



## STEP THERAPY POLICY

**POLICY:** Proton Pump Inhibitors Step Therapy Policy

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

OTC – Over-the-counter.

**REVIEW DATE:** 05/21/2025

### 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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see

"Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. 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.

## Cigna National Formulary Coverage:

### 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.<sup>1-14,19,20</sup> Several PPIs are available over-the-counter (OTC).<sup>1-4</sup> 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.<sup>15-18</sup> 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.

### Pediatrics

Esomeprazole magnesium capsules, esomeprazole oral suspension, omeprazole capsules, and Prilosec oral suspension are indicated for use in children  $\geq 1$  month old.<sup>5-7</sup> Aciphex Sprinkle, lansoprazole capsules, and lansoprazole orally disintegrating tablets (ODT) are indicated for use in children  $\geq 1$  year of age.<sup>8,9</sup> Pantoprazole products are only indicated for patients  $\geq 5$  years of age.<sup>10</sup> 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.<sup>11</sup> Dexilant is indicated in patients  $\geq 12$  years of age.<sup>13</sup> Omeprazole/sodium bicarbonate capsules and oral suspension, Konvomep, Voquezna, and the OTC PPI products lack pediatric indications.<sup>12,13,19,20</sup> 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.

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 dextlansoprazole 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)

***Proton Pump Inhibitors Step Therapy Policy product(s) is(are) covered as medically necessary when the following step therapy criteria is(are) met. Any other exception is considered not medically necessary.***

#### **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 and 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.

## REFERENCES

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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.
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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.
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19. Konvomep oral suspension [prescribing information]. Woburn, MA. Azurity; August 2023.
20. Voquezna® tablets [prescribing information]. Buffalo Grove, IL: Phathom; July 2024.

## HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/13/2023
Selected Revision	<b>Voquezna:</b> Voquezna tablet was added to the Policy to Step 2.	01/10/2024
Annual Revision	No criteria changes.	12/04/2024
Early Annual Revision	<b>Step 2 Products:</b> Generic esomeprazole strontium delayed-release capsules was removed (obsolete).	05/21/2025

	<p><b>Criteria:</b> For the existing exception in a patient &lt; 1 year of age, brand Nexium delayed-release granules for oral suspension (packets) was removed as an approval option.</p> <p>A new exception for a patient &lt; 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.</p>	
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