Guidance for Completing a Letter of Medical Necessity for VOQUEZNA® (vonoprazan) tablets

You can customize the following Letter of Medical Necessity template to include important details about your patient's medical history, diagnosis, and treatment plan. Using this sample letter does not guarantee that health plans will cover VOQUEZNA (vonoprazan) tablets. If health plans have specific forms or procedures for the authorization process, use those instead of this sample letter. Keep complete records, including copies of the materials sent, and a log of telephone calls made to the patient's health plan.

See Letter of Medical Necessity template on **pages 5 and 6.**

Please see Important Safety Information on pages 2-4 and click here to see full Prescribing Information for VOQUEZNA.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

VOQUEZNA® (vonoprazan) 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.

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.

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.

IMPORTANT SAFETY INFORMATION (cont'd)

WARNINGS AND PRECAUTIONS (cont'd)

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%).

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.

IMPORTANT SAFETY INFORMATION (cont'd)

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

Pregnancy: There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to VOQUEZNA during pregnancy. Healthcare providers are encouraged to register patients by calling 1-866-609-1612 or visiting https://voqueznapregnancyregistry.com/.

Lactation: There are no data on the effects of vonoprazan on the breastfed child or the effects on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for VOQUEZNA and any potential adverse effects on the breastfed child from VOQUEZNA or from the underlying maternal condition.

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.

INDICATIONS AND USAGE

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.

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 click here to see full Prescribing Information for VOQUEZNA.

[Physician Letterhead]
[Date]
[Health plan name]
ATTN: [Contact title/medical director]
[Contact name (if available)]
[Health plan address]
[City, state, zip]
Patient: [Patient first and last name]
Date of Birth: [MM/DD/YYYY]
Policy ID and Group Number: [Policy ID and Group Number]
Date of Service: [MM/DD/YYYY]

Re: Letter of Medical Necessity for VOQUEZNA® (vonoprazan) tablets

Dear [Contact title],

I am writing on behalf of my patient, [patient first and last name], to document the medical necessity and request coverage for VOQUEZNA (vonoprazan) for [the healing of Erosive Esophagitis, maintenance of healing of Erosive Esophagitis, relief of heartburn associated with Non-Erosive Gastroesophageal Reflux Disease (GERD), treatment of *Helicobacter pylori*] [include primary and secondary ICD-10 codes]. I have read and acknowledged your drug coverage policy and [include brief summary for why VOQUEZNA is a medically appropriate treatment for your patient]. This letter details my clinical rationale along with information about the patient's medical history and treatment.

Patient's Clinical History
[Patient first and last name] has been diagnosed with [Erosive Esophagitis/heartburn associated with Non-Erosive GERD/*H. Pylori*] as of [date of diagnosis]. They have been in my care since [date].

My rationale for prescribing VOQUEZNA is based on [include summary of patient's disease course, prior treatments and durations of each, reasons for discontinuing prior treatments, current symptoms, as well as any other important factors (e.g., comorbidities, age) that impacted your decision, as applicable].

Treatment Plan
VOQUEZNA (vonoprazan) is a potassium-competitive acid blocker (PCAB) that has been shown to provide faster and more sustained acid suppression compared to a traditional proton pump inhibitor (PPI). In my clinical opinion, [patient's name] should receive VOQUEZNA for the following reasons:

[List your rationale for why VOQUEZNA is appropriate for this patient based on diagnosis and medical history. Include documentation of past treatments, as applicable].

I have reviewed your formulary for [Erosive Esophagitis/heartburn associated with Non-Erosive GERD/*H. pylori*] and [summarize why the preferred drugs on formulary are not medically appropriate for your patient at this time].

Summary
Based on the clinical evidence and [patient's name]'s medical history, I believe that VOQUEZNA is the most appropriate treatment option for managing their [insert diagnosis]. I have attached relevant [lab results/medical records/clinical studies] to support my decision. If you have any questions about this matter, please contact me at [physician's phone number] or via email at [physician's email]. Thank you for your time and consideration.

Sincerely,

[Physician's signature]

Enclosures
[List and attach enclosures, which may include:

- Medical records
- Laboratory results
- VOQUEZNA Prescribing Information
- Other supporting documentation]