

Pharmacy Policy Bulletin

Title: Proton Pump Inhibitors

Policy #: Rx.01.75

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, quantity, or formulary restrictions (ie limits on non-preferred drugs). Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

Intent:

The intent of this policy is to communicate the medical necessity criteria for proton pump inhibitors (PPIs) as provided under the member's prescription drug benefit.

Description:

Proton Pump Inhibitors (PPIs) suppress gastric acid secretion by inhibiting hydrogen-potassium adenosinetriphosphatase (H⁺/K⁺ ATPase) on the surface of parietal cells, the final step in acid secretion. PPIs are the most potent gastric acid suppression agents and are most effective when the parietal cells are stimulated to produce acid post-prandially.

PPIs are useful in treating peptic ulcer disease (including prevention and treatment of NSAID induced gastric ulcers), gastroesophageal reflux disease (GERD) with and without esophageal erosions, hypersecretory diseases, and helicobacter pylori infections (as part of an antibiotic containing regimen).

According to the American College of Gastroenterology's recommendation for the diagnosis and management of GERD, there is "no major difference in efficacy between the different PPIs" when used for an 8-week course to heal erosive esophagitis. However, no clear recommendation on pharmacologically equivalent doses among the PPIs exists and some individuals report better response to one agent compared to others.

Policy:

INITIAL CRITERIA Brand proton pump inhibitor capsules and tablets (e.g., Aciphex® tablets, Protonix® tablets, Dexilant® capsules, Prilosec® capsules), dexlansoprazole or generic esomeprazole is approved when BOTH of the following are met:

- A. An FDA or compendia approved indication; and
- B. Inadequate response to a two-week trial or inability to tolerate THREE of the following generic proton pump inhibitors:
 - a. omeprazole
 - b. lansoprazole
 - c. pantoprazole
 - d. rabeprazole

Initial authorization duration: H. Pylori 14 days; all other indications 2 years

REAUTHORIZATION CRITERIA Brand proton pump inhibitor capsules and tablets (e.g., Aciphex® tablets, Protonix® tablets, Dexilant® capsules, Prilosec® capsules), dexlansoprazole or generic esomeprazole is re-approved when BOTH of the following are met:

- A. Documentation of positive clinical response to therapy; and
- B. Documentation of continued need for treatment beyond 2 years

Reauthorization duration: 2 years

INITIAL CRITERIA Formulations other than capsules or tablets (e.g. lansoprazole [Prevacid® solu-tab], rabeprazole (Aciphex®) Sprinkles, Zegerid® packet, Prilosec® granules for suspension, pantoprazole [Protonix® packets] and esomeprazole [Nexium®] packets) require prior authorization for members age 12 years and older and are approved when there is documentation of BOTH of the following:

- A. An FDA approved indication or clinically accepted use; and
- B. One of the following:
 - 1. Drug will be administered via nasogastric or gastrostomy tube; or
 - 2. Member is unable to swallow an intact capsule or tablet

Initial authorization duration: H. Pylori 14 days; all other indications 2 years

REAUTHORIZATION CRITERIA Formulations other than capsules or tablets (e.g. lansoprazole [Prevacid® solutab], rabeprazole [Aciphex®] Sprinkles, Zegerid® packet, Prilosec® granules for suspension, pantoprazole [Protonix® packets] and esomeprazole [Nexium®] packets) require prior authorization for members age 12 years and older and are re-approved when BOTH of the following criteria are met:

- A. Documentation of positive clinical response to therapy; and
- B. Documentation of continued need for treatment beyond 2 years

Reauthorization duration: 2 years

Black Box Warning as shown in the drug Prescribing Information:

None

Guidelines:

Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the prescription drug benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

References:

Aciphex® (rabeprazole) [prescribing information]. Woodcliff Lake, NJ: Eisai, Inc; September 2019. Available from: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=5d103551-978f-472a-9c62-51e6e4dea068&type=display>. Accessed October 17, 2022.

