

PREFERRED STEP THERAPY POLICY

- POLICY:** *Helicobacter Pylori* Infection Combination Products Preferred Step Therapy Policy
- Lansoprazole capsules/amoxicillin capsules/clarithromycin tablets triple therapy pack – generic only
 - Pylera® (bismuth subcitrate potassium/metronidazole/tetracycline hydrochloride capsules – Allergan USA)
 - Talicia® (omeprazole/amoxicillin/rifabutin capsules – RedHill Biopharma)

REVIEW DATE: 12/02/2020

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

POLICY STATEMENT

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.

Automation: A patient with a history of one Step 1 Product within the 130-day look-back period is excluded from Step Therapy.

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

Step 2: Pylera

CRITERIA

1. If the patient has tried one Step 1 Product, approve a Step 2 Product.

2. If the patient 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 patient has a penicillin or amoxicillin allergy, approve a Step 2 Product.
4. No other exceptions are recommended.

REFERENCES

1. Lansoprazole/amoxicillin/clarithromycin kit [prescribing information]. Mason, OH: Prasco Labs; December 2018.
2. Pylera[®] capsules [prescribing information]. Madison, NJ: Allergan USA, Inc.; October 2018.
3. Talicia[®] capsules [prescribing information]. Raleigh, NC: RedHill Biopharma Inc.; March 2020.
4. Hooi JKY, Lai WY, Ng WK, et al. Global prevalence of Helicobacter pylori infection: Systematic review and meta-analysis. *Gastroenterology*. 2017;153:420-429.
5. Crowe SE. Helicobacter pylori Infection. *New Engl J Med*. 2019;380:1158-1165.
6. Bravo D, Hoare A, Soto C, et al. Helicobacter pylori in human health and disease: Mechanisms for local gastric and systemic effects. *World J Gastroenterol*. 2018;24:3071-3089.
7. Chey WD, Leontiadis GI, Howden CW, et al. American College of Gastroenterology Clinical Guideline: Treatment of Helicobacter pylori infection. *Am J Gastroenterol*. 2017;112:212-238.
8. Chey WD, Wong BCY, and the Practice Parameters Committee of the American College of Gastroenterology. American College of Gastroenterology guideline on the management of Helicobacter pylori infection. *Am J Gastroenterol*. 2007;102:1808-1825.