Preferred Step Therapy

*Helicobacter Pylori* Infection Combination Products

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**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.

**NPF Coverage Policy**

**Drugs Affected**

- Lansoprazole capsules/amoxicillin capsules/clarithromycin tablets triple therapy pack – generic only
- Pylera® (bismuth subcitrate potassium/metronidazole/tetracycline hydrochloride capsules)
- Talicia® (omeprazole/amoxicillin/rifabutin capsules)

This program has been developed to encourage the use of a Step 1 Product prior to the use of a Step 2 Product. If the Preferred Step Therapy rule is not met for a Step 2 Product at the point of service, coverage will be determined by the Preferred Step Therapy criteria below. All approvals are provided for 1 month in duration. **Note:** Omeclamox-Pak® (omeprazole delayed-release capsules/clarithromycin tablets/amoxicillin capsules), also approved for the treatment of *H. pylori* infection, is not targeted in this policy.

**Step 1:** Generic lansoprazole capsules/amoxicillin capsules/clarithromycin tablets triple therapy pack, Talicia

**Step 2:** Pylera

Cigna covers Step 2 agents as medically necessary when the following criteria are met:
1. If the individual has tried one Step 1 Product, approve a Step 2 Product.

2. If the individual has tried one regimen of single-entity products (e.g., clarithromycin + amoxicillin + proton pump inhibitor [e.g., omeprazole, lansoprazole]; bismuth subcitrate + tetracycline + metronidazole + proton pump inhibitor [e.g., omeprazole, lansoprazole]), approve a Step 2 Product.

3. If the individual has a penicillin or amoxicillin allergy, approve a Step 2 Product.

Conditions Not Covered

Any other exception is considered not medically necessary.

Background

Overview

Lansoprazole capsules, amoxicillin capsules, and clarithromycin tablets triple therapy pack and Pylera are indicated for the following uses:\(^1\,^2\)

- **Treatment of *Helicobacter pylori* infection.**
- **Duodenal ulcer disease,** to eradicate *H. pylori.*

Talicia is indicated for the treatment of *H. pylori infection* in adults.\(^3\)

*H. pylori* is a gram-negative microorganism which infects the stomach epithelial lining.\(^4\) *H. pylori* infection is a common, chronic infection, estimated to occur in approximately one-half of the world population, with estimated rates as high as 70% in developing countries.\(^5\)\(^-\)\(^7\) It is estimated that approximately 35% of the US population is infected with *H. pylori.*\(^4\) Infection usually occurs in childhood; however, the infection rate in children is falling and is likely to result in decreased prevalence of *H. pylori* in the future in the US.\(^8\)

References


Last Revision Details

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