

## Policies Repository



**Policy Title** Proton Pump Inhibitors

**Policy Number** FS.CLIN.43

***Application of Pharmacy Policy is determined by benefits and contracts. Benefits may vary based on product line, group or contract. Some medications may be subject to precertification, age, gender or quantity edits. Individual member benefits must be verified.***

***This Pharmacy Policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety or FDA approval may have changed. If the Medical/Pharmacy Reviewer is aware of any new information on the subject of this document, please provide it promptly to the Medical/Pharmacy Policy Department. This information may include new FDA approved indications, withdrawals or other FDA alerts. This type of information is relevant not only when considering whether this Policy should be updated, but also when applying it to current requests for coverage.***

***Members are advised to use participating pharmacies in order to receive the highest level of benefits.***

**Policy** Proton pump inhibitors (PPIs) are indicated in the treatment or symptomatic relief of various stomach disorders, including gastric and duodenal ulcers, gastroesophageal reflux disease (GERD), pathological hypersecretory conditions, and erosive esophagitis.

Bismuth subcitrate potassium, metronidazole, and tetracycline hydrochloride (Pylera®) is indicated for the treatment of individuals who have Helicobacter pylori infection and duodenal ulcer disease.

The use of rabeprazole (Aciphex®), lansoprazole (Prevacid®), lansoprazole (Prevacid®) disintegrating tablets, lansoprazole/naproxen (Prevacid NapraPAC®), esomeprazole (Nexium®), esomeprazole (Nexium®) for delayed-release suspension, Protonix®, omeprazole/sodium bicarbonate (Zegerid®), dexlansoprazole (Kapidex®), omeprazole (Prilosec™) for delayed-release oral suspension and bismuth subcitrate potassium, metronidazole, and tetracycline hydrochloride (Pylera®) require prior authorization (ie, clinical pharmacy and/or Medical Director review).

**Policy Description** Proton pump inhibitors (PPIs) reduce the production of acid by blocking the enzyme in the wall of the stomach that produces acid. The reduction of acid prevents ulcers and allows any ulcers that exist in the esophagus, stomach, or duodenum to heal. PPIs are used for the prevention and treatment of acid-related conditions such as ulcers, gastroesophageal reflux disease, and Zollinger-Ellison (ZE) syndrome. They are also used in combination with antibiotics for the eradication of Helicobacter pylori, a bacterium that, together with acid, causes ulcers of the stomach and duodenum.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of bismuth subcitrate potassium, metronidazole, and tetracycline hydrochloride (Pylera®), it should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria.

## Policy Guideline Inclusion

### ESOMEPRAZOLE (NEXIUM®) AND LANSOPRAZOLE (PREVACID®)

Esomeprazole (Nexium®) or lansoprazole (Prevacid®) is approved when **all** of the following inclusion criteria are met:

- Documentation of any of the indications specified for the drug
- A documented trial and failure of a prescription generic omeprazole **or** pantoprazole lasting at least 14 days or contraindication/intolerance/allergy to both generic omeprazole and pantoprazole

### ESOMEPRAZOLE (NEXIUM®) FOR DELAYED-RELEASE ORAL SUSPENSION AND LANSOPRAZOLE (PREVACID®) ORALLY DISINTEGRATING TABLETS

Esomeprazole (Nexium®) for delayed-release oral suspension, and lansoprazole (Prevacid®) orally disintegrating tablets are approved when **one** of the following inclusion criteria is met:

- The individual is under 12 years of age with documentation of any of the indications specified for the drug.
- Documentation of the inability to swallow capsules/tablets (eg, dysphagia, gastrointestinal [GI] tubes) along with documentation of any of the indications specified for the drug

### OMEPRAZOLE (PRILOSEC™) FOR DELAYED-RELEASE ORAL SUSPENSION

Omeprazole (Prilosec™) for delayed-release oral suspension is approved when the following inclusion criteria are met:

