Pharmacy Medical Necessity Guidelines: Proton Pump Inhibitors (PPIs)

Effective: March 1, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Proton Pump Inhibitors are indicated for the following conditions:

- Gastroesophageal reflux disease (GERD): For the relief of heartburn and other symptoms associated with GERD (dexlansoprazole, esomeprazole, lansoprazole, omeprazole, omeprazole/sodium bicarbonate, pantoprazole, rabeprazole)
- Duodenal Ulcer: For short-term treatment of active duodenal ulcers (lansoprazole, omeprazole, omeprazole/sodium bicarbonate, rabeprazole), and to maintain healing (lansoprazole)
- Duodenal ulcer associated with H. pylori infection: Dual therapy in combination with clarithromycin (omeprazole) or amoxicillin (lansoprazole) or triple therapy in combination with clarithromycin and amoxicillin (esomeprazole, lansoprazole, omeprazole, rabeprazole)
- Erosive esophagitis: For short-term treatment and maintenance of healing of erosive esophagitis (dexlansoprazole, esomeprazole, lansoprazole, omeprazole, omeprazole/sodium bicarbonate, pantoprazole, rabeprazole)
- Gastric Ulcer: For the short-term treatment of active benign gastric ulcers (lansoprazole, omeprazole, omeprazole/sodium bicarbonate)
- Helicobacter pylori eradication in combination with antimicrobial agents
- Pathological hypersecretory conditions, including Zollinger-Ellison syndrome: For the long-term treatment of pathological hypersecretory conditions (esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole)
- Risk reduction of nonsteroidal anti-inflammatory drug-associated gastric ulcer: Reduction in the occurrence of gastric ulcers associated with continuous NSAID therapy in patients at risk (esomeprazole, lansoprazole)
- Risk reduction of upper GI bleeding in critically ill patients: omeprazole/sodium bicarbonate oral solution

Prescription omeprazole in 10 mg, 20 mg, and 40 mg capsules and pantoprazole 20 mg and 40 mg tablets are the preferred proton pump inhibitors (PPI). They are covered without prior authorization.

COVERAGE GUIDELINES

The plan may authorize coverage of a non-preferred proton pump inhibitor for Members when the following criteria for a particular PPI are met and limitations do not apply:

lansoprazole capsules (Prevacid), rabeprazole (Aciphex)

1. The Member tried and failed therapy, or the provider indicates clinical inappropriateness of therapy with omeprazole and pantoprazole

Esomeprazole over-the-counter (Nexium OTC)

1. The Member tried and failed therapy, or the provider indicates clinical inappropriateness of therapy with omeprazole, pantoprazole, and either lansoprazole or rabeprazole

AND

2. **If request is for Nexium 24HR OTC tablets:** Member has tried and failed therapy, or the provider indicates clinical inappropriateness of treatment with generic esomeprazole over-the-counter capsules

Esomeprazole capsules (Rx) (Nexium)

1. The Member tried and failed therapy with, or the provider indicates clinical inappropriateness of therapy with omeprazole, pantoprazole, and either lansoprazole or rabeprazole

AND

2. The Member had an inadequate response to esomeprazole over-the-counter (Nexium 24HR OTC) and the provider submits a clinical rationale as to why the member requires treatment with the prescription formulation instead of the over-the-counter formulation.

Dexlansoprazole (Dexilant), omeprazole/sodium bicarbonate capsules (Zegerid)

1. The Member tried and failed therapy or the provider indicates clinical inappropriateness of therapy with omeprazole, pantoprazole, esomeprazole (OTC), and either lansoprazole or rabeprazole

Esomeprazole granules (Nexium packet), lansoprazole dispersible tablets (Prevacid SoluTabs), omeprazole granules for suspension (Prilosec Suspension), omeprazole/sodium bicarbonate packets (Zegerid) and suspension (Konvomep), pantoprazole suspension (Protonix Suspension), rabeprazole (Aciphex Sprinkles)

1. The Member is 8 years of age or younger, or the Member is unable to swallow oral tablets/capsules

AND

2. **Aciphex Sprinkles and Omeprazole/sodium bicarbonate packet or suspension:** The Member tried and failed therapy, or the provider indicates clinical inappropriateness of therapy with at least two of the following:
    - Esomeprazole granules (Nexium packet)
    - Lansoprazole dispersible tablets (Prevacid SoluTabs)
    - Omeprazole granules for suspension (Prilosec Suspension)
    - Pantoprazole suspension (Protonix Suspension)

LIMITATIONS

1. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.
2. The quantity for omeprazole/sodium bicarbonate capsules and packets is limited to one unit per day.

CODES

None

REFERENCES

1. Aciphex Sprinkle (rabeprazole) [prescribing information]. Englewood, CO; Aytu Therapeutics: November 2020.
2. Aciphex tablets (rabeprazole) [prescribing information]. Woodcliff Lake, NJ; Eisai, Inc: November 2020.
3. Dexilant (dexlansoprazole) [prescribing information]. Lexington, MA; Takeda Pharmaceuticals America, Inc: July 2023.
4. Konvomep (omeprazole/sodium bicarbonate) [prescribing information]. Waltham, MA: Azurity Pharmaceuticals, Inc: August 2023.
5. Moayyedi PM, Lacy BE, Andrews CN, et al. ACG and CAG Clinical Guidelines: Management of Dyspepsia. *Am J Gastroenterol* advance online publication, 20 June 2017; doi: 10.1038/ajg.2017.154.
6. Nexium (esomeprazole magnesium) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals, LP: July 2023.
7. Prevacid (lansoprazole) [prescribing information]. Lexington, MA; Takeda Pharmaceuticals America, Inc: August 2023.
8. Prilosec (omeprazole) delayed-release oral suspension [prescribing information]. Zug, Switzerland; Covis Pharma: March 2024.
9. Prilosec (omeprazole) [prescribing information]. Zug, Switzerland; Covis Pharma: March 2022.
10. Protonix (pantoprazole) [prescribing information]. Philadelphia, PA; Wyeth Pharmaceuticals Inc: June 2023.
11. Zegerid (omeprazole/sodium bicarbonate) powder and capsules [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals; July 2023.

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. May 9, 2023: Effective June 1, 2023, added Konvomep to the MNG. Updated criteria for esomeprazole granules, lansoprazole ODT, omeprazole granules, omeprazole/sodium bicarbonate packets, pantoprazole suspension, and rabeprazole sprinkles to allow for treatment with either First-Omeprazole or First-Lansoprazole rather than both.

2. May 14, 2024: Effective June 1, 2024, updated RxUM fax number.
3. December 2025 E-vote: Effective March 1, 2026: Removed First-Lansoprazole and First-Omeprazole from medical necessity guideline. Updated criteria for Esomeprazole granules (Nexium packet), lansoprazole dispersible tablets (Prevacid SoluTabs), omeprazole granules for suspension (Prilosec Suspension), omeprazole/sodium bicarbonate packets (Zegerid) and suspension (Konvomep), pantoprazole suspension (Protonix Suspension), rabeprazole (Aciphex Sprinkles) to remove prerequisite trial with either First-Omeprazole or First-Lansoprazole and updated pediatric age criterion.

ACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services