Proton Pump Inhibitors

Description

Aciphex (rabeprazole), Dexilant, Dexilant Solutabs (dexlansoprazole), Esomeprazole Strontium, First-Lansoprazole suspension, Nexium (esomeprazole magnesium), Prevacid (lansoprazole), Protonix (pantoprazole), Zegerid* (omeprazole / sodium bicarbonate)

*Prior authorization for the brand formulation applies only to formulary exceptions due to being a non-covered medication.

Background

Omeprazole, esomeprazole, lansoprazole, dexlansoprazole, rabeprazole, and pantoprazole belong to a class of medications called proton pump inhibitors (PPI) that are used to decrease the amount of acid produced in the stomach. This reduction helps aid in the healing of acid-related damage to the lining of the esophagus caused by acid reflux. They also work to aid in the healing of ulcers (1-10).

Regulatory Status

The individual agent proton pump inhibitor products addressed by this policy are FDA-approved for use in one or more of the following conditions:

- Duodenal ulcer
- Gastric ulcer
- Gastroesophageal reflux disease (GERD)
• Erosive esophagitis (EE)
• *Helicobacter pylori* eradication to reduce the risk of duodenal ulcer recurrence
• Pathological hypersecretory conditions, including Zollinger-Ellison Syndrome
• Relief of heartburn

Zegerid (omeprazole / sodium bicarbonate); FDA-approved indications:
• Short-term treatment of active duodenal ulcer
• Short-term treatment of active benign gastric ulcer
• Treatment of gastroesophageal reflux disease (GERD)
• Maintenance of healing of erosive esophagitis
• Reduction of risk of upper GI bleeding in critically ill patients (9)

The safety and effectiveness of Zegerid Powder for Oral Suspension and Capsules in pediatric patients (<18 years of age) have not been established (10).

Proton Pump therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine. The risk of fracture was increased in patients who received high-dose, defined as multiple daily doses, and long-term PPI therapy (a year or longer). Patients should use the lowest dose and shortest duration of PPI therapy appropriate to the condition being treated (1-10).

Proton pump inhibitor therapy may be associated with an increased risk of *Clostridium difficile* associated diarrhea (CDAD) and hypomagnesemia. Low magnesium levels may occur in patients treated with PPIs for at least three months, in most cases after a year of therapy. Serious adverse events include tetany, arrhythmias, and seizures. Discontinuation of the PPI may be required. For patients expected to be on prolonged treatment or who take PPIs with medications such as digoxin or drugs that cause hypomagnesemia, healthcare professionals may consider monitoring magnesium levels prior to initiation of PPI treatment and periodically (1-10).

Related policies

**Policy**

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.
Proton Pump Inhibitors are **medically necessary** for the indications listed below.

Proton Pump Inhibitors may be considered **investigational** in all other patients.

**Prior-Approval Requirements**

**Diagnoses**

Patient must have **ONE** of the following:

1. **Esophagitis**
   a. Barrett’s*
   b. Erosive*
   c. GERD (includes laryngeal and pharyngeal)
   d. Sclerodermal (part of CREST syndrome) *
2. **Gastropathy**
   a. Medication related
   b. NSAID related*
3. **GI Bleed**
4. **H.Pylori** – currently undergoing treatment and in combination with antibiotic therapy
5. **Hypersecretory disease** such as Zollinger-Ellison Syndrome*
6. **Ulcer** – duodenal, gastric or peptic

**OR**

1. **ANY** GI related diagnosis
   "AND ONE" of the following:
   a. Failure of therapy with one H2 blocker
   b. Failure of therapy with one of the other PPI
   c. Prescriber is **ONE** of the following
      i. Gastroenterologist
      ii. Ear, Nose and Throat Specialist
      iii. Pulmonologist

**Prior – Approval Renewal Requirements**

Same as above
Policy Guidelines

Pre - PA Allowance

Quantity  
90 dosage units  
900 ml of First-lansoprazole (3 mg/ml) suspension

Duration  
365 days

Prior - Approval Limits

Quantity  
up to 3 dosage units per day  
2,700 ml of First-lansoprazole (3 mg/ml) suspension every 90 days

Duration  
1 year

* These diagnoses may be approved for 2 years

Prior – Approval Renewal Limits

Same as above

Rationale

Summary
Proton pump inhibitors are the potent suppressors of gastric acid secretion. In typical doses, they diminish the daily production of acid by 80-95%. PPIs are generally safe, although caution should be used in patients being treated concurrently with anticoagulants, tacrolimus, theophylline, and methotrexate. Proton Pump therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine. Proton pump inhibitor therapy may be associated with an increased risk of Clostridium difficile-associated diarrhea (CDAD) and hypomagnesemia (1-10).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of the proton pump inhibitors while maintaining optimal therapeutic outcomes.

References

### Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>September 2004</td>
<td>In order to be consistent with current benefit design, Zegerid was included in the overall current upfront PPI 90 quantity allowance per year.</td>
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<tr>
<td>January 2009</td>
<td>Removal of Prilosec/omeprazole from the FEP PA Program (all strengths). Prescription Prilosec/omeprazole 20mg will be covered by the plan.</td>
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<tr>
<td>February 2009</td>
<td>Addition of Kapidex to PA process.</td>
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<tr>
<td>March 2009</td>
<td>Removal of Prevacid Naprapac due to discontinuation by the manufacturer in December of 2008.</td>
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<tr>
<td>March 2010</td>
<td>Kapidex name change to Dexilant due to dispensing errors.</td>
</tr>
<tr>
<td>June 2010</td>
<td>Line extension, addition of Vimovo, a FDA approved fixed-dose combination of delayed-release enteric-coated naproxen, a non-steroidal anti-inflammatory drug (NSAID), and immediate-release esomeprazole, a stomach acid-reducing proton pump inhibitor (PPI), approved for the relief of signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis and to decrease the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers.</td>
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<tr>
<td>November 2011</td>
<td>Addition of short bowel syndrome as an approvable diagnosis with 2-year approval.</td>
</tr>
<tr>
<td>December 2012</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>March 2013</td>
<td>Annual editorial review and reference update</td>
</tr>
<tr>
<td>April 2013</td>
<td>Removal of Vimovo into separate criteria.</td>
</tr>
<tr>
<td>September 2013</td>
<td>Line-extension First-Lansoprazole</td>
</tr>
<tr>
<td>June 2014</td>
<td>Annual editorial review and reference update.</td>
</tr>
<tr>
<td>March 2015</td>
<td>Annual editorial review and reference update. Removal of non supported diagnoses</td>
</tr>
<tr>
<td>March 2016</td>
<td>Addition of Dexilant Solutabs.</td>
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</table>
Policy number change from 5.09.01 to 5.50.01

June 2016       Annual review
September 2016  Annual editorial review and reference update.
                Esomeprazole Strontium removed due to product discontinuation.
March 2017      Annual editorial review and reference update
February 2018   Esomeprazole Strontium products currently available on the market, added
                back into criteria
March 2018      Annual editorial review and reference update
June 2018       Annual review and reference update
March 2019      Annual review and reference update
September 2019  Changed approval duration from lifetime to 2 years for Barrett’s, Erosive,
                and Scleroderma esophagitis; and hypersecretory disease (Zollinger-
                Ellison Syndrome)
December 2019   Annual review. Moved Zegerid to MFE with PA only. Revised First-
                Lansoprazole PA quantity from 10,800 mL/365 to 2,700 mL/90

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective January 1, 2020.