



H. PYLORI INFECTION AGENTS

Lansoprazole, amoxicillin, clarithromycin

Omeclamox-Pak (omeprazole, clarithromycin, amoxicillin)

Pylera (bismuth subcitrate, metronidazole, tetracycline)

Talicia (omeprazole, amoxicillin, rifabutin)

Voquezna Dual Pak (vonoprazan, amoxicillin)

Voquezna Triple Pak (vonoprazan, amoxicillin, clarithromycin)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Helicobacter pylori (*H. pylori*) is a gram-negative microaerophilic bacterium recognized as a major cause of peptic ulcer disease and gastritis. Infected people have an increased risk of developing gastric cancer and mucosal associated-lymphoid-type (MALT) lymphoma compared with their uninfected counterparts. Asymptomatic infections do not need to be treated. Patients with active duodenal or gastric ulcers should be treated if they are infected. *H. pylori* is typically treated with a combination of antibiotics plus a proton pump inhibitor (PPI), and treatment should be determined on an individual basis (1).

Regulatory Status

FDA-approved indications:

- **Lansoprazole/amoxicillin/clarithromycin** triple therapy is indicated for treating *H. pylori* and duodenal ulcer disease (active or one-year history of a duodenal ulcer) to eradicate *H. pylori* (2).
- **Omeclamox-Pak**, a co-packaged product containing omeprazole, a proton pump inhibitor, clarithromycin, a macrolide antimicrobial, and amoxicillin, a penicillin class antibacterial, is indicated for the treatment of patients with *H. pylori* infection and duodenal ulcer disease (active or up to one-year history) to eradicate *H. pylori* (3).
- **Pylera** is a combination of metronidazole, a nitroimidazole antimicrobial, tetracycline, a tetracycline class antimicrobial and bismuth subcitrate potassium, indicated for use, in combination with omeprazole, for the treatment of patients with *H. pylori* infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate *H. pylori* (4).
- **Talicia** is a three-drug combination of omeprazole, a proton pump inhibitor, amoxicillin, a penicillin-class antibacterial, and rifabutin, a rifamycin antibacterial, indicated for the treatment of *H. pylori* infection in adults (5).



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- **Voquezna Dual Pak** is a co-packaged product containing vonoprazan, a PCAB, and amoxicillin, a penicillin class antibacterial, indicated for the treatment of *H. pylori* infection in adults (6).
- **Voquezna Triple Pak** is a co-packaged product containing vonoprazan, a potassium competitive acid blocker (PCAB), amoxicillin, a penicillin class antibacterial, and clarithromycin, a macrolide antimicrobial, indicated for the treatment of *H. pylori* infection in adults (6).

The safety and effectiveness of the *H. pylori* infection agents included in this policy have not been established in pediatric patients (2-6).

Summary

Lansoprazole/amoxicillin/clarithromycin, Omeclamox-Pak, and Pylera are indicated for the treatment of patients with *H. pylori* infection and duodenal ulcer disease (active or one-year history) to eradicate *H. pylori*. Talicia, Voquezna Dual Pak, and Voquezna Triple Pak are indicated for the treatment of *H. pylori*. The safety and effectiveness of the *H. pylori* infection agents included in this policy have not been established in pediatric patients (2-6).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of lansoprazole/amoxicillin/clarithromycin, Omeclamox-Pak, Pylera, Talicia, Voquezna Dual Pak, and Voquezna Triple Pack while maintaining optimal therapeutic outcomes.

References

1. Connor B. Chapter 4, Travel-Related Infectious Diseases. *Helicobacter pylori*. Centers for Disease Control and Prevention. <https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/helicobacter-pylori>. Accessed on June 7, 2022.



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Voquezna Dual Pak (vonoprazan, amoxicillin)

Voquezna Triple Pak (vonoprazan, amoxicillin, clarithromycin)

2. Lansoprazole/amoxicillin/clarithromycin [package insert]. Princeton, NJ: Sandoz Inc; July 2021.
3. Omeclamox-Pak [package insert]. Nashville, TN: [Cumberland Pharmaceuticals Inc](#); March 2022.
4. Pylera [package insert]. Irvine, CA: Allergan USA, Inc.; Dec 2021.
5. Talicia [package insert]. Raleigh, NC: Redhill Biopharma Inc.; March 2022.
6. Voquezna Dual/Triple Pak [package insert]. Buffalo Grove, IL: Phathom Pharmaceuticals, Inc.; May 2022.