Dexilant® (dexlansoprazole) [package insert]. Deerfield, IL: Takeda Pharmaceuticals America Inc. November 2020. Available from: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=9819f033-3bbe-442e-8e92-45fec77b237d&type=display>. Accessed October 17, 2022.

Esomeprazole strontium [package insert]. Glasgow, KY. Amneal Pharmaceuticals. December 2014. Available from: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=61a5a84e-0194-4f11-91f8-83d7ac404932&type=display>. Accessed October 17, 2022.

Katz PO, Gerson LB, Vela MF. Diagnosis and Management of Gastroesophageal Reflux Disease: American College of Gastroenterology. Am J Gastroenterol 2013;108:308-328. DOI: 10.1038/ajg.2012.80. Available from: http://gi.org/wp-content/uploads/2013/10/ACG_Guideline_GERD_March_2013_plus_corrigendum.pdf

Laine L, Jensen JM. Management of patients with ulcer bleeding. Am J Gastroenterol. 2012;107:345-60. DOI 10.1038/ajg.2011.480 Available from: <http://s3.gi.org/physicians/guidelines/UlcerBleeding.pdf>

Nexium® (esomeprazole) [package insert]. Wilmington DE. AstraZeneca Pharmaceuticals LP. October 2017. Available from: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=f4853677-1622-4037-688b-fdf533a11d96&type=display>. Accessed

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Prevacid® (lansoprazole) [package insert]. Deerfield, IL; Takeda Pharmaceuticals America Inc. June 2018. Available from: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=71ba78cb-7e46-43eb-9425-fa130f537f84&type=display>. Accessed October 17, 2022.

Prilosec® (omeprazole) [package insert]. AstraZeneca Pharmaceuticals, Wilmington, DE, 2005. December 2016. Available from: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=a1b077e6-b070-43f2-a98e-380cc635419d&type=display>. Accessed October 17, 2022.

Protonix® (pantoprazole) [package insert]. Philadelphia, PA: Pfizer; June 2018. Available from: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=08098cb2-c048-4640-f387-6beec4a38936&type=display>. Accessed October 17, 2022.

Wolfe MM. Overview and comparison of the proton pump inhibitors for the treatment of acid-related disorders. UpToDate. July 2020. Available from: https://www.uptodate.com/contents/overview-and-comparison-of-the-proton-pump-inhibitors-for-the-treatment-of-acid-related-disorders?source=search_result&search=proton%20pump%20inhibitors&selectedTitle=1~150. Accessed October 17, 2022.

Zegerid® [package insert] Raleigh, NC. Salix Pharmaceuticals Inc.; June 2018. [Salix Web site]. Available at: <https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=cd6868b9-5824-442b-8d65-4db29ecb70a4&type=display>. Accessed October 17, 2022

Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

Brand Name	Generic Name
Aciphex® [Sprinkles]	rabeprazole
Dexilant®	dexlansoprazole
Prevacid® [Solutab]	lansoprazole
Nexium® [Suspension]	esomeprazole magnesium
Prilosec® [Suspension]	omeprazole
Protonix® [Suspension]	pantoprazole
Zegerid® Suspension	omeprazole/sodium bicarbonate

Cross References:

Off-Label Use Rx.01.33

Quantity Level Limits for Pharmaceuticals Covered Under the Prescription Drug Benefit Rx.01.76

Policy Version Number:	23.00
P&T Approval Date:	September 15, 2022
Policy Effective Date:	January 01, 2023
Next Required Review Date:	September 15, 2023

The Policy Bulletins on this web site were developed to assist the Company in administering the provisions of the respective benefit programs, and do not constitute a contract. If you have coverage through the Company, please refer to your specific benefit program for the terms, conditions, limitations and exclusions of your coverage. Company does not provide health care services,

medical advice or treatment, or guarantee the outcome or results of any medical services/treatments. The facility and professional providers are responsible for providing medical advice and treatment. Facility and professional providers are independent contractors and are not employees or agents of the Company. If you have a specific medical condition, please consult with your doctor. The Company reserves the right at any time to change or update its Policy Bulletins.

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