PRIOR AUTHORIZATION RESOURCE GUIDE

VOQUEZNA® (vonoprazan) is a potassium-competitive acid blocker (PCAB) indicated in adults:

- for the healing of all grades of Erosive Esophagitis (Erosive Gastroesophageal Reflux Disease or Erosive GERD) and relief of heartburn associated with Erosive GERD.
- to maintain healing of all grades of Erosive GERD and relief of heartburn associated with Erosive GERD.
- for the relief of heartburn associated with Non-Erosive GERD.
- in combination with amoxicillin and clarithromycin for the treatment of *Helicobacter pylori* (*H. pylori*) infection.
- in combination with amoxicillin for the treatment of *H. pylori* infection.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

VOQUEZNA is contraindicated in patients with a known hypersensitivity to vonoprazan or any component of VOQUEZNA, or in patients receiving rilpivirine-containing products.

For information about contraindications of antibacterial agents (clarithromycin and amoxicillin) indicated in combination with VOQUEZNA, refer to the Contraindications section of the corresponding prescribing information.

WARNINGS AND PRECAUTIONS

Presence of Gastric Malignancy: In adults, symptomatic response to therapy with VOQUEZNA does not preclude the presence of gastric malignancy. Consider additional follow-up and diagnostic testing in patients who have a suboptimal response or an early symptomatic relapse after completing treatment with VOQUEZNA. In older patients, also consider endoscopy.

Please see additional Important Safety Information throughout and <u>accompanying</u> full Prescribing Information.



PRIOR AUTHORIZATION

Your patient's health plan may require a prior authorization (PA). A PA is a requirement from a health plan that a healthcare provider must satisfy before a patient's medication can be covered. Without an approved PA, the health plan may refuse to cover the medication, leaving the patient responsible for the full cost.

This checklist can help guide you through the information health plans may need from you. Incomplete information may lead to a denial of VOQUEZNA.

Coverage criteria may vary, so it is important to review specific health plan guidelines. Some plans may require a specific PA form.

PRIOR AUTHORIZATION CHECKLIST

PATIENT INFORMATION

- Name
- Address
- Date of birth
- Social Security number

HCP INFORMATION

- Name
- Specialty
- Tax ID number
- Office address
- Phone/fax number
- NPI number

INSURANCE INFORMATION

- Phone number
- Name of policy holder
- Plan ID number
- Group number
- Address
- Copy of insurance card
- Completed and signed plan-specific PA form

MEDICAL DOCUMENTATION

ICD-10-CM Diagnosis Code

- K21.9—Gastro-esophageal reflux disease without esophagitis
- K21.00—Gastro-esophageal reflux disease with esophagitis, without bleeding
- K21.01—Gastro-esophageal reflux disease with esophagitis, with bleeding
- B96.81—Helicobacter Pylori

Patient History

- Frequency and severity of symptoms
- Complications
- Diagnosis testing results
- Endoscopy, if available

Previous/Current Treatments

- Dosage and start therapy dates
- Documentation of history of failure, contraindication, or intolerance to other treatments
- Documentation of any other PPI products the patient has tried

Copy of chart notes

Details about diagnosis, current condition, and treatment history



APPEALS AND DENIALS

Please be sure to check your documentation carefully, as the most likely reason for denial is incorrect information or lack of documentation.

If your patient is denied, you can appeal the decision by submitting a formal request to the health plan. You can request a formulary exception or tiering exception if VOQUEZNA is essential, asking the insurer to make an exception for your patient's case. Continue to follow up with the health plan if the plan does not respond within 30 days.

APPEAL CHECKLIST

DENIAL REASON

Include denial reason or copy of explanation of benefits letter.

APPEAL LETTER

Include a summary of the patient's medical history and the rationale for VOQUEZNA treatment as an exception to the criteria.

SUPPORTING DOCUMENTS

Clinical documents that demonstrate a medical necessity.



HCPs can send the VOQUEZNA prescription to the patient's selected pharmacy or BlinkRx.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Acute Tubulointerstitial Nephritis: Acute tubulointerstitial nephritis (TIN) has been reported with VOQUEZNA. If suspected, discontinue VOQUEZNA and evaluate patients with suspected acute TIN.

Clostridioides difficile-Associated Diarrhea: Published observational studies suggest that proton pump inhibitors (PPIs) may be associated with an increased risk of Clostridioides difficile-associated diarrhea (CDAD), especially in hospitalized patients. VOQUEZNA may also increase the risk of CDAD. Consider CDAD in patients with diarrhea that does not improve. Use the shortest duration of VOQUEZNA appropriate to the condition being treated.

CDAD has been reported with use of nearly all antibacterial agents. For more information specific to antibacterial agents (clarithromycin and amoxicillin) indicated for use in combination with VOQUEZNA, refer to Warnings and Precautions section of the corresponding prescribing information.

