



Proton Pump Inhibitors

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

*Prior authorization for certain formulations applies only to formulary exceptions due to being a non-covered medication. Please review plan formulary options.

RATIONALE FOR INCLUSION IN PA PROGRAM

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)



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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 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).

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).



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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

1. Aciphex [package insert] Woodcliff Lake, NJ: Eisai Inc.; November 2020.
2. Dexilant [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; November 2020.
3. Esomeprazole Strontium [package insert]. Glasgow, KY: Amneal Pharmaceuticals; January 2021.
4. Nexium [package insert]. Wilmington DE: AstraZeneca LP; November 2020.
5. Nexium IV [package insert]. Wilmington DE: AstraZeneca LP; November 2020.
6. Prevacid [package insert]. Warren, NJ: Takeda Pharmaceuticals America, Inc.; November 2020.
7. Prilosec [package insert]. Wilmington DE: AstraZeneca LP.; December 2016.
8. Protonix [package insert]. Philadelphia, PA: Pfizer Inc.; June 2018.
9. Protonix IV [package insert]. Philadelphia, PA: Pfizer Inc.; June 2018.
10. Zegerid [package insert]. San Diego, CA: Santarus, Inc.; November 2020.