Pharmacy Policy Bulletin: J-0244 Talicia (omeprazole, amoxicillin, and rifabutin) – Commercial and Healthcare Reform	
Number: J-0244	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Other Managed Prior Authorization = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0244-007	**Original Date:** 01/29/2020
Effective Date: 12/20/2024	**Review Date:** 12/04/2024

Drugs Product(s):	• Talicia (omeprazole, amoxicillin, and rifabutin)
FDA-Approved Indication(s):	• Treatment of *Helicobacter pylori* infection in adults

Background:	• Talicia is a three-drug combination of omeprazole, a proton pump inhibitor (PPI); amoxicillin, a penicillin-class antibacterial; and rifabutin, a rifamycin antibacterial. Omeprazole acts through suppressing gastric acid secretion by blocking the acid pump within the gastric parietal cells. Amoxicillin acts through the inhibition of cell wall biosynthesis that leads to the death of bacteria. Rifabutin inhibits DNA-dependent RNA polymerase in susceptible microorganisms, but not in mammalian cells, preventing chain initiation. • *Helicobacter pylori* is the most prevalent chronic bacterial infection and is associated with peptic ulcer disease, chronic gastritis, gastric adenocarcinoma, and gastric mucosa associated lymphoid tissue (MALT) lymphoma. • All patients with evidence of active infection with *H. pylori* should be offered *H. pylori* eradication treatment. • The 2024 ACG Clinical Guideline: Treatment of *Helicobacter pylori* Infection updated their recommendations for treatment of *H. pylori.* Optimized bismuth-based quadruple therapy (BQT) for 14-days is the recommended therapy for treatment naïve patients as well as treatment-experienced patients who failed to eradicate *H. pylori* with an initial course of PPI-clarithromycin triple therapy. Optimized BQT consists of PPI twice daily, tetracycline 500 mg 4 times daily, metronidazole 500 mg 3 or 4 times daily, and bismuth subcitrate or bismuth subsalicylate 4 times daily for 14 days. Rifabutin-based triple therapy (e.g., Talicia) is a suggested salvage regimen. The guideline specifically recommends against using PPI-clarithromycin triple therapy unless antibiotic sensitivity has been performed and clarithromycin-sensitivity has been proven. • Prescribing Considerations:

	○ Administer Talicia as 4 capsules three times daily (at least 4 hours apart, e.g., morning, mid-day, and evening) with food for 14 days. Do not crush or chew. ○ The choice of initial antibiotic regimen to treat *H. pylori* should be guided by the presence of risk factors for macrolide resistance. ○ If BQT is not an option, then consider referral for formal penicillin allergy testing and/or desensitization. ○ Factors associated with treatment failure include poor patient compliance and resistance of the patient's *H. pylori* strain to the prescribed antibiotics. ○ When a patient has been treated for *H. pylori* and the treatment has failed to eradicate the infection, the patient then requires salvage therapy. Antibiotics included in the initial regimen should generally be avoided; however, amoxicillin can be reused as resistance rarely develops. ○ Rifabutin-based triple therapy has the potential to increase the prevalence of rifabutin-resistant mycobacteria. ○ Reinfection with *H. pylori* following successful bacterial cure is unusual. Recurrence of infection most commonly represents recrudescence of the original bacterial strain. ○ Urine, feces, saliva, sputum, perspiration, tears and skin may be colored brown-orange due to the rifabutin components.

Approval Criteria

I. Approval Criteria

When a benefit, coverage of Talicia may be approved when all of the following criteria are met **(A., B., and C.):**

A. The member is 18 years of age or older.

B. The member has a diagnosis of *H. pylori* infection (ICD-10: B96.81) confirmed by one (1) of the following **(1. or 2.)**:
- **1.** Invasive techniques (e.g., endoscopic)
- **2.** Non-invasive techniques (e.g., urea breath test, stool antigen assay test)

C. The member has previously been treated with all of the following components of a first-line treatment regimen and post-treatment testing has confirmed the treatments have failed to eradicate the *H. pylori* infection **(1. through 4.):**
- **1.** PPI
- **2.** bismuth subcitrate OR bismuth subsalicylate
- **3.** tetracycline
- **4.** metronidazole

II. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 14 day authorization may be granted.

Automatic Approval Criteria

None

References:

1. Talicia [package insert]. Raleigh, NC: RedHill Biopharma Ltd.;May 2024.
2. Niv Y. H pylori recurrence after successful eradication. *World J Gastroenterol*. 2008;14(10):1477-1478.
3. Chey, WD, et al. ACG Clinical Guideline: Treatment of Helicobacter pylori Infection. *Am J Gastroenterol.* 2024; 119:1730-53