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Section:	Prescription Drugs	**Effective Date:**	January 1, 2025
Subsection:	Gastrointestinal Agents	**Original Policy Date:**	February 9, 2024
Subject:	Voquezna	**Page:**	1 of 4

Last Review Date: December 13, 2024

Voquezna

Description

Voquezna (vonoprazan)

Background
Voquezna (vonoprazan) is a potassium-competitive acid blocker (P-CAB) that suppresses basal and stimulated gastric acid secretion. In contrast to a proton pump inhibitor (PPI), Voquezna does not require acid activation and binds reversibly to the H+,K+-ATPase to inhibit acid production (1).

Regulatory Status
FDA-approved indications: Voquezna is indicated (1):

- 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.
- for the relief of heartburn associated with non-erosive gastroesophageal reflux disease in adults.
- in combination with amoxicillin and clarithromycin for the treatment of Helicobacter pylori (*H. pylori*) infection in adults.
- in combination with amoxicillin for the treatment of H. pylori infection in adults.

Voquezna therapy, like other treatments raising the pH of the stomach, may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine. The risk of fracture

was increased in patients who received high-dose, defined as multiple daily doses, and long-term PPI therapy (a year or longer). Bone fracture was reported during use of Voquezna. Patients should use the lowest dose and shortest duration of Voquezna therapy appropriate to the condition being treated (1).

Voquezna therapy may also be associated with an increased risk of Clostridium difficile associated diarrhea (CDAD) and hypomagnesemia. This association was first recorded with PPI use, however since Voquezna raises gastric pH in a similar way, patients with diarrhea that does not improve should be evaluated for CDAD. Patients with hypomagnesemia may require replacement treatment, and possible discontinuation of Voquezna (1).

The safety and effectiveness of Voquezna in pediatric patients less than 18 years of age have not been established (1).

Related policies
H Pylori Infection Agents, Proton Pump Inhibitors

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Voquezna may be considered **medically necessary** if the conditions indicated below are met.

Voquezna may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Erosive esophagitis
2. Non-erosive gastroesophageal reflux disease (GERD)
3. *H. pylori* infection
    a. Used in combination with amoxicillin **OR** amoxicillin and clarithromycin

AND the following for **ALL** indications:

1. Inadequate treatment response, intolerance, or contraindication to **ALL** of the

following:

a. Proton pump inhibitor (PPI)
b. Histamine-2 (H2) receptor antagonist

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 40 mg per day

Duration 6 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Voquezna is a reversible, non-covalent inhibitor of the H+,K+-ATPase resulting in lower basal and stimulated gastric acid production. Voquezna is indicated for the treatment and maintenance of healing of erosive esophagitis, the treatment of non-erosive GERD, and it is also used in combination with antibiotics for the treatment of *H. pylori* infection. The safety and effectiveness of Voquezna in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Voquezna while maintaining optimal therapeutic outcomes.

References

1. Voquezna [package insert]. Buffalo Grove, IL: Phathom Pharmaceuticals, Inc.; July 2024.

Policy History

Date	Action
February 2024	Addition to PA
March 2024	Annual review
June 2024	Annual review
August 2024	Per PI update, added indication of non-erosive GERD
December 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 13, 2024 and is effective on January 1, 2025.