Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Acid Suppressive Therapy

Effective: January 1, 2027

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

This guideline applies to the following medications when they are covered by the plan:

- Proton Pump Inhibitors (PPIs) in oral solution, oral suspension, packet and orally disintegrating tablet formulations
- Histamine 2-Receptor Antagonists in oral solution and oral suspension formulations

Clinical Guideline Coverage Criteria

Oral solution, oral suspension, packet and orally disintegrating tablet formulations

Initial Criteria:

The plan may authorize coverage of oral solution, oral suspension, packet and orally disintegrating tablet formulations for patients when the following criteria are met:

1. Documentation of **one (1)** of the following:
   a. Submission of medical records documenting a swallowing disorder and inability to use a tablet or capsule formulation (i.e. cannot use a prescription or over the counter (OTC) alternative)

   OR

   b. Patient is 8 years of age or younger

Reauthorization criteria:

The plan may re-authorize coverage of oral solution, oral suspension, packet and orally disintegrating tablet formulations for patients when the following criteria are met:

1. Documentation of **one (1)** of the following:
   a. Documentation of both of the following:
      i. Member continues to meet initial criteria with one of the following:
         1. Submission of medical records documenting a swallowing disorder and inability to use a tablet or capsule formulation (i.e. cannot use a prescription or over the counter (OTC) alternative)

         OR

         2. Patient is 8 years of age or younger

      AND

      ii. Patient continues to require the use of the requested medication.

   OR

   b. The patient is new to the plan, has been stable on the requested medication with another plan, and the plan's initial criteria has been met.

Limitations

1. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.
2. Initial approval will be authorized for 12 months. Reauthorization will be provided in 12-month intervals.

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) [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc. November 2020.
3. Nexium (esomeprazole) [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2021.
4. Prevacid Solutab (lansoprazole) [package insert]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; May 2021.
5. Prilosec (omeprazole) [package insert]. Switzerland: Covis Pharma LP; November 2020.
6. Protonix (pantoprazole) [package insert]. Philadelphia, PA: Wyeth Pharmaceuticals Inc; December 2020.
7. 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).
8. Zegerid (omeprazole and sodium bicarbonate) [package insert]. Bridgewater, NJ: Salix Pharmaceuticals; November 2020.
9. Bracken, Louise, et al. "Can children swallow tablets? Outcome data from a feasibility study to assess the acceptability of different-sized placebo tablets in children (creating acceptable tablets (CAT))." *BMJ open* 10.10 (2020): e036508.

Approval And Revision History

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

- July 11, 2023: Added lansoprazole suspension as an option for oral suspensions, granules, packets, and orally disintegrating formulations.
- August 13, 2024: Effective November 1, 2024. Added high dose PPI equivalents for dexlansoprazole criteria. Added initial and reauthorization criteria and updated approval duration for a duration of 6 months for initial approval and 12 months for subsequent authorizations.
- September 9, 2025: Updated criteria for PPI Oral Suspensions, Granules, Packets, and Orally Disintegrating Formulations to remove prerequisite trial requirement with omeprazole suspension or lansoprazole suspension, and added pediatric age criterion. Effective 1/1/26.
- September e-Vote: Removed Dexilant (dexlansoprazole) coverage criteria. Updated initial approval duration from 6 months to 12 months. Administrative update to remove CareLink from the Medical Necessity Guideline template. (eff 10/1/26)
- September e-Vote: Added oral solution and oral suspension formulations of histamine H2-receptor antagonists that are covered by the plan to the Overview section, as these formulations are subject to prior authorization. Minor wording edits were made to the initial and reauthorization coverage criteria to align with this update. Updated the title of Medical Necessity Guideline from Proton Pump Inhibitors to Acid Suppressive Therapy. (eff 1/1/27)
- October e-vote: effective January 1, 2027, added additional criteria to clarify member need to use a special formulation (inability to take oral capsule or tablet, available via Prescription or OTC).

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.