

STEP THERAPY POLICY

POLICY: Proton Pump Inhibitors Step Therapy Policy

Proton Pump Inhibitor	Product	Manufacturer
Dexlansoprazole	Dexilant [®] delayed-release capsules	Takeda, generic
Esomeprazole	Nexium [®] delayed-release capsules	AstraZeneca, generic
	Nexium [®] delayed-release granules for oral suspension	
	Nexium [®] 24HR delayed-release capsules OTC	
Lansoprazole	Prevacid [®] delayed-release capsules	Takeda, generic
	Prevacid [®] SoluTab [®] delayed-release orally disintegrating tablets	GSK, generic
	Prevacid [®] 24HR delayed-release capsules OTC	
Omeprazole	Omeprazole delayed-release capsules	generics only
	Prilosec [®] delayed-release granules for oral suspension	AstraZeneca
	Prilosec OTC [®] delayed-release tablets	Procter & Gamble, generic
Omeprazole/ sodium bicarbonate	Zegerid [®] capsules	Salix, generic
	Zegerid [®] powder for oral suspension	Procter & Gamble, generic
	Zegerid OTC [®] capsules	Bayer, generic
	Konvomep [®] oral suspension	Azurity
Pantoprazole	Protonix [®] delayed-release tablets	Wyeth, generic
	Protonix [®] delayed-release granules for oral suspension	
Rabeprazole	Aciphex [®] delayed-release tablets	Eisai, generic
	Aciphex [®] Sprinkle [™] delayed-release capsules	
Vonoprazan	Voquezna [®] tablets	Phathom

OTC – Over-the-counter.

REVIEW DATE: 04/15/2026

OVERVIEW

Although proton pump inhibitors (PPIs) vary in their specific FDA-approved indications, all PPIs are used for the treatment and/or management of acid-related diseases, such as duodenal and gastric ulcerations, gastroesophageal reflux disease, Zollinger-Ellison syndrome, and *Helicobacter pylori* infections.^{1-14,19,20} Several PPIs are available over-the-counter (OTC).¹⁻⁴ Patients should not take the OTC products for more than a 14 day period or more often than every 4 months unless under the supervision of a physician.

Several treatment guidelines support the overall safety and efficacy of these agents for acid-related diseases.¹⁵⁻¹⁸ PPIs are the treatment of choice for many gastrointestinal disorders in adults and pediatrics. Though the available clinical data are not entirely complete for the comparison of these agents, many clinical trials have shown the PPIs to be similar in efficacy and safety. Voquezna[®] (vonoprazan tablets) is an acid-suppressive agent approved for select acid-related indications in adults. Although Voquezna is classified as a potassium-competitive acid blocker, both potassium-competitive acid blockers and PPIs suppress gastric acid secretion through inhibition of the H⁺/K⁺-ATPase (proton pump). Current US clinical practice guidelines continue to support PPIs as the primary treatment option for most acid-related gastrointestinal disorders.²¹

Pediatrics

Esomeprazole magnesium capsules, esomeprazole oral suspension, omeprazole capsules, and Prilosec oral suspension are indicated for use in children ≥ 1 month old.⁵⁻⁷ Aciphex Sprinkle, lansoprazole capsules, and lansoprazole orally disintegrating tablets (ODT) are indicated for use in children ≥ 1 year of age.^{8,9} Pantoprazole products are indicated for patients ≥ 5 years of age.¹⁰ Rabeprazole tablets are not recommended for use in pediatric patients < 12 years of age because the lowest available tablet strength (20

mg) exceeds the recommended dose for these patients.¹¹ Dexilant is indicated in patients ≥ 12 years of age.¹³ Omeprazole/sodium bicarbonate capsules and oral suspension, Konvomep, Voquezna, and the OTC PPI products lack pediatric indications.^{12,13,19,20} The labeling for esomeprazole delayed-release granules for oral suspension (Nexium) and Prilosec delayed-release granules for oral suspension permit administration with French size 6 or larger tubes via nasogastric or gastric tubes which is the smallest size of the available PPIs.

POLICY STATEMENT

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Step Therapy criteria below. All approvals are provided for 1 year in duration.

Automation: A patient with a history of one Step 1 Product or Nexium 24HR (OTC) within the 130-day look-back period is excluded from Step Therapy.

Note: Automation is NOT in place for Step 2 Konvomep, Zegerid, Zegerid OTC, and generic omeprazole/sodium bicarbonate products (Rx/OTC).

Step 1: Generic esomeprazole delayed-release capsules (Rx and OTC), generic lansoprazole delayed-release capsules (Rx and OTC), generic omeprazole delayed-release capsules and tablets (Rx and OTC), generic pantoprazole delayed-release tablets, generic rabeprazole delayed-release tablets

Step 2: Aciphex, Aciphex Sprinkle, Dexilant, generic dexlansoprazole capsules, Konvomep, Nexium (Rx and OTC), generic esomeprazole delayed-release granules for oral suspension, Prevacid (Rx and OTC), Prevacid SoluTab, generic lansoprazole orally disintegrating tablets, Prilosec (Rx and OTC), Prilosec granules for oral suspension, Protonix, generic pantoprazole granules for oral suspension, Voquezna, Zegerid (Rx and OTC), generic omeprazole/sodium bicarbonate capsules (Rx and OTC)

