

Pharmacy Medical Necessity Guidelines: Proton Pump Inhibitors (PPIs)

Effective: October 13, 2020

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
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <ul style="list-style-type: none"> <input type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input type="checkbox"/> Tufts Health Freedom Plan products – small group plans • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <ul style="list-style-type: none"> <input type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan 		<p>Fax Numbers: RXUM: 617.673.0988</p>	

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, 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 (lansoprazole, omeprazole, rabeprazole)
- Erosive esophagitis: For short-term treatment and maintenance of healing of erosive esophagitis (dexlansoprazole, 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, e.g., Zollinger-Ellison syndrome, multiple endocrine adenomas, mastocytosis: For the long-term treatment of pathological hypersecretory conditions (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 (lansoprazole)
- Risk reduction of upper GI bleeding in critically ill patients: omeprazole/sodium bicarbonate

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.

For Members who are unable to swallow oral tablets or capsules, lansoprazole suspension (First-Lansoprazole) and omeprazole suspension (First-Omeprazole) are preferred PPIs. They are covered without prior authorization for Members 13 years of age and younger.

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

Lansoprazole suspension (First-Lansoprazole), omeprazole suspension (First-Omeprazole)

1. The Member is unable to swallow oral tablets/capsules

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

1. The Member is 13 years of age or younger or the Member is unable to swallow oral tablets/capsules
- AND**
2. The Member tried and failed therapy, or the provider indicates clinical inappropriateness of therapy with both omeprazole suspension (First-Omeprazole) and lansoprazole suspension (First-Lansoprazole)
- AND**
3. **Aciphex Sprinkles and Omeprazole/sodium bicarbonate packets only:** 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. Prilosec (omeprazole) [prescribing information]. Wilmington, DE; AstraZeneca: November 2019.
2. Prevacid (lansoprazole) [prescribing information]. Deerfield, IL; Takeda Pharmaceuticals Inc: September 2020.
3. Protonix (pantoprazole) [prescribing information]. Philadelphia, PA; Wyeth Pharmaceuticals Inc: April 2019.
4. Aciphex tablets (rabeprazole) [prescribing information]. Woodcliff Lake, NJ; Eisai, Inc: September 2019.
5. Aciphex capsules (rabeprazole) [prescribing information]. Research Triangle Park, NC; Eisai: June 2018.

6. Dexilant (dexlansoprazole) [prescribing information]. Lexington, MA; Takeda Pharmaceuticals America, Inc: September 2020.
7. Zegerid (omeprazole/sodium bicarbonate) powder and capsules [prescribing information]. Bridgewater, NJ: Salix Pharmaceuticals; September 2019.
8. 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.

APPROVAL HISTORY

March 14, 2013: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. February 10, 2015: Approval will be limited to one year; esomeprazole OTC is a preferred agent.
2. April 14, 2015: Incorporated criteria for Aciphex Sprinkles.
3. September 16, 2015: Approval duration approved for life of plan
4. January 1, 2016: Administrative change to rebranded template.
5. September 13, 2016: Removed trial of esomeprazole from criteria for lansoprazole capsules and rabeprazole. Added trial with pantoprazole and either lansoprazole or rabeprazole to Nexium OTC criteria. Updated criteria for Dexilant and esomeprazole (RX) to include a trial with either rabeprazole or lansoprazole.
6. October 18, 2016: Moved generic esomeprazole (RX) to Not Covered.
7. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
8. September 12, 2017: Administrative update. Removed language from the limitations section stating that approval duration will be for the life of the plan.
9. November 12, 2018: Effective 4/1/2019, updated criteria for over-the-counter (OTC) esomeprazole, requiring trial and failure with the capsules before approval of the tablets. Administrative changes made to the template.
10. January 8, 2019: Effective 4/1/2019, added criteria for prescription esomeprazole.
11. April 9, 2019: Effective 4/18/19, added criteria for omeprazole/sodium bicarbonate capsules. Effective 7/1/19, added criteria for omeprazole/sodium bicarbonate packets and updated criteria for Aciphex Sprinkles and added quantity limits for omeprazole/sodium bicarbonate capsules and packets.
12. October 13, 2020: No changes.

BACKGROUND, 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.

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