- Documentation of **one** of the following:
  - The individual is under 12 years of age with documentation of any of the indications specified for the drug.
  - Documentation of the inability to swallow capsules/tablets (eg, dysphagia, gastrointestinal [GI] tubes) along with documentation of any of the indications specified for the drug
- Documented trial and failure/intolerance/allergy with the following agents:
  - Esomeprazole (Nexium®) for delayed-release oral suspension
  - Lansoprazole (Prevacid®) orally disintegrating tablets

### LANSOPRAZOLE/NAPROXEN (PREVACID NAPRAPAC®)

Lansoprazole/naproxen (Prevacid NapraPAC®) is approved when the following inclusion criterion is met:

- Documentation of a history of a gastric ulcer in patients who require the use of an NSAID

### RABEPRAZOLE (ACIPHEX®), PANTOPRAZOLE (PROTONIX®), OMEPRAZOLE/SODIUM BICARBONATE (ZEGERID®), AND DEXLANSOPRAZOLE (KAPIDEX®)

Rabeprazole (Aciphex®), pantoprazole (Protonix®), omeprazole/sodium bicarbonate (Zegerid®) or dexlansoprazole (Kapindex®) is approved when **all** of the following inclusion criteria are met:

- Documentation of any of the indications specified for the drug
- A documented trial and failure of a prescription generic omeprazole **or** pantoprazole lasting at least 14 days or contraindication/intolerance/allergy to both generic omeprazole and pantoprazole
- A documented trial of products containing esomeprazole (Nexium®) **and** lansoprazole (Prevacid®)

#### **BISMUTH SUBCITRATE POTASSIUM, METRONIDAZOLE, AND TETRACYCLINE HYDROCHLORIDE (PYLERA®)**

Bismuth subcitrate potassium, metronidazole, and tetracycline hydrochloride (Pylera®) is approved when the following inclusion criterion is met:

- Documented diagnosis of *Helicobacter pylori*.

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#### **Policy Guideline Exclusion**

#### **ESOMEPRAZOLE (NEXIUM®) AND LANSOPRAZOLE (PREVACID®)**

Esomeprazole (Nexium®) or lansoprazole (Prevacid®) is denied when **any** of the following exclusion criteria are present:

- No documentation of any of the indications specified for the drug
- No documented trial and failure of a prescription generic omeprazole or pantoprazole lasting at least 14 days or contraindication/intolerance/allergy to both generic omeprazole and pantoprazole

#### **ESOMEPRAZOLE (NEXIUM®) FOR DELAYED-RELEASE ORAL SUSPENSION AND LANSOPRAZOLE (PREVACID®) ORALLY DISINTEGRATING TABLETS**

Esomeprazole (Nexium®) for delayed-release oral suspension and lansoprazole (Prevacid®) orally disintegrating tablets are denied when **any** of the following exclusion criteria are present:

- The individual is more than 12 years of age with no documentation of the inability to swallow capsules/tablets (eg, dysphagia, GI tubes)
- No documentation of any of the indications specified for the drug exist.

#### **OMEPRAZOLE (PRILOSEC™) FOR DELAYED-RELEASE ORAL SUSPENSION**

Omeprazole (Prilosec™) for delayed-release oral suspension is denied when the following exclusion criteria are present:

- No documentation of one of the following:
  - The individual is under 12 years of age with documentation of any of the indications specified for the drug.
  - Documentation of the inability to swallow capsules/tablets (eg, dysphagia, gastrointestinal [GI] tubes) along with documentation of any of the indications specified for the drug
- No documented trial and failure/intolerance/allergy with the following agents:
  - Esomeprazole (Nexium®) for delayed-release oral suspension
  - Lansoprazole (Prevacid®) orally disintegrating tablets

**LANSOPRAZOLE/NAPROXEN (PREVACID NAPRAPAC®)**

Lansoprazole/Naproxen (Prevacid NapraPAC®) is denied when the following exclusion criterion is present:

- No documentation of a history of a gastric ulcer in patients who require the use of an NSAID

**RABEPRAZOLE (ACIPHEX®), PANTOPRAZOLE (PROTONIX®), OMEPRAZOLE/SODIUM BICARBONATE (ZEGERID®) AND DEXLANSOPRAZOLE (KAPIDEX®)**

