**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.

**Preferred Medications (step 1)**
- Lansoprazole delayed release capsules (generic, Rx and OTC)
- Lansoprazole orally disintegrating tablets (generic)
- Omeprazole delayed release capsules and tablets (generic, Rx and OTC)
- Pantoprazole delayed release tablets (generic)

**Non-Preferred Medications (step 2)**
- Esomeprazole delayed release capsules (generic)
- Rabeprazole delayed release tablets (generic)

**Non-Preferred Medications (step 3)**
- Aciphex, Aciphex Sprinkle
- Dexilant
- Esomeprazole strontium delayed release capsules
- Nexium
- Omeprazole/sodium bicarbonate capsules and packets (generic, Rx and OTC)
- Prevacid, Prevacid 24HR, Prevacid SoluTab
- Prilosec (Rx and OTC)
- Protonix
- Zegerid, Zegerid OTC

**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).
Preferred Step Therapy 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.

Initial Approval/ Extended Approval.
A) Initial Approval: 1 year
B) Extended Approval: 1 year

Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; OR

B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; OR

C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:

1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
2. When 130 days of the patient’s prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

**Documentation Required:** When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

**Approval Duration:** All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

**Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

**REFERENCES**