Please see additional Important Safety Information throughout and <u>accompanying</u> full Prescribing Information.



ELIGIBLE PATIENTS MAY SAVE ON THEIR PRESCRIPTIONS

There are potential savings with **BLINKR**

Eligible patients with commercial insurance may **pay as little as \$25** for their VOQUEZNA prescription with BlinkRx.

Patients with commercial insurance without VOQUEZNA coverage can access the product through BlinkRx for as little as \$50 per month.

NEED HELP GETTING ELIGIBLE PATIENTS STARTED ON VOQUEZNA?

PROVIDES ASSISTANCE TO ELIGIBLE PATIENTS

- Available nationwide
- Patients receive a text message with a secure link to their out-of-pocket cost
- Prior authorization support to help limit any delays in therapy
- Delivery of VOQUEZNA from a licensed pharmacy partner
- Onboarding and adherence support from a team of pharmacists and technicians





Commercially insured patients may pay as little as \$25 for their prescription*



VOQUEZNA SAVINGS CARD TERMS AND CONDITIONS

*By using the VOQUEZNA® Savings Card ("Card"), you attest that you meet the eligibility criteria, agree to and will comply with the terms and conditions described below. For patients with commercial drug insurance coverage for VOQUEZNA tablets: Offer available only for 30-count bottle of VOQUEZNA tablets. Patient must have commercial drug insurance with insurance provider coverage for VOQUEZNA to pay as little as \$25. Offer subject to a per fill cap of \$247 and other program limitations. Must be 18 years of age or older to redeem this offer. Patient is responsible for any applicable taxes, fees, amounts exceeding per-fill and program caps or costs that may be applicable after reimbursement limits are reached, including additional copayment and coinsurance amounts. This offer is invalid for patients without commercial drug insurance or whose prescription claims for VOQUEZNA are eligible to be reimbursed, in whole or in part, by any governmental program, including, without limitation, Medicaid, Medicare, Medicare Part D, Medigap, DoD, VA, TRICARE®/ CHAMPUS, or any state patient or pharmaceutical assistance program. This offer is not valid for: Massachusetts residents if an AB-rated generic equivalent is available; California residents if an FDA-approved therapeutic equivalent is available. Available only in the US for residents of the US. By accepting this offer, you agree that if you are required to do so under the terms of your insurance coverage for this prescription or are otherwise required to do so by law, you should notify your insurance carrier of your redemption of this Card. By redeeming this offer, you and the pharmacist agree not to seek reimbursement for all or any part of the benefit received by you through the Savings Card from any third party, such as insurance plans, flexible spending plans or health savings accounts. This Card expires on 12/31/2025. This offer cannot be combined or utilized with any other program, discount, discount card, cash discount card, coupon, incentive, or similar offer involving VOQUEZNA It is prohibited for any person to sell, purchase or trade; or to offer to sell, purchase or trade, or to counterfeit this Card. This offer may be terminated, rescinded, revoked or amended by Phathom Pharmaceuticals, Inc. at any time without notice. Card activation required. This Card is not health insurance. Certain information pertaining to your use of this Card will be shared with Phathom, the sponsor of the Card, and companies working on Phathom's behalf. For more information, please see the Phathom Privacy Policy at https://www.phathompharma.com/privacy-policy/.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

Bone Fracture: Several published observational studies suggest that PPI therapy may be associated with an increased risk for osteoporosis-related fractures of the hip, wrist, or spine, especially in patients receiving high dose (multiple daily doses) and long-term therapy (a year or longer). Bone fracture, including osteoporosis-related fracture, has also been reported with vonoprazan. Use the shortest duration of VOQUEZNA appropriate to the condition being treated. Patients at risk for osteoporosis-related fractures should be managed according to the established treatment guidelines.

Severe Cutaneous Adverse Reactions (SCAR):

Severe cutaneous adverse reactions, including Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN) have been reported with VOQUEZNA. Discontinue VOQUEZNA at the first signs or symptoms of SCAR or other signs of hypersensitivity and consider further evaluation.

Vitamin B12 (Cobalamin) Deficiency: Long-term use of acid-suppressing drugs can lead to malabsorption of Vitamin B12 caused by hypo- or achlorhydria. Vitamin B12 deficiency has been reported postmarketing with vonoprazan. If clinical symptoms consistent with vitamin B12 deficiency are observed in patients treated with VOQUEZNA, consider further workup.

Hypomagnesemia and Mineral Metabolism:

Hypomagnesemia has been reported postmarketing with vonoprazan. Hypomagnesemia may lead to hypocalcemia and/or hypokalemia and may exacerbate underlying hypocalcemia in at-risk patients.

