

STEP THERAPY POLICY

POLICY: Proton Pump Inhibitors Step Therapy Policy

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

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OVERVIEW

Proton pump inhibitors (PPIs) [i.e., dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole, and rabeprazole] are commonly used antisecretory agents that are highly effective at suppressing gastric acid and subsequently treating associated conditions, including gastroesophageal reflux disease (GERD).^{1,2} Although the PPIs vary in their specific FDA-approved indications,³⁻¹⁶ all of the PPIs have demonstrated the ability to control GERD symptoms and to heal esophagitis when used at prescription doses.¹ Most comparative studies between PPIs to date have demonstrated comparable efficacies for the treatment/management of acid-related diseases, including duodenal and gastric ulcerations, GERD, Zollinger-Ellison syndrome, and *Helicobacter pylori* infections. 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 safety.

Omeprazole is available generically and over-the-counter (OTC). Omeprazole OTC is prescription strength (20 mg).³ Lansoprazole is also available generically and OTC. Lansoprazole OTC is available as 15 mg capsules.⁴ Zegerid capsules are available generically and OTC; the OTC product contains omeprazole 20 mg and sodium bicarbonate 1100 mg.⁵ Nexium is available generically and OTC. Nexium® 24HR (esomeprazole magnesium 22.3 mg delayed-release capsules) is the OTC product and is equivalent to 20 mg of esomeprazole.⁶ The OTC products are indicated for the short-term (14 days) treatment of heartburn. 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.³⁻⁶

Esomeprazole delayed-release (DR) capsules, Nexium oral suspension, omeprazole DR capsules, and Prilosec oral suspension are indicated for use in children \geq 1 month old.^{7,12} Aciphex Sprinkle, lansoprazole DR capsules, and lansoprazole orally disintegrating tablets (ODT) [Prevacid SoluTab] are indicated for use

in children ≥ 1 year of age.^{8,11} Pantoprazole DR tablets and Protonix oral suspension are only indicated for patients ≥ 5 years of age.⁹ Rabeprazole DR 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.¹⁰ Omeprazole/sodium bicarbonate capsules and oral suspension, Dexilant, and the OTC PPI products lack pediatric indications.^{13,14}

Omeprazole capsules, esomeprazole capsules, lansoprazole capsules, Aciphex Sprinkle, and Dexilant capsules may be opened for easier administration to patients who cannot take capsules, such as those with gastric tubes or children.^{7,8,11,12,14} Omeprazole, esomeprazole, lansoprazole, Aciphex Sprinkle, and Dexilant granules/pellets from their respective capsule formulations may be added to one tablespoonful of applesauce prior to administration. Studies indicate that non-encapsulated, intact omeprazole granules are also effective when taken with orange juice, water, or aspirin-free Alka-Seltzer[®] (calcium carbonate) antacid tablets.¹⁷⁻¹⁹ Administration of the enteric-coated granules in this way does not appear to affect the bioavailability of either agent to a clinically significant degree.

Omeprazole capsules, Prilosec oral suspension, esomeprazole capsules, Nexium oral suspension, lansoprazole capsules, lansoprazole ODT [Prevacid SoluTab], Protonix oral suspension, and omeprazole/sodium bicarbonate oral suspension labeling describe use for administration via a nasogastric or gastric tube.^{7-9,12-14} Omeprazole/sodium bicarbonate capsules are to be swallowed intact with water, they are not to be opened and sprinkled on food.¹³

Prophylactic use of PPIs has been shown to reduce marginal ulceration after gastric bypass surgery.²⁰ Capsule formulations of PPIs have been opened and used successfully in patients post-bariatric surgery to treat marginal ulceration following surgery.²¹

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 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 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 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.
2. 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).
3. 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.
4. No other exceptions are recommended.

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