

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)
 - Talicia® (omeprazole/amoxicillin/rifabutin capsules – RedHill Biopharma)
 - Voquezna™ Dual Pak™ (vonoprazan tablets and amoxicillin capsules – Phantom)
 - Voquezna™ Triple Pak™ (vonoprazan tablets, amoxicillin capsules, and clarithromycin tablets – Phantom)

REVIEW DATE: 12/01/2021; selected revision 09/28/2022

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 and Voquezna are indicated for the **treatment of *H. pylori* infection** in adults.^{3,4}

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 (30 days) 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, Voquezna

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 Pylera.
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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; October 2018.
3. Talicia® capsules [prescribing information]. Raleigh, NC: RedHill Biopharma; March 2020.
4. Voquezna™ Dual Pak and Triple Pak [prescribing information]. Princeton, NJ: Phantom; May 2022.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	12/02/2020
Annual Revision	No criteria changes.	12/01/2021
Selected Revision	Voquezna products: Voquezna products were added to the policy as Step 2 Products. Exception criteria for a patient who has a penicillin or amoxicillin allergy was made specific for Pylera.	09/28/2022