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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Gastrointestinal Agents	**Original Policy Date:**	September 8, 2011
Subject:	*H. pylori* Infection Agents	**Page:**	1 of 6

Last Review Date: March 8, 2024

H. pylori Infection Agents

Description

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)

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).
- **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).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Lansoprazole/amoxicillin/clarithromycin, **Omeclamox-Pak, Pylera, Talicia**, **Voquezna Dual Pak**, and **Voquezna Triple Pak** may be considered **medically necessary** if the conditions indicated below are met.

Lansoprazole/amoxicillin/clarithromycin, **Omeclamox-Pak, Pylera, Talicia**, **Voquezna Dual Pak**, and **Voquezna Triple Pak** may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must the following:

H. pylori infection

AND ALL of the following:

a. Diagnosis has been confirmed by endoscopy, breath testing, or stool testing
b. Lansoprazole/amoxicillin/clarithromycin, Omeclamox-Pak, and Voquezna Triple Pak **only: NOT** clarithromycin-resistant
c. Pylera **only**: will be co-administered with omeprazole
d. **ALL** of the following for Talicia **only**:
    i. Suspected to be clarithromycin-resistant
    ii. **NO** concurrent use with certain HIV medications, such as rilpivirine and delavirdine
e. **NO** previous use of the requested therapy regimen in the last 365 days

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

Quantity

Drug	Quantity per 365 days
Lansoprazole/amoxicillin/clarithromycin	112 capsules **OR**
Omeclamox-Pak	80 capsules **OR**
Pylera	120 capsules **OR**
Talicia	168 capsules **OR**
Voquezna Dual Pak	112 units (84 capsules and 28 tablets) **OR**

Voquezna Triple Pak	112 units (56 capsules and 56 tablets)

Regimens needing more than the quantities listed above are not covered.

Duration 12 months

Prior – Approval Limits

Quantity

Drug	Quantity for 14 days
Lansoprazole/amoxicillin/clarithromycin	112 capsules **OR**
Omeclamox-Pak	80 capsules **OR**
Pylera	120 capsules **OR**
Talicia	168 capsules **OR**
Voquezna Dual Pak	112 units (84 capsules and 28 tablets) **OR**
Voquezna Triple Pak	112 units (56 capsules and 56 tablets)

Regimens needing more than the quantities listed above are not covered.
Must be a different therapy regimen than Pre-PA.

Duration 2 weeks

Prior – Approval *Renewal* Limits

Same as above

Rationale

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.
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.

Policy History

Date	Action
January 2013	Addition of Omeclamox Annual editorial review
June 2014	Annual review and addition of Pylera
September 2015	Annual editorial review and reference update
March 2016	Annual editorial review, Subsection changed from anti-infective agents to gastrointestinal agents, Policy code changed from 5.03.21 to 5.50.21,
September 2016	Annual editorial review and reference update.
March 2017	Annual editorial review and reference update
March 2018	Annual editorial review and reference update
July 2018	Update in Pre-PA, Prior Approval, and Prior Approval *Renewal* Limits Addition of no previous use of the requested therapy regimen in the last 365 days to criteria
September 2018	Annual review
March 2019	Annual review
November 2019	Addition of Talicia and renamed policy Prevpac Pylera Omeclamox Talicia

March 2020	Annual review. Added Talicia requirements that infection is suspected to be clarithromycin-resistant and no concurrent use with certain HIV medications, such as rilpivirine and delavirdine per SME
June 2020	Annual review
September 2021	Annual review
June 2022	Addition of Voquezna. Removed Prevpac brand name due to being discontinued. Renamed policy *H. pylori* Infection Agents.
September 2022	Annual review. Per SME, removed duodenal ulcer disease from criteria and collapsed criteria requirements into one section. Per SME, added requirement that H. pylori infection diagnosis confirmed by endoscopy, breath testing, or stool testing
June 2023	Annual review
March 2024	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.