Rabeprazole (Aciphex®), pantoprazole (Protonix®), omeprazole/sodium bicarbonate (Zegerid®), or dexlansoprazole (Kapidex®) is denied when **any** of the following exclusion criteria are present:

- No documentation of any of the indications specified for the drug
- No documented trial and failure of a prescripion generic omeprazole **or** pantoprazole lasting at least 14 days or contraindication/intolerance/allergy to both generic omeprazole and pantoprazole
- No documented trial of products containing esomeprazole (Nexium®) **and** lansoprazole (Prevacid®)

**BISMUTH SUBCITRATE POTASSIUM, METRONIDAZOLE, AND TETRACYCLINE HYDROCHLORIDE (PYLERA®)**

Bismuth subcitrate potassium, metronidazole, and tetracycline hydrochloride (Pylera®) is denied when the following exclusion criterion is present:

- No documented diagnosis of *Helicobacter pylori*.

**Policy List of Applicable Drugs**

Brand Name	Generic Name
Aciphex	rabeprazole
Kapidex	dexlansoprazole
Nexium	esomeprazole
Nexium suspension	esomepraolze
Prevacid	lansoprazole
Prevacid NapraPac	lansoprazole/naproxen
Prevacid ODT	lansoprazole
Prilosec Suspension	omeprazole
Protonix	pantoprazole
Pylera	bismuth subcitrate potassium, metronidazole, and tetracycline
Zegerid	omeprazole/sodium bicarbonate

**Dosing and Administration**

Refer to the specific manufacturer's prescribing information for administration and dosage details for each specific agent.

Aciphex® (rabeprazole) [prescribing information]. Titusville, NJ: Janssen Pharmaceutical, Inc;

## Policy References

August 2003. [Aciphex® (rabeprazole) Web site]. Available at: <http://www.aciphex.com>. Accessed May 1, 2009.

Lippincott Williams & Wilkins, Inc. Proton pump inhibitors. [e-facts Drug Facts and Comparisons Web site]. Available at: <http://www.factsandcomparisons.com/efacts.asp> [via subscription only]. Accessed May 1, 2009.

Nexium® esomeprazole magnesium [package insert]. Wilmington, DE: AstraZeneca; 2006. [Nexium® Web site]. Available at: <http://www.astrazeneca-us.com/pi/Nexium.pdf>. Accessed May 1, 2009.

Omeprazole/sodium bicarbonate (Zegerid®) [package insert]. North Norwich, NY: Santarus, Inc; April 2007. Available at: [http://www.zegerid.com/assets/pdfs/prescribing\\_information.pdf](http://www.zegerid.com/assets/pdfs/prescribing_information.pdf). Accessed May 1, 2009.

Prevacid® (lansoprazole) [prescribing information]. Lake Forest, IL: TAP Pharmaceuticals; September 2006. [Prevacid® Web site]. Available at: <http://www.prevacid.com/pi.aspx>. Accessed May 1, 2009.

Prevacid® NapraPAC™ (lansoprazole/naproxen) [prescribing information]. Lake Forest, IL: TAP Pharmaceuticals; August 2006. [Prevacid® Lansoprazole Web site]. Available at: <http://www.prevacid.com/pi.aspx>. Accessed May 1, 2009.

Protonix® [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; December 2005. [Protonix Web site]. Available at: <http://www.protonix.com>. Accessed May 1, 2009.

Pylera® [package insert]. Birmingham, AL; Axcan Pharma, Inc.; February 2007.

Product Information: Kapidex delayed release capsules, dexlansoprazole delayed release capsules. Takeda Pharmaceuticals America, Inc, Deerfield, IL, 2009. Available at: <https://www.kapidex.com/default.aspx>. Accessed May 1, 2009.

Product Information: Prilosec (omeprazole) delayed-release capsules/Prilosec (omeprazole magnesium) for delayed-release oral suspension. AstraZeneca Pharmaceuticals, Wilmington, DE, 2005. Rev. 3/09.

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## Policy Link to Related Policies

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