Proton Pump Inhibitors

**BENEFIT APPLICATION**

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

**DESCRIPTION**

The intent of the Proton Pump Inhibitors (PPIs) Quantity Limit criteria is to encourage appropriate prescribing quantities as recommended by FDA-approved product labeling. The intent of the proton pump inhibitors (PPIs) step therapy is to ensure appropriate selection of patients for therapy based on product labeling, clinical guidelines and clinical studies. The criteria will encourage the use of the more cost effective generic PPIs prior to the use of a brand or more costly generic when clinically appropriate while maintaining optimal therapeutic outcomes.

Aciphex (rabeprazole), Dexilant (dextlanosoprazole), Esomeprazole Strontium, Nexium (esomeprazole), Prevacid (lansoprazole), Prilosec (omeprazole), and Protonix (pantoprazole) are all PPIs that suppress gastric acid secretion by specific inhibition of the H+/K+ ATPase enzyme system at the secretory surface of the gastric parietal cell. They reduce gastric acidity by acting specifically on the proton pump which is the final step in acid production.

**POLICY**

I. Prior authorization for Omeprazole 10mg & 40mg (generic Prilosec), Lansoprazole (generic Prevacid), Pantoprazole (generic Protonix), or rabeprazole (generic Aciphex) is not required for quantities less than or equal to 2 dosage units per day. Additional quantities may be considered **medically necessary** if the patient has a diagnosis of Barrett’s esophagus confirmed by biopsy or Zollinger-Ellison Syndrome confirmed by a diagnostic test.

II. Prior authorization for Omeprazole 20 mg (generic Prilosec) is not required for quantities less than or equal to 4 dosage units per day. Additional quantities may be considered **medically necessary** if the patient has a diagnosis of Barrett’s esophagus confirmed by biopsy or Zollinger-Ellison Syndrome confirmed by a diagnostic test.

III. Dexilant, Esomeprazole strontium, and brand or generic Nexium may be considered **medically necessary** if the following criteria is met:

- Patient must have tried and failed a therapeutic trial of at least **two** preferred PPIs (Prilosec (omeprazole), Prevacid (lansoprazole), Protonix (pantoprazole), and/or Aciphex (rabeprazole) unless the patient is currently receiving a positive therapeutic outcome on the requested
medications through health insurance (excludes obtainment as samples or via manufacturer’s patient assistance programs).
- The requested amount does not exceed 2 dosage units per day for Esomeprazole strontium and Nexium or 1 dosage unit per day for Dexilant unless the patient has a diagnosis of Barrett’s esophagus confirmed by biopsy or Zollinger-Ellison Syndrome confirmed by a diagnostic test.

**Approval will be 12 months**

IV. **Aciphex Sprinkles** may be considered **medically necessary** if the following criteria are met:

- Patient must be unable to swallow an intact capsule or tablet
- Patient must have tried and failed a therapeutic trial of BOTH lansoprazole AND omeprazole when the capsules are opened and the contents are sprinkled on soft food or liquid without crushing or chewing the capsules or the granules unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer’s patient assistance programs).
- The requested amount does not exceed 1 dosage unit per day unless the patient has a diagnosis of Barrett’s esophagus confirmed by biopsy or Zollinger-Ellison Syndrome confirmed by a diagnostic test.

**Approval will be 12 months**

V. **Prilosec packets, Protonix Packets, and Nexium Packets** may be considered **medically necessary** if the following criteria are met:

- Patient must be unable to swallow an intact capsule or tablet
- Patient must have a contraindication to or tried and failed a therapeutic trial of BOTH lansoprazole AND omeprazole when the capsules are opened and the contents are sprinkled on soft food or liquid without crushing or chewing the capsules or the granules unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer’s patient assistance programs).
- The requested amount does not exceed 2 dosage units per day unless the patient has a diagnosis of Barrett’s esophagus confirmed by biopsy or Zollinger-Ellison Syndrome confirmed by a diagnostic test.

**Approval will be 12 months**

VI. **Prevacid Solutabs** may be considered **medically necessary** if the following criteria are met:

- Patient must be unable to swallow an intact capsule or tablet
- Patient must have a contraindication to or tried and failed a therapeutic trial of BOTH lansoprazole AND omeprazole when the capsules are opened and the contents are sprinkled on soft food or liquid without crushing or chewing the capsules or the granules unless the patient is currently receiving a positive therapeutic outcome on the requested medications through health insurance (excludes obtainment as samples or via manufacturer’s patient assistance programs); OR is unable to swallow capsules related to a medical condition or due to a nasogastric or gastrostomy tube.
- The requested amount does not exceed 2 dosage units per day unless the patient has a diagnosis of Barrett’s esophagus confirmed by biopsy or Zollinger-Ellison Syndrome confirmed by a diagnostic test.
Approval will be 12 months

VII. Medications included in this policy are considered not medically necessary for patients who do not meet the criteria set forth above.

Quantity limits apply:

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Standard Benefit Allowance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aciphex (rabeprazole)</td>
<td>60 tablets per 30 days</td>
</tr>
<tr>
<td>Aciphex Sprinkles (rabeprazole)</td>
<td>30 capsules per 30 days</td>
</tr>
<tr>
<td>Dexilant (dexlansoprazole)</td>
<td>30 capsules per 30 days</td>
</tr>
<tr>
<td>Esomeprazole Strontium (esomeprazole strontium)</td>
<td>60 capsules per 30 days</td>
</tr>
<tr>
<td>Nexium (esomeprazole)</td>
<td>60 capsules/packets per 30 days</td>
</tr>
<tr>
<td>Prevacid (lansoprazole)</td>
<td>60 capsules/solutabs per 30 days</td>
</tr>
<tr>
<td>Prilosec (omeprazole)</td>
<td>60 capsules/packets per 30 days</td>
</tr>
<tr>
<td>Protonix (pantoprazole)</td>
<td>60 capsules/packets per 30 days</td>
</tr>
</tbody>
</table>

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT® codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

- Code(s), if applicable

REFERENCES

- Esomeprazole Strontium [package insert]. Glasgow, KY: Amneal Pharmaceuticals; August 2013

POLICY HISTORY

Policy #: 05.01.69
Policy Creation: April 2006
Reviewed: September 2017
Revised: September 2017
Current Effective Date: October 13, 2017