STEP THERAPY POLICY

POLICY: Proton Pump Inhibitors Step Therapy Policy

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

REVIEW DATE: 12/07/2022

OVERVIEW

Although proton pump inhibitors (PPIs) vary in their specific FDA-approved indications, all PPIs are used for the treatment/management of acid-related diseases, including duodenal and gastric ulcerations, gastroesophageal reflux disease, Zollinger-Ellison syndrome, and *Helicobacter pylori* infections.[1-14] 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.[15-19] PPIs are the most potent acid reducing agents available and 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 also shown the PPIs to be similar in efficacy and safety.

Esomeprazole capsules, Nexium 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 only 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] Omeprazole/sodium bicarbonate capsules and oral suspension, Dexilant, and the OTC PPI products lack pediatric indications.[12,13]

Capsules of omeprazole, esomeprazole, lansoprazole, Aciphex Sprinkle, and Dexilant may be opened for easier administration to patients who cannot take capsules, such as those with gastric tubes or children.[5,7-9,13] Additionally, granules/pellets from their respective capsule formulations may be added to one tablespoonful of applesauce prior to administration.

Omeprazole products, esomeprazole products, lansoprazole products, Protonix oral suspension, and omeprazole/sodium bicarbonate oral suspension labeling describe use for administration via a nasogastric or gastric tube.[5-8,10,12] Omeprazole/sodium bicarbonate capsules are to be swallowed intact with water, they are not be opened and sprinkled on food.[12]

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 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 Zegerid, Zegerid OTC, and generic omeprazole/sodium bicarbonate products (Rx/OTC).

Step 1: Generic esomeprazole delayed-release capsules, 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, generic esomeprazole delayed-release granules for oral suspension, esomeprazole strontium delayed-release capsules, generic lansoprazole orally disintegrating tablets, Nexium, Prevacid, Prevacid 24HR, Prevacid SoluTab, Prilosec (Rx and OTC), Protonix, generic pantoprazole granules, Zegerid, Zegerid OTC, generic omeprazole/sodium bicarbonate capsules (Rx and OTC)

CRITERIA

1. 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 Zegerid, Zegerid OTC, and generic omeprazole/sodium bicarbonate capsules [Rx and OTC]).
Note: A trial of a generic OTC PPI would qualify.

2. If the patient has tried a Step 1 Product under the supervision of a physician, approve a Step 2 Product (except Zegerid, Zegerid OTC, and generic omeprazole/sodium bicarbonate capsules [Rx and OTC]).
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.

3. If the patient is < 1 year of age, approve generic esomeprazole delayed-release granules for oral suspension (packets), Nexium delayed-release granules for oral suspension (packets), or Prilosec delayed-release granules for oral suspension (packets).

4. If the requested product is Zegerid, Zegerid OTC, or generic omeprazole/sodium bicarbonate capsules (Rx or OTC), approve if the patient has tried five generic PPIs (i.e., esomeprazole, 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.

5. No other exceptions are recommended.

REFERENCES

1. Prilosec OTC® delayed-release tablets [prescribing information]. Cincinnati, OH: Procter and Gamble; October 2022.
2. Prevacid® 24HR delayed-release capsules [prescribing information]. Allegan, MI: Perrigo; June 2022.
3. Zegerid OTC® capsules [prescribing information]. Whippany, NJ: Bayer; December 2021.
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 [prescribing information]. Wilmington, DE: AstraZeneca; August 2021.
8. Prevacid® delayed-release capsules and orally disintegrating tablets [prescribing information]. Deerfield, IL: Takeda; November 2020.
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; November 2020.
11. Aciphex® delayed-release tablets [prescribing information]. Woodcliff Lake, NJ: Eisai, November 2020.
12. Zegerid® capsules [prescribing information]. Bridgewater, NJ: Salix; November 2020.
13. Dexilant™ delayed-release capsules [prescribing information]. Deerfield, IL: Takeda; October 2020.
14. Esomeprazole strontium delayed-release capsules [prescribing information]. Glasgow, KY: Amneal; January 2021.
15. Katz P, Dunbar K, Schnoll-Sussman F, et al. ACG clinical guideline for the diagnosis and management of gastroesophageal reflux disease. *Am J Gastroenterol*. 2022;117(1):27-56.
16. Moayyedi P, Lacy BE, Andrews CN, et al. ACG and CAG Clinical Guideline: Management of Dyspepsia. *Am J Gastroenterol.* 2017;112(7):988-1013.
17. 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.
18. 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.
19. 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.