Effective Date 11/15/2022
Next Review Date… 11/1/2023
Coverage Policy Number IP0009

H. Pylori Infection Products

Table of Contents

Overview 1
Medical Necessity Criteria 1
Reauthorization Criteria 2
Authorization Duration 2
Background 3
References 3

Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This policy supports medical necessity review for the following H. Pylori Infection Products:

- **Omeclamox®-Pak** [amoxicillin (500 mg) / clarithromycin (500 mg) / omeprazole (20 mg)]
- **Pylera®** [(bismuth subcitrate (140 mg) / metronidazole (125 mg) / tetracycline (125 mg)]
- **Voquezna™ Dual Pak** [vonoprazan (20 mg) / amoxicillin (1000 mg)]
- **Voquezna™ Triple Pak** [vonoprazan (20 mg) / amoxicillin (1000 mg) / clarithromycin (500 mg)]
- **Talicia®** [(omeprazole (10 mg), amoxicillin (250 mg), rifabutin (12.5)] delayed-release

Receipt of sample product does not satisfy any criteria requirements for coverage.

Medical Necessity Criteria

Coverage varies across plans and requires the use of preferred products. Refer to the customer's benefit plan document for coverage details.

The products in the table below are considered medically necessary when the following are met:

Employer Group Non-Covered Products and the Preferred Covered Alternatives:

Non-Covered Product	Criteria
Omeclamox-Pak [amoxicillin (500 mg) / clarithromycin (500 mg) / omeprazole (20 mg)]	There is documentation the individual has had an inadequate response, contraindication, or is intolerant to **TWO** of the following generic regimens (1, 2, 3, 4): 1. Proton Pump Inhibitor (PPI) + amoxicillin + clarithromycin 2. Proton Pump Inhibitor (PPI) + bismuth-containing product + tetracycline + metronidazole 3. Proton Pump Inhibitor (PPI) + amoxicillin + rifabutin 4. Proton Pump Inhibitor (PPI) + levofloxacin + amoxicillin
Pylera [(bismuth subcitrate (140 mg) / metronidazole (125 mg) / tetracycline (125 mg)]	**BOTH** of the following (1 and 2): 1. The individual has had an inadequate response, contraindication, or is intolerant to a Proton Pump Inhibitor (PPI) + amoxicillin + clarithromycin 2. Documented inability to obtain or take generic metronidazole, tetracycline, and bismuth subsalicylate concurrently
Voquezna Dual Pak [vonoprazan (20 mg) / amoxicillin (1000 mg)]	There is documentation the individual has had an inadequate response, contraindication, or is intolerant to **TWO** of the following generic regimens (1, 2, 3, 4, 5): 1. Proton Pump Inhibitor (PPI) + amoxicillin + clarithromycin 2. Proton Pump Inhibitor (PPI) + bismuth-containing product + tetracycline + metronidazole 3. Proton Pump Inhibitor (PPI) + amoxicillin + rifabutin 4. Proton Pump Inhibitor (PPI) + levofloxacin + amoxicillin 5. Proton Pump Inhibitor (PPI) + amoxicillin
Voquezna Triple Pak [vonoprazan (20 mg) / amoxicillin (1000 mg) / clarithromycin (500 mg)]	There is documentation the individual has had an inadequate response, contraindication, or is intolerant to **TWO** of the following generic regimens (1, 2, 3, 4): 1. Proton Pump Inhibitor (PPI) + amoxicillin + clarithromycin 2. Proton Pump Inhibitor (PPI) + bismuth-containing product + tetracycline + metronidazole 3. Proton Pump Inhibitor (PPI) + amoxicillin + rifabutin 4. Proton Pump Inhibitor (PPI) + levofloxacin + amoxicillin
Talicia [(omeprazole (10 mg), amoxicillin (250 mg), rifabutin (12.5)] delayed-release	**BOTH** of the following (1 and 2): 1. The individual has had an inadequate response, contraindication, or is intolerant to a Proton Pump Inhibitor (PPI) + amoxicillin + clarithromycin 2. Documented inability to obtain or take generic amoxicillin, rifabutin, and a prescription-strength Proton Pump Inhibitor (PPI) concurrently

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Reauthorization Criteria

Not applicable for continuation beyond initial approval duration.