Consider monitoring magnesium levels prior to initiation of VOQUEZNA and periodically in patients expected to be on prolonged treatment, in patients taking drugs that may have increased toxicity in the presence of hypomagnesemia or drugs that may cause hypomagnesemia. Treatment of hypomagnesemia may require magnesium replacement and discontinuation of VOQUEZNA.

Consider monitoring magnesium and calcium levels prior to initiation of VOQUEZNA and periodically while on treatment in patients with a preexisting risk of hypocalcemia. Supplement with magnesium and/ or calcium, as necessary. If hypocalcemia is refractory to treatment, consider discontinuing VOQUEZNA.

Interactions with Diagnostic Investigations for Neuroendocrine Tumors: Serum chromogranin A (CgA) levels increase secondary to drug-induced decreases in gastric acidity. The increased CgA level may cause false positive results in diagnostic investigations for neuroendocrine tumors. Temporarily discontinue VOQUEZNA treatment at least 4 weeks before assessing CgA levels and consider repeating the test if initial CgA levels are high.

Fundic Gland Polyps: Use of VOQUEZNA is associated with a risk of fundic gland polyps that increases with long-term use, especially beyond one year. Fundic gland polyps have been reported with vonoprazan in clinical trials and during postmarketing use with PPIs. Most patients who developed fundic gland polyps were asymptomatic and fundic gland polyps were identified incidentally on endoscopy. Use the shortest duration of VOQUEZNA appropriate to the condition being treated.

ADVERSE REACTIONS:

Healing of Erosive GERD: The most common adverse reactions (≥2% of patients in the VOQUEZNA arm) include gastritis (3%), diarrhea (2%), abdominal distention (2%), abdominal pain (2%), and nausea (2%).

Maintenance of Healed Erosive GERD: The most common adverse reactions (≥3% of patients in the VOQUEZNA arm) include gastritis (6%), abdominal pain (4%), dyspepsia (4%), hypertension (3%), and urinary tract infection (3%).



IMPORTANT SAFETY INFORMATION (cont'd)

ADVERSE REACTIONS (cont'd):

Relief of Heartburn Associated with Non-Erosive GERD: The most common adverse reactions (≥2% of patients in the VOQUEZNA arm) include abdominal pain (2%), constipation (2%), diarrhea (2%), nausea (2%), and urinary tract infection (2%).

Treatment of *H. Pylori* Infection (VOQUEZNA and Amoxicillin): The most common adverse reactions (≥2% in any treatment arm) include diarrhea (5%), abdominal pain (3%), vulvovaginal candidiasis (2%), nasopharyngitis (2%), dysgeusia (1%), headache (1%), and hypertension (1%).

Treatment of *H. Pylori* Infection (VOQUEZNA, Amoxicillin and Clarithromycin): The most common adverse reactions (≥2% in any treatment arm) include dysgeusia (5%), diarrhea (4%), vulvovaginal candidiasis (3%), headache (3%), abdominal pain (2%), hypertension (2%), and nasopharyngitis (<1%).

For more information on adverse reactions and laboratory changes with amoxicillin or clarithromycin, refer to *Adverse Reactions* section of the corresponding prescribing information.

DRUG INTERACTIONS

VOQUEZNA has the potential for clinically important drug interactions, including interactions with drugs dependent on gastric pH for absorption, drugs that are substrates for certain CYP enzymes, and some diagnostic tests. Avoid concomitant use of VOQUEZNA with atazanavir or nelfinavir. See full Prescribing Information for more details about important drug interactions. Consult the labeling of concomitantly used drugs to obtain further information about interactions with vonoprazan.

For information about drug interactions, contraindications, and warnings and precautions of antibacterial agents (amoxicillin or clarithromycin) indicated in combination with VOQUEZNA, refer to their corresponding prescribing information.

USE IN SPECIFIC POPULATIONS

Lactation: Breastfeeding is not recommended during treatment. Because of the potential risk of adverse liver effects shown in animal studies with vonoprazan, advise patients not to breastfeed during treatment with VOQUEZNA.

Renal Impairment: For the healing of Erosive GERD, dosage reduction is recommended in patients with severe renal impairment (eGFR <30 mL/min). Use of VOQUEZNA is not recommended for the treatment of *H. pylori* infection in patients with severe renal impairment.

Hepatic Impairment: For the healing of Erosive GERD, dosage reduction is recommended in patients with moderate to severe hepatic impairment (Child-Pugh Class B and C). Use of VOQUEZNA is not recommended for the treatment of H. pylori infection in patients with moderate to severe hepatic impairment.

You are encouraged to report suspected adverse reactions by contacting Phathom Pharmaceuticals at 1-888-775-PHAT (7428) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see additional Important Safety Information throughout and <u>accompanying</u> full Prescribing Information for VOQUEZNA.