Pharmacy Medical Necessity Guidelines: Proton Pump Inhibitors

Effective: August 11, 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

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:

RXUM: 617.673.0988

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

OVERVIEW

FOOD AND DRUG ADMINISTRATION (FDA)-APPROVED INDICATIONS

The proton pump inhibitors (PPIs) are the most potent medications available for the management of acid-related disorders. They are effective in the treatment of peptic ulcer disease, Zollinger-Ellison syndrome, and gastroesophageal reflux disease; eradication of Helicobacter pylori; and treatment and prevention of gastroduodenal ulcers associated with nonsteroidal anti-inflammatory drugs. PPIs work by blocking acid secretion by irreversibly binding to and inhibiting the hydrogen/potassium ATPase that resides on the luminal surface of the parietal cell.

COVERAGE GUIDELINES

Dexilant (dexlansoprazole)

The plan may authorize coverage of Dexilant (dexlansoprazole) for Members, when **ALL** the following criteria are met:

1. Member at least 12 years of age

AND

2. Documented trial and failure of **ALL** of the following: omeprazole, pantoprazole, lansoprazole, rabeprazole, and esomeprazole (OTC)

Coverage of oral suspensions and orally disintegrating formulations:

The plan may authorization coverage of Nexium (esomeprazole) suspension, Prevacid (lansoprazole) orally disintegrating tablet, Prilosec (omeprazole) suspension, Protonix (pantoprazole) suspension, Zegerid (omeprazole/sodium bicarbonate) suspension for Members, when **ALL** of the following criteria are met:

1. Documentation of swallowing disorder

AND

2. Documented trial and failure, or a contraindication or intolerance to omeprazole suspension

Additional coverage criteria for the following branded prescription proton-pump inhibitors with an A-rated generic (i.e., AA, AB, AN, AO, AP, or AT rating):

The plan may authorize coverage of Prilosec capsules, Prevacid capsules and soluble tablets, Protonix tablets, Aciphex tablets, Zegerid capsules and packet when all the following criteria are met:

1a. Documentation from the requesting physician that the Member had an allergy to an ingredient in the A-rated generic product that is not contained in the brand-name product

AND

1b. Documentation from the requesting physician that the Member has had a treatment failure or a contraindication or intolerance to **ALL** of the following generic Proton Pump Inhibitors: omeprazole, pantoprazole, lansoprazole, rabeprazole, and esomeprazole (OTC)

OR

2. The request for the brand-name product is due to a drug shortage

LIMITATIONS

- Brand-name drugs that are approved due to a drug shortage will only be authorized for 3-months, subsequent authorizations will require an additional review.
- Coverage of following medications is limited to 90 units per 90 days: Aciphex tablets, Dexilant capsules, Nexium suspension, Prevacid capsules and soluble tablets, Prilosec capsules and suspension, Protonix tablets and suspension, and Zegerid (omeprazole/sodium bicarbonate) capsules and packets.
- The plan does not cover the following medications on all Commercial formularies: Aciphex sprinkle capsules, and esomeprazole strontium capsules. Refer to the Pharmacy Medical Necessity Guidelines for Noncovered Drugs with Suggested Alternatives and submit a formulary exception request to Tufts Health Plan, as indicated.
- Select high cost NDCs of Zegerid (omeprazole/sodium bicarbonate) capsules as well as brand Zegerid OTC capsules may be excluded from coverage.
- Only Over-The-Counter esomeprazole products are covered. Prescription esomeprazole products are excluded from coverage.

CODES

None

REFERENCES

1. Bergsland, E. Management and prognosis of the Zollinger-Ellison syndrome (gastrinoma). In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on March 14, 2017).
2. Dexilant (dexlansoprazole) [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; October 2016.
3. Nexium (esomeprazole) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2016.
4. Prevacid Solutab (lansoprazole) [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; October 2016.
5. Prilosec (omeprazole) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; December 2016.
6. Protonix (pantoprazole) [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc; October 2016.
7. Zegerid (omeprazole and sodium bicarbonate) [package insert]. Bridgewater, NJ: Salix Pharmaceuticals; June 2018.
8. Wolfe, MM. Overview and comparison of the proton pump inhibitors for the treatment of acid-related disorders. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on March 14, 2017).

APPROVAL HISTORY

April 11, 2017: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. April 11, 2017: Administrative update, Adding Tufts Health RITogether to the template.
2. May 8, 2018: Reflected the change in coverage of Prevacid Solutab. Brand Prevacid Solutab moved to Not-covered for the small groups and individuals and Tufts Health Direct formularies. Effective October 1, 2018, Prevacid Solutab will move to NC for all COMM formularies.
3. April 9, 2019: Effective 7/1/19, added Zegerid (omeprazole/sodium bicarbonate) to MNG with 90 unit/90 day quantity limitation for capsules and packet and added generic omeprazole/sodium bicarbonate packets to existing criteria, requiring documented swallowing disorder and trial and failure with preferred suspensions.
4. August 13, 2019: Effective 1/1/2020, added coverage criteria to multi-source brands that moved form Not-Covered to PA. Updated the criteria for oral suspensions and dispersible tablet formulations to step through omeprazole suspension. Updated the limitations section with the list medications that have quantity limit, Not-Covered and excluded medications. Clarified that the duration of approval for requests that are approved due to a drug shortage is limited to 3 months.
5. August 11, 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.