Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
# Voquezna (vonoprazan)

*Effective: June 1, 2025*

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| **Guideline Type** | ☒ Prior Authorization<br>☐ Non-Formulary<br>☐ Step-Therapy<br>☐ Administrative |

**Applies to:**

**Commercial Products**

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

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

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

**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

**Food and Drug Administration – Approved Indications**

**VOQUEZNA Tablet** is indicated for healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults, to maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults, and for the relief of heartburn associated with non-erosive gastroesophageal reflux disease in adults.

**VOQUEZNA TRIPLE PAK**, is a co-packaged product containing vonoprazan, a potassium-competitive acid blocker (PCAB), amoxicillin, a penicillin class antibacterial, and clarithromycin, a macrolide antimicrobial, indicated for the treatment of Helicobacter pylori (H. pylori) infection in adults.

**VOQUEZNA DUAL PAK**, is a co-packaged product containing vonoprazan, a PCAB, and amoxicillin, a penicillin class antibacterial, indicated for the treatment of H. pylori infection in adults.

## Clinical Guideline Coverage Criteria

**VOQUEZNA Tablets**

***Initial Authorization Criteria:***

The plan may initially authorize coverage of **VOQUEZNA TABLETS**, when **ALL** of the following criteria are met:

1. Documented diagnosis of one of the following:
    a. Erosive esophagitis (GERD) of any stage
    b. Heartburn associated with erosive esophagitis (GERD)
    c. Heartburn associated with non-erosive gastroesophageal reflux disease (GERD)

**AND**

2. Patient is 18 years of age or older

**AND**

3. Prescribed by or in consultation with a gastroenterologist

**AND**

4. There has been previous treatment failure with or contraindication to all of the following: omeprazole AND pantoprazole AND lansoprazole AND rabeprazole

***Reauthorization criteria:***

The plan may reauthorize coverage of **VOQUEZNA TABLETS**, when **ALL** of the following criteria are met:

1. Continues to have one of one of the following after an initial treatment course:
    a. Erosive esophagitis of any stage (GERD)
    b. Heartburn associated with erosive esophagitis (GERD)

**AND**

2. The patient has responded to an initial treatment and continues to require treatment for maintenance.

**VOQUEZNA Paks**

The plan may authorize coverage of **VOQUEZNA TRIPLE PAK** and **VOQUEZNA DUAL PAK**, when **ALL** of the following criteria are met:

1. Documented diagnosis of helicobacter pylori (H. pylori)

**AND**

2. Patient is 18 years of age or older

**AND**

3. Prescribed by or in consultation with a gastroenterologist or infectious disease specialist

**AND**

4. The patient has had a trial and failure, intolerance or contraindication to bismuth quadruple therapy (e.g., bismuth and metronidazole and tetracycline and proton pump inhibitor)

## Limitations

- Initial approval of Voquezna tablets for erosive esophagitis will be for a duration of 8 weeks. Reauthorization of Voquezna tablets for erosive esophagitis will be for a duration of 6 months.
- Approval of Voquezna tablets for non-erosive gastroesophageal reflux disease will be for a duration of 4 weeks. Subsequent requests for Voquezna tablets for non-erosive gastroesophageal reflux disease should be reviewed against initial approval criteria.
- Voquezna Triple Pak and Voquezna Dual Pak will be authorized for 14 days based on package labeling.
- 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.

## Codes

None

## References


1. Voquezna prescribing information. Phathom Pharmaceuticals, Inc. Buffalo Grove, IL. July 2024.
2. Chey WD, Leontiadis GI, Howden CW, Moss SF. ACG Clinical Guideline: Treatment of Helicobacter pylori Infection. Am J Gastroenterol 2017; 112:212.
3. Argueta EA, et al. Impact of antimicrobial resistance rates on eradication of Helicobacter pylori in a US population. Gastroenterology. 2021;160(6):2181-2183.e1.
4. Savoldi A, Carrara E, Graham DY, et al. Prevalence of Antibiotic Resistance in Helicobacter pylori: A Systematic Review and Meta-analysis in World Health Organization Regions. Gastroenterology 2018; 155:1372.

   Chey, William D., et al. "ACG clinical guideline: treatment of Helicobacter pylori infection." *Official journal of the American College of Gastroenterology| ACG* 119.9 (2024): 1730-1753.


## Approval And Revision History

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

Subsequent endorsement date(s) and changes made:

- October 10, 2023: No changes.
- April 9, 2024: Effective 5/1/24, Updated name of MNG to Voquezna (vonoprazan), added criteria for Voquezna tablets.
- December 10, 2024: Effective 1/1/25, updated Voquezna tablets coverage criteria to add the expanded indication of heartburn associated with non-erosive GERD. Added approval duration for non-erosive GERD.
- March 11, 2025: Effective 6/1/25, updated Voquezna Paks coverage criteria to remove clarithromycin-based therapy as a required prerequisite for members who have a contraindication or intolerance to bismuth quadruple therapy. Minor wording update made to bismuth quadruple therapy prerequisite criterion for Voquezna Paks.

## 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.