OVERVIEW
Proton pump inhibitors (PPIs) [i.e., esomeprazole, dexlansoprazole, 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). Omeprazole is available generically and over-the-counter (OTC). Omeprazole OTC is prescription strength (20 mg). Lansoprazole is also available generically and OTC. Lansoprazole OTC is available as 15 mg capsules. Zegerid capsules are available generically and OTC; the OTC product contains omeprazole 20 mg and sodium bicarbonate 1100 mg. Nexium® 24HR (esomeprazole magnesium 22.3 mg delayed-release capsules) is available OTC and is equivalent to 20 mg of esomeprazole base. The OTC products are indicated for the short-term (14 days) treatment of heartburn. Patients should not take the OTC products for more than 14 days or more often than every 4 months unless under the supervision of a physician.

Although the PPIs vary in their specific Food and Drug Administration (FDA)-approved indications, all of the PPIs have demonstrated the ability to control GERD symptoms and to heal esophagitis when used at prescription doses. Most comparative studies between PPIs to date have demonstrated comparable efficacies for acid-related diseases, including duodenal and gastric ulcerations, GERD, Zollinger-Ellison syndrome, and H. pylori eradication therapies. 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 safety and efficacy.

Currently, esomeprazole DR capsules, Nexium oral suspension, omeprazole DR capsules, and Prilosec oral suspension are indicated for use in children ≥ 1 month old. Rabeprazole DR tablets, Aciphex Sprinkle, lansoprazole DR capsules, and Prevacid SoluTab are indicated for use in children ≥ 1 year of age. Pantoprazole DR tablets and Protonix oral suspension are only indicated for patients ≥ 5 years of age. Zegerid oral suspension, omeprazole/sodium bicarbonate capsules, Dexilant, and the OTC PPI products lack a pediatric indication.

Omeprazole capsules, Prilosec oral suspension, esomeprazole capsules, Nexium oral suspension, lansoprazole (capsules), Prevacid SoluTab, Dexilant SoluTab, Protonix oral suspension, and Zegerid oral suspension labeling describe use for administration via a nasogastric or gastric tube. Lansoprazole capsules (granules) and Zegerid capsules are NOT to be administered through enteral tubes according to their prescribing information.

POLICY STATEMENT
A step therapy program has been developed to encourage the use of one generic Step 1 product prior to the use of a Step 2 product or Step 3 products. A trial of a Step 1 and Step 2 product is required for a Step 3 product. If the step therapy rule is not met for a Step 2 or Step 3 agent at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 1 year in duration. Please note that not all plans cover over-the-counter drugs, please check corresponding benefit materials for additional information.
**Automation:** Patients with a history of one Step 1 and Step 2 drug within the 130-day look-back period are excluded from step therapy. **Note:** Automation is NOT in place for Step 3 Zegerid, Zegerid OTC, and generic omeprazole/sodium bicarbonate products (Rx/OTC).

- **Step 1:** generic lansoprazole delayed-release capsules (Rx and OTC), generic omeprazole delayed-release capsules and tablets (Rx and OTC), generic pantoprazole delayed-release tablets
- **Step 2:** generic esomeprazole delayed-release capsules, generic rabeprazole delayed-release tablets
- **Step 3:** Aciphex, Aciphex Sprinkle, Dexilant, esomeprazole strontium delayed-release capsules, Nexium, Prevacid, Prevacid 24HR, Prevacid SoluTab, Prilosec (Rx and OTC), Protonix, Zegerid, Zegerid OTC, generic omeprazole/sodium bicarbonate capsules (Rx and OTC) and packets

**Criteria**

1. If the patient has tried a Step 1 PPI under the supervision of a physician, then authorization may be given for a Step 2 PPI 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 has tried a Step 1 PPI and Step 2 PPI under the supervision of a physician, then authorization may be given for a Step 3 PPI 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, then authorization may be given for Nexium oral suspension (packets) or Prilosec oral suspension (packets). Both Nexium and Prilosec are indicated down to 1 month of age.

4. If the requested drug is Zegerid, Zegerid OTC, or generic omeprazole/sodium bicarbonate (Rx or OTC), authorization may be given 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.

**Approval Duration**

Approval = 365 days (1 year)

**References**

- Prevacid® [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc; October 2016.