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Voquezna Drug Use Criteria

Created: 2/4/2025 Reviewed: 2/4/2025

Includes:

Voquezna© (Vonoprazan)

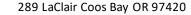
GUIDELINE FOR USE:

Initial Request:

- 1. Is the member diagnosed with one of the following conditions: **Erosive Esophagitis (EE):** Confirmed by endoscopy; **Non-Erosive GERD:** Experiencing heartburn symptoms
 - a. If yes, go to 2
 - b. If no, deny as not meeting criteria. Off-label use of medication is not a covered benefit on OHP.
- 2. Is the member 18 years of age or older?
 - a. If yes, go to 3
 - b. If no, deny as not meeting criteria. Voquezna is not FDA-approved for pediatric use.
- 3. Does the member have severe hepatic impairment (Child-Pugh Class C)?
 - a. If yes, deny as criteria not met. Voquezna is contraindicated.
 - b. If no, go to 4
- 4. Is the member taking pimozide, ergot alkaloids, lomitapide, lovastatin, simvastatin, or colchicine in patients with renal or hepatic impairment?
 - a. If yes, deny as criteria not met. Voquezna is contraindicated.
 - b. If no, got to 5
- 5. <u>For GERD indications:</u> Has the patient experienced inadequate response or intolerance to at least an 8-week course of a formulary proton pump inhibitor (PPI) at the maximum tolerated dose?
 - a. If yes, approve for up to 8 weeks (Erosive Esophagitis) or up to 4 weeks (non-erosive GERD)
 - b. If no, deny as not meeting criteria. Trial with formulary PPI as a first-line therapy is required.

Renewal Request:

- 1. Does the member have a diagnosis of Erosive Esophagitis?
 - a. If yes, go to 2



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b. If no, deny as not meeting criteria. Voquezna is not FDA-approved for maintenance therapy for indications other than erosive esophagitis. Off-label use of medication is not a covered benefit on OHP.

- 2. Has the patient demonstrated clinical benefit from Voquezna therapy without significant adverse effects?
 - a. If yes, approve for up to 6 months
 - b. If no, deny as not meeting criteria

<u>Rationale:</u> To define a process for covering Potassium-competitive acid blockers (PCABs) that is consistent with clinical practice guidelines and medical evidence while ensuring that less costly formulary options are trialed first.

FDA Approved Indications:

- Gastroesophageal reflux disease, erosive or nonerosive
- Helicobacter pylori eradication

<u>Mechanism of Action:</u> A potassium-competitive acid blocker suppresses basal and stimulated gastric acid secretion at the secretory surface of the gastric parietal cell through inhibition of the H+, K+-ATPase enzyme system in a potassium competitive manner.

References:

- 1. FDA Prescribing Information for Voquezna (vonoprazan): This document provides comprehensive details on indications, contraindications, dosing recommendations, and safety considerations for Voquezna.
- 2. Vonoprazan (VOQUEZNA) National Drug Monograph: Published by the U.S. Department of Veterans Affairs in May 2024, this monograph offers an in-depth analysis of vonoprazan's efficacy, safety profile, and clinical trial data, particularly in the treatment of erosive esophagitis.
- 3. PHALCON-EE: A Phase 3 Study of VOQUEZNA in Erosive GERD: This clinical trial evaluated the efficacy and safety of Voquezna in patients with erosive gastroesophageal reflux disease, demonstrating its effectiveness in healing and maintaining remission.
- 4. Vonoprazan: A New Potassium-Competitive Acid Blocker: Published in the journal *Pharmacy and Therapeutics*, this article reviews vonoprazan's pharmacology, clinical efficacy, and safety, highlighting its role in acid-related disorders.
- 5. A Comprehensive Review on the Efficacy and Safety of Vonoprazan: This review article provides an extensive analysis of vonoprazan's clinical trial data, comparing its efficacy and safety to proton pump inhibitors in various gastrointestinal conditions.