AdvancedHealth
Bridging the Future of Healthcare

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Voquezna Drug Use Criteria

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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. **For GERD indications:** 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

Rationale: 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

Mechanism of Action: 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.