



Effective Date..... 2/1/2023
 Next Review Date..... 2/1/2024

Step Therapy Proton Pump Inhibitors

Table of Contents

National Formulary Medical Necessity 1
 Conditions Not Covered.....2
 Background.....2
 References3
 Revision History.....4

Product Identifier(s)

Effective 1/1/23 to 3/21/23: 110489
Effective 3/22/23: 14530

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

National Formulary Medical Necessity

Drugs Affected

Proton Pump Inhibitor	Product
Dexlansoprazole	Dexilant™ delayed-release capsules, generic
Esomeprazole	Nexium® delayed-release capsules, generic
	Nexium® delayed release granules for oral suspension, generic
	Esomeprazole strontium delayed-release capsules
Lansoprazole	Prevacid® delayed-release capsules, generic
	Prevacid® SoluTab™ delayed-release orally disintegrating tablets, generic
	Prevacid® 24HR delayed-release capsules, generic
Omeprazole	Omeprazole delayed-release capsules, generic only
	Prilosec® delayed release granules for oral suspension
	Prilosec OTC® delayed-release tablets, generic
Omeprazole/ sodium bicarbonate	Zegerid® capsules, generic
	Zegerid® powder for oral suspension, generic
	Zegerid OTC® capsules, generic

Pantoprazole	Protonix® delayed-release tablets, generic
	Protonix® delayed release oral suspension, generic
Rabeprazole	Aciphex® delayed-release tablets, generic
	Aciphex® Sprinkle™ delayed-release capsules

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.

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)

Cigna covers Step 2 agents as medically necessary when the following criteria are met:

1. If the individual 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 individual 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 individual was using it for at least 14 days.
3. If the individual 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 individual 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 individual was using it for at least 14 days.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

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 \geq 1 month old.⁵⁻⁷ Aciphex Sprinkle, lansoprazole capsules, and lansoprazole orally disintegrating tablets (ODT) are indicated for use in children \geq 1 year of age.^{8,9} Pantoprazole products are only indicated for patients \geq 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

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.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	No criteria changes.	12/07/2022

"Cigna Companies" refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc. and HMO or service company subsidiaries of Cigna Health Corporation. The Cigna name, logo, and other Cigna marks are owned by Cigna Intellectual Property, Inc. © 2023 Cigna.