Authorization Duration

Initial approval duration: up to 1 month
Reauthorization approval duration: not applicable

Background

OVERVIEW

Indications:

Pylera; lansoprazole capsules, amoxicillin capsules, and clarithromycin tablets (LAC) pack; and Omeclamox-Pak are all indicated for the treatment of patients with Helicobacter pylori infection and duodenal ulcer disease to eradicate H. pylori.[1,2,3]

Talicia, Voquezna Dual Pak, and Voquezna Triple Pak are indicated for the treatment of H. pylori infection in adults.[4,5]

How Supplied:

Pylera and Talicia are three-in-one capsules; the other products in this class are supplied as individual components packaged for daily administration. With the exception of vonoprazan, the individual components of each of these products are available generically (lansoprazole, omeprazole, tetracycline, metronidazole, amoxicillin, clarithromycin, and rifabutin) or over-the-counter (bismuth subsalicylate). While rifabutin is available generically, it is not available in a strength that would allow dosing to match Talicia.

Guidelines:

The 2017 American College of Gastroenterology (ACG) guidelines for the management of H. pylori infection recommend regimens which include at least two drugs.[6]

- Current first-line regimens include a proton pump inhibitor (PPI) and at least two antibiotics administered for 10 to 14 days. Antibiotics include clarithromycin, amoxicillin, metronidazole, bismuth, tetracycline, and levofloxacin. Common regimens include clarithromycin triple therapy (PPI, clarithromycin, and amoxicillin), bismuth quadruple therapy (PPI, bismuth, tetracycline, and metronidazole), and levofloxacin triple therapy (PPI, levofloxacin, and amoxicillin). With the increasing clarithromycin resistance, the ACG recommends clarithromycin triple therapy in regions with clarithromycin resistance < 15% and in patients who have not received a macrolide antibiotic for any indication. The components of Omeclamox-Pak, LAC pack, or Pylera plus a PPI are examples of first-line therapy options.
- Refractory therapy regimens recommended by the ACG (2017) and the American Gastroenterological Association (AGA) [2021] include a PPI and at least one antibiotic administered for 10 to 14 days. Regimens include bismuth quadruple therapy, levofloxacin triple therapy (PPI, amoxicillin, and levofloxacin) or rifabutin triple therapy (PPI, amoxicillin, and rifabutin).[6,7] The AGA and ACG also recommend prescribers conduct a review of prior antibiotic use. If the patient has a history of any treatment with macrolides or fluoroquinolones, then levofloxacin-based or clarithromycin-based treatments, respectively, should be avoided given the high likelihood of resistance. However, resistance to amoxicillin, tetracycline, or rifabutin is rare, and these regimens can be considered for subsequent therapies in refractory H pylori infection.[6,7]

References

1. Omeclamox-Pak® [prescribing information]. Nashville, TN: Cumberland; November 2020.
2. Lansoprazole capsules, amoxicillin capsules, and clarithromycin tablets [prescribing information]. Princeton, NJ: Sandoz; July 2021.
3. Pylera® capsules [prescribing information]. Madison, NJ: Allergan; December 2021
4. Talicia® capsules [prescribing information]. Raleigh, NC: RedHill; October 2021.
5. Voquezna™ Dual Pak™ and Triple Pak™ [prescribing information]. Princeton, NJ: Phantom; May 2022.
6. Chey WD, Leontiadis GI, Howden CW, et al. ACG Clinical Guideline: Treatment of Helicobacter pylori infection. Am J Gastroenterol. 2017; 112:212-238.
7. Shah SC, Iyer PG, Moss SF. AGA clinical practice update on the management of refractory Helicobacter pylori infection: Expert review. Gastroenterology. 2021 Apr; 160(5):1831-1841.

"Cigna Companies" refers to operating subsidiaries of Cigna Corporation. All products and services are provided exclusively by or through such operating subsidiaries, including Cigna Health and Life Insurance Company, Connecticut General Life Insurance Company, Evernorth Behavioral Health, Inc., Cigna Health Management, Inc., and HMO or service company subsidiaries of Cigna Health Corporation. The Cigna name, logo, and other Cigna marks are owned by Cigna Intellectual Property, Inc. © 2022 Cigna.