

STEP THERAPY POLICY

POLICY: Proton Pump Inhibitors Step Therapy Policy

OTC – Over-the-counter.

REVIEW DATE: 12/13/2023; selected revision 01/10/2024

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, including 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.

Pediatrics

Esomeprazole magnesium 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 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}

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 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, generic esomeprazole delayed-release granules for oral suspension, esomeprazole strontium delayed-release capsules, generic lansoprazole orally disintegrating tablets, Konvomep, Nexium, Prevacid, Prevacid 24HR, Prevacid SoluTab, Prilosec (Rx and OTC), Protonix, generic pantoprazole

granules, Voquezna, 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 Konvomep, 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 Konvomep, 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 Konvomep, Zegerid, Zegerid OTC, or generic omeprazole/sodium bicarbonate capsules (Rx or OTC), approve if the patient has tried five generic PPIs (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.
5. No other exceptions are recommended.

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Proton Pump Inhibitors Step Therapy Policy
Page 3

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