

Proton Pump Inhibitors

Override(s)	Approval Duration
Prior Authorization	<u>Non-Preferred PPI:</u> 1 year
Quantity Limit	h. pylori diagnosis 14 days
	<u>Non-Preferred PPI quantity override:</u> 1 year
	h. pylori diagnosis 14 days

Quantity Limit

Quantity Limits apply to Zegerid and Konvomep

For Zegerid:

Quantity limit = 1 dose/day

For Konvomep:

Quantity limit = 20 mL/day

Requests for a greater quantity of Zegerid may be approved if the following criteria are met:

- I. Increased dosing of up to two times the stated dosing limit (2 doses per day) for 14 days may be approved for a diagnosis of: *Helicobacter pylori*, for eradication;
- OR**
- II. Increased dosing beyond two times the stated dosing limit (2 doses per day) is approvable for:
 - A. Hypersecretory syndromes (Zollinger-Ellison syndrome, multiple endocrine adenomas, or systemic mastocytosis); **OR**
 - B. Barrett's Esophagus; **OR**
 - C. Laryngeal, esophageal or gastric cancer; **OR**
 - D. Scleroderma or limited scleroderma (CREST syndrome)
- OR**
- III. Increased dosing up to two times the stated dosing limit (2 doses per day) is approvable for the following:
 - A. Individual does not respond after a 30-day trial of the stated dosing limit with the requested PPI; **OR**
 - B. Individual has been diagnosed with eosinophilic esophagitis

For Konvomep: may approve an additional 20 mL in the first day of therapy, as a loading dose, for the indication of reduction of risk of upper GI bleeding in critically ill patients.

Medications	Comment
esomeprazole magnesium capsules (generic prescription Nexium, all strengths) lansoprazole capsules (generic prescription Prevacid, all strengths) omeprazole (generic prescription Prilosec, all strengths) pantoprazole (generic prescription Protonix, all strengths) – except pantoprazole pak 40mg Rabeprazole	Preferred Generic
AcipHex (rabeprazole) brand and generic AcipHex Sprinkle (rabeprazole DR) brand and generic Dexilant (dexlansoprazole) brand and generic esomeprazole strontium (all strengths) Konvomep (omeprazole/sodium bicarbonate) Nexium (esomeprazole) brand Nexium DR packets for oral suspension (esomeprazole) brand and generic Prevacid (lansoprazole) brand Prevacid Solutab (lansoprazole ODT) brand and generic Brand Prilosec Prilosec Oral suspension	Non-Preferred

Brand Protonix Protonix Oral suspension and generic pantoprazole pak 40mg Brand Rabeprazole DR Sprinkle Zegerid (omeprazole/sodium bicarbonate) brand and generic Zegerid Oral Suspension (omeprazole/sodium bicarbonate) brand and generic	
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APPROVAL CRITERIA

Requests for a non-preferred proton pump inhibitor (PPI) may be approved for individuals who meet the following criteria:

- I. Individual has had trials of and inadequate response or intolerance to **two** preferred proton pump inhibitors (PPIs). Medication samples/coupons/discount cards are excluded from consideration as a trial;
 - A. Esomeprazole magnesium capsules (generic prescription Nexium, all strengths);
 - B. Lansoprazole capsules (generic prescription Prevacid, all strengths);
 - C. Omeprazole (generic Prilosec, all strengths);
 - D. Pantoprazole (generic Protonix, all strengths);

OR

- II. Individual is less than one year of age.

Requests for **brand** Aciphex, Dexilant, Nexium, Prevacid, Prevacid Solutab, or Zegerid must also meet the following criteria, in addition to the above Prior Authorization criteria:

- I. Individual has failed an adequate trial (medication samples/coupons/discount cards are excluded from consideration as a trial) of one chemically equivalent generic agent;

AND

 - A. Generic had inadequate response; **OR**
 - B. Generic caused adverse outcome; **OR**
 - C. The individual has a genuine allergic reaction an inactive ingredient in generic agent. Allergic reaction(s) must be clearly documented in the individual's medical record.

Key References:

1. Chey WD, Leontiadis GI, Howden CW, Moss SF. ACG Clinical Guideline: Treatment of *Helicobacter pylori* infection. *Am J Gastroenterol*. 2017; 112:212-238. Doi:10.1038/ajg.2016.563. Available from: https://journals.lww.com/ajg/Fulltext/2017/02000/ACG_Clinical_Guideline_Treatment_of_Helicobacter.12.aspx#pdf-link.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Katz PO, Dunbar KB, Schnoll-Sussman FH. Guidelines for the Diagnosis and Management of Gastroesophageal Reflux Disease. *Am J Gastroenterol*. 2022;117:27–56. <https://doi.org/10.14309/ajg.0000000000001538>; published online November 22, 2021. Available at file:///C:/Users/AF38863/Downloads/ACG_Clinical_Guideline_for_the_Diagnosis_and.14.pdf.
5. Laine L, DeVault K, Katz P, et. al. Vonoprazan versus Lansoprazole for Healing and Maintenance of Healing Erosive Esophagitis: A Randomized Trial. *Gastroenterology* 2023;164:61-71. Available at [Vonoprazan Versus Lansoprazole for Healing and Maintenance of Healing of Erosive Esophagitis: A Randomized Trial \(gastrojournal.org\)](https://gastrojournal.org).
6. Laine L, Barkun AN, Saltzman JR, et. al. Upper Gastrointestinal and Ulcer bleeding. *Am J Gastroenterol*. 2021;116:899–917. <https://doi.org/10.14309/ajg.0000000000001245>. Available from: file:///C:/Users/AF38863/Downloads/ACG_Clinical_Guideline_Upper_Gastrointestinal_and.14.pdf.
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; Updated periodically.
8. American College of Gastroenterology (ACG). Peptic Ulcer Disease. April 2021. Available at <https://gi.org/topics/peptic-ulcer-disease/>.
9. Plavix [package insert]. Bridgewater, NJ: Briston-Myers Squibb/Sanofi Pharmaceuticals Partnership.
10. Shaheen NJ, Falk GW, Iyer PG, et al. ACG Clinical Guideline: Diagnosis and management of Barrett's Esophagus. *Am J Gastroenterol*. 2022; 117:559-587 | DOI: 10.14309/ajg.0000000000001680. Available from: https://journals.lww.com/ajg/Fulltext/2022/04000/Diagnosis_and_Management_of_Barrett_s_Esophagus_.17.aspx.

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