Pharmacy Policy Bulletin: J-1210 Voquezna (vonoprazan) Products – Commercial and Healthcare Reform	
Number: J-1210	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial**: **Prior Authorization (1):** 1. Other Managed Prior Authorization = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-1210-007	**Original Date:** 06/01/2022
Effective Date: 02/27/2025	**Review Date:** 02/20/2025

Drugs Product(s):	• Voquezna Triple Pak (vonoprazan/amoxicillin/clarithromycin) • Voquezna Dual Pak (vonoprazan/amoxicillin) • Voquezna (vonoprazan)
FDA-Approved Indication(s):	• Voquezna Triple Pak (vonoprazan/amoxicillin/clarithromycin) and Voquezna Dual Pak (vonoprazan/amoxicillin) o Treatment of *Helicobacter pylori* (*H. pylori*) infection in adults • Voquezna (vonoprazan) o Healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults. o Maintain healing of all grades of erosive esophagitis and relief of heartburn associated with erosive esophagitis in adults. o Relief of heartburn associated with non-erosive gastroesophageal reflux disease in adults. o In combination with amoxicillin and clarithromycin for the treatment of *H. pylori* infection in adults o In combination with amoxicillin for the treatment of H. pylori infection in adults.

Background:	• Vonoprazan is a potassium-competitive acid blocker that suppresses basal and stimulated gastric acid secretion at the secretory surface of the gastric and parietal cell through inhibition of the H+, K+-ATPase enzyme system which is considered the acid pump within the parietal cell. Amoxicillin is an antibiotic that binds to penicillin-binding proteins while clarithromycin is an antibiotic that binds to the bacterial 50S ribosomal subunit. ***Helicobacter pylori*** • *H. pylori* is the most prevalent chronic bacterial infection and is associated with peptic ulcer disease, chronic gastritis, gastric adenocarcinoma, and gastric mucosa associated lymphoid tissue (MALT) lymphoma. • *H. pylori* is a gastric pathogen that affects approximately 115 million people in the United States. *H. pylori* is more likely to occur in children with risk factors

including living in crowded conditions with poor sanitation, consuming nonfiltered water, smoking, and a family history of peptic ulcer disease
- All patients with evidence of active infection with *H. pylori* should be offered *H. pylori* eradication treatment.
- The 2024 American College of Gastroenterology (ACG) Clinical Guideline: Treatment of *Helicobacter pylori* infection recommends optimized bismuth-based quadruple therapy (BQT) for 14-days for treatment naïve patients as well as treatment-experienced patients who failed to eradicate *H. pylori* with an initial course of PPI-clarithromycin triple therapy. Optimized BQT consists of PPI twice daily, tetracycline 500 mg 4 times daily, metronidazole 500 mg 3 or 4 times daily, and bismuth subcitrate or bismuth subsalicylate 4 times daily for 14 days. It is recommended against using PPI-clarithromycin triple therapy unless antibiotic sensitivity has been performed and clarithromycin-sensitivity has been proven.
- Voquezna DualPak is suggested (conditional; moderate quality of evidence) in treatment-naïve patients, and may be considered for treatment-experienced/salvage patients as an empiric or proven antibiotic sensitivity regimen when other treatment options are not appropriate. Voquezna TriplePak is suggested (conditional; moderate quality of evidence) for treatment-experienced/salvage patients as a proven antibiotic sensitivity regimen.
- Voquezna Triple Pak and Voquezna Dual Pak were shown to be non-inferior to lansoprazole plus amoxicillin plus clarithromycin (LAC) in patients who did not have a clarithromycin- or amoxicillin-resistant strain of *H. pylori* at baseline.
- Voquezna Triple Pak and Voquezna Dual Pak were shown to be superior to LAC in patients who had a clarithromycin-resistant strain of *H. pylori* at baseline.
- In patients with persistent *H. pylori* infection, every effort should be made to avoid antibiotics that have been previously taken by the patient.

Erosive Esophagitis (EE)
- Erosive esophagitis occurs when excessive reflux of acid and pepsin results in necrosis of surface layers of esophageal mucosa, causing erosions and ulcers. It is characterized by endoscopically visible breaks in the distal esophageal mucosa with or without symptoms of GERD.
- The American College of Gastroenterology guidelines recommend PPI treatment over treatment with histamine type-2 receptor antagonists (H2RA) for healing erosive esophagitis and for maintenance healing from erosive esophagitis.

Non-Erosive Gastroesophageal Reflux Disease (NERD)
- NERD is defined by quantifiably excessive esophageal acid exposure based on testing with pH-metry in the absence of erosive esophagitis.
- The American College of Gastroenterology guidelines recommend on-demand/or intermittent PPI therapy for heartburn symptom control in patients with nonerosive reflux disease.

- Prescribing Considerations:
  - When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy.
  - According to the package insert for Voquezna:
    - Healing of erosive esophagitis should be for a duration of 8 weeks
    - Maintenance of healing for erosive esophagitis should be for a duration of up to 6 months
    - Relief of heartburn associated with non-erosive gastroesophageal reflux disease should be for a duration of 4 weeks, however, the clinical trial allowed continuation for 20 weeks.
    - Treatment of an *H. pylori* infection should be for a duration of 14 days.