CRITERIA

1. If the patient is < 1 year of age, approve generic esomeprazole delayed-release granules for oral suspension (packets) or Prilosec delayed-release granules for oral suspension (packets).
 2. If the patient is < 11 years of age and requires administration via a feeding tube, approve generic esomeprazole delayed-release granules for oral suspension (packets) or Prilosec delayed-release granules for oral suspension (packets).
 3. If the patient requires administration via a feeding tube and has tried a Step 1 Product under the supervision of a physician, approve a Step 2 Product (except Konvomep, Zegerid, Zegerid OTC, and generic omeprazole/sodium bicarbonate capsules [Rx and OTC]).
Note: A trial of a generic OTC proton pump inhibitor would qualify.
 4. If the patient has tried a Step 1 Product under the supervision of a physician, approve a Step 2 Product (except Konvomep, Zegerid, Zegerid OTC, and generic omeprazole/sodium bicarbonate capsules [Rx and OTC]).
Note: A trial of a generic OTC proton pump inhibitor (PPI) would qualify, if OTC PPIs are a covered benefit and the patient was using it for at least 14 days.
-

5. If the requested product is Konvomep, Zegerid, Zegerid OTC, or generic omeprazole/sodium bicarbonate capsules (Rx or OTC), approve if the patient has tried five generic proton pump inhibitors (i.e., esomeprazole [Rx or OTC], lansoprazole [Rx or OTC], omeprazole [Rx or OTC], pantoprazole, AND rabeprazole).

Note: A trial of a generic OTC PPI would qualify, if OTC PPIs are a covered benefit and the patient was using it for at least 14 days.

6. No other exceptions are recommended.

REFERENCES

1. Prilosec OTC[®] delayed-release tablets [prescribing information]. Cincinnati, OH: Procter and Gamble; October 2024.
 2. Prevacid[®] 24HR delayed-release capsules [prescribing information]. Allegan, MI: Perrigo; August 2023.
 3. Zegerid OTC[®] capsules [prescribing information]. Whippany, NJ: Bayer; November 2023.
 4. Nexium[®] 24HR delayed-release capsules and tablets [prescribing information]. Warren, NJ: GlaxoSmithKline; June 2022.
 5. Omeprazole delayed-release capsules [prescribing information]. North Wales, PA: Teva; November 2020.
 6. Prilosec[®] delayed-release suspension [prescribing information]. Zug, Switzerland: Covis; November 2020.
 7. Nexium[®] delayed-release capsules and oral suspension [prescribing information]. Wilmington, DE: AstraZeneca; July 2023.
 8. Prevacid[®] delayed-release capsules and orally disintegrating tablets [prescribing information]. Deerfield, IL: Takeda; March 2022.
 9. Aciphex[®] Sprinkle[™] delayed-release capsules [prescribing information]. Woodcliff Lake, NJ: Eisai; December 2020.
 10. Protonix[®] delayed-release tablets and oral suspension [prescribing information]. Philadelphia, PA: Wyeth; March 2022.
 11. Aciphex[®] delayed-release tablets [prescribing information]. Woodcliff Lake, NJ: Eisai; November 2020.
 12. Zegerid[®] capsules [prescribing information]. Bridgewater, NJ: Salix; March 2022.
 13. Dexilant[™] delayed-release capsules [prescribing information]. Deerfield, IL: Takeda; March 2022.
 14. Esomeprazole strontium delayed-release capsules [prescribing information]. Glasgow, KY: Amneal; January 2021.
 15. Moayyedi P, Lacy BE, Andrews CN, et al. ACG and CAG Clinical Guideline: Management of Dyspepsia. *Am J Gastroenterol.* 2017; 112(7):988-1013.
 16. Katz PO, Dunbar KB, Schnoll-Sussman FH, et al. ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease. *Am J Gastroenterol.* 2022;117(1):27-56.
 17. Rosen R, Vandenplas Y, Singendonk M, et al. Pediatric Gastroesophageal Reflux Clinical Practice Guidelines: Joint Recommendations of the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition and the European Society for Pediatric Gastroenterology, Hepatology, and Nutrition. *J Pediatr Gastroenterol Nutr.* 2018; 66(3):516-554.
 18. Shaheen NJ, Falk GW, Iyer PG, et al. Diagnosis and Management of Barrett's Esophagus: An Updated ACG Guideline. *Am J Gastroenterol.* 2022; 117(4):559-587.
 19. Konvomep oral suspension [prescribing information]. Woburn, MA. Azurity; August 2023.
 20. Voquezna[®] tablets [prescribing information]. Buffalo Grove, IL: Phathom; July 2024.
 21. Patel A, Laine L, Moayyedi P, Wu J. AGA Clinical Practice Update on Integrating Potassium-Competitive Acid Blockers Into Clinical Practice: Expert Review. *Gastroenterology.* 2024;167(6):1228-1238.
-

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/04/2024
Early Annual Revision	Step 2 Products: Generic esomeprazole strontium delayed-release capsules was removed (obsolete). Criteria: For the existing exception in a patient < 1 year of age, brand Nexium delayed-release granules for oral suspension (packets) was removed as an approval option. A new exception for a patient < 11 years of age <u>and</u> requiring administration via a feeding tube to approve generic esomeprazole delayed-release granules for oral suspension (packets) or Prilosec delayed-release granules for oral suspension (packets) was added.	05/21/2025
Early Annual Revision	No criteria changes.	04/15/2026
