, Dinis-Ribeiro M, et al. Diagnosis and management of Barrett esophagus: European Society of Gastrointestinal Endoscopy (ESGE) Guideline. *Endoscopy*. 2023 Dec;55(12):1124-1146. doi: 10.1055/a-2176-2440. Epub 2023 Oct 9.
15. 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&usage_type=default&display_rank=2#patient_information. Updated April 09, 2020. Accessed July 13, 2020.
16. 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

Appendix A

Table 1: Formulary Proton Pump Inhibitors

Preferred	Prior authorization (PA) Required
Esomeprazole capsules (20mg, 40mg) Lansoprazole capsules (15mg, 30mg) Omeprazole capsules (10mg, 20mg, 40mg) Pantoprazole sodium tablets (20mg, 40mg) Rabeprazole sodium tablets (20mg)	Dexlansoprazole capsules (30mg, 60mg) Esomeprazole packet (2.5 mg, 5 mg, 10mg, 20mg, 40mg), <i>only in those 13 years of age and older</i>

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, 11/01/2025, 08/03/2026