Approval Criteria

I. Voquezna Dual Pak and Voquezna Triple Pak

A. Approval Criteria

When a benefit, coverage of Voquezna Dual Pak or Voquezna Triple Pak may be approved when all of the following criteria are met **(1. and 2.)**:

1. The member is 18 years of age or older.

2. The member has a diagnosis of *H. pylori* infection (ICD-10: B96.81) confirmed by one (1) of the following **(a. or b.)**:

a. Invasive techniques (e.g., endoscopic)

b. Non-invasive techniques (e.g., urea breath test, stool antigen assay test)

II. Voquezna

A. Erosive Esophagitis

1. Initial Therapy (Healing): 0 to 8 weeks of previous therapy

When a benefit, coverage of Voquezna may be approved when all of the following criteria are met **(a., b., and c.)**:

a. The member is 18 years of age or older.

b. The member is using Voquezna for the healing of erosive esophagitis (ICD-10: K22.1) and for relief of heartburn associated with erosive esophagitis

c. The member has experienced therapeutic failure, contraindication, or intolerance to all of the following plan-preferred products **(i. and ii.)**:

i. omeprazole

ii. pantoprazole

2. Maintenance Therapy (Healing): > 8 weeks to 6 months of previous therapy

When a benefit, maintenance of Voquezna may be approved when all of the following criteria are met **(a., b., and c.)**:

a. The member is 18 years of age or older.

b. The member is using Voquezna to maintain healing of erosive esophagitis (ICD-10: K22.1) and for relief of heartburn associated with erosive esophagitis.

c. The member has responded to an initial treatment course and continues to have erosive esophagitis that requires treatment for maintenance.

B. Non-Erosive Gastroesophageal Reflux Disease (NERD)

1. Initial Authorization

When a benefit, coverage of Voquezna may be approved when all of the following criteria are met **(a., b., and c.)**:

a. The member is 18 years of age or older.

b. The member is using Voquezna for the relief of heartburn associated with non-erosive gastroesophageal reflux disease (ICD-10: K21.9)

c. The member has experienced therapeutic failure, contraindication, or intolerance to all of the following plan-preferred products **(i. and ii.)**:

i. omeprazole

ii. pantoprazole

2. Reauthorization

When a benefit, reauthorization of Voquezna may be approved when all of the following criteria are met **(a., b., and c.)**:

a. The member continues to have a diagnosis of non-erosive gastrointestinal reflux disease which requires additional Voquezna therapy.

b. The prescriber attests the member has experienced symptom improvement or control during the initial 4-week treatment course.

c. The total treatment duration with Voquezna will not exceed 24 weeks in the past 365 days.

C. ***H. pylori***

1. Approval Criteria

When a benefit, coverage of Voquezna may be approved when all of the following criteria are met **(a., b., and c.)**:

a. The member is 18 years of age or older.

b. The member has a diagnosis of *H. pylori* infection (ICD-10: B96.81) confirmed by one (1) of the following **(i. or ii.)**:

i. Invasive techniques (e.g., endoscopic)

ii. Non-invasive techniques (e.g., urea breath test, stool antigen assay test)

c. The member meets one (1) of the following criteria **(i. or ii.)**:

i. Voquezna is being used in combination with amoxicillin.

ii. Voquezna is being used in combination with amoxicillin and clarithromycin.

III. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

Commercial and HCR Plans:

- ***H. pylori* infection:** If approved, up to a 14-day authorization may be granted.
- **Erosive esophagitis:**
  - **Initial Authorization:** If approved, up to an 8-week authorization may be granted.
  - **Maintenance/Reauthorization:** If approved, up to a 6-month authorization may be granted.
- **Non-erosive gastroesophageal reflux disease:**
  - **Initial Authorization:** If approved, up to a 4-week authorization may be granted.
  - **Reauthorization:** If approved, up to a 20-week authorization may be granted.

Automatic Approval Criteria

None

References:

1. Voquezna. Buffalo Grove, IL. Phathom Pharmaceuticals; July 2024.
2. Voquezna Triple Pak. Buffalo Grove, IL. Phathom Pharmaceuticals; July 2024.
3. Voquezna Double Pak. Buffalo Grove, IL. Phathom Pharmaceuticals; July 2024.
4. DRUGDEX System (Micromedex 2.0). Greenwood Village, CO: Truven Health Analytics; 2024.
5. Chey et al. ACG Clinical Guideline: Treatment of Helicobacter pylori Infection. *Am J Gastroenterol*. 2017;112:212.
6. GlobeNewsWire. Phathom Pharmaceuticals Announces FDA Approval of VOQUEZNA™ TRIPLE PAK™ (vonoprazan, amoxicillin, clarithromycin) and VOQUEZNA™ DUAL PAK™ (vonoprazan, amoxicillin) for the Treatment of H. pylori Infection in Adults. Available at: https://www.globenewswire.com/news-release/2022/05/03/2435147/0/en/Phathom-

Pharmaceuticals-Announces-FDA-Approval-of-VOQUEZNA-TRIPLE-PAK-vonoprazan-amoxicillin-clarithromycin-and-VOQUEZNA-DUAL-PAK-vonoprazan-amoxicillin-for-the-Treatment-of-H-pylo.html. Accessed December 4, 2024.
7. Katz PO, et al. ACG Clinical Guideline for the Diagnosis and Management of Gastroesophageal Reflux Disease. *Am J Gastroenterol*. 2022 Jan 1;117(1):27-56.