

Clinical Policy: Ulcer Therapy Combinations

Reference Number: CP.PMN.277

Effective Date: 06.01.22

Last Review Date: 05.22

Line of Business: Commercial, HIM, Medicaid

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

The following are ulcer therapy combination products that require prior authorization:

- Bismuth subcitrate potassium/metronidazole/tetracycline hydrochloride (Pylera[®])
- Omeprazole/clarithromycin/amoxicillin (Omeclamox-Pak[®])
- Rifabutin/omeprazole/amoxicillin (Talicia[®])

FDA Approved Indication(s)

- Pylera is indicated for use, in combination with omeprazole, for the treatment of patients with *Helicobacter pylori* infection and duodenal ulcer disease (active or history of within the past 5 years) to eradicate *H. pylori*.*
 - Talicia is indicated for the treatment of *Helicobacter pylori* infection in adults.*
 - Omeclamox-Pak is indicated for the treatment of patients with *Helicobacter pylori* infection and duodenal ulcer disease (active or up to one-year history) to eradicate *H. pylori*.*
- * To reduce the development of drug-resistant bacteria and maintain the effectiveness of Pylera/Talicia/Omeclamox-Pak and other antibacterial drugs, these products should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.*

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Omeclamox-Pak, Pylera, and Talicia are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. *Helicobacter pylori* Infection (must meet all):

1. Diagnosis of *H. pylori* infection;
2. Prescribed by or in consultation with a gastroenterologist or infectious disease specialist;
3. Age \geq 18 years;
4. One of the following (a or b):
 - a. Member must instead use the individual components concurrently (i.e., for Talicia generic rifabutin, amoxicillin, omeprazole), unless contraindicated or clinically significant adverse effects are experienced;
 - b. Member must use generic Prevpac (lansoprazole, amoxicillin, clarithromycin), unless contraindicated or clinically significant adverse effects are experienced;

5. For Pylera requests, prescribed in combination with a proton pump inhibitor (e.g., omeprazole);
6. Dose does not exceed one of the following (a, b, or c):
 - a. Omeclamox-Pak: two omeprazole capsules, two clarithromycin tablets, and four amoxicillin capsules per day for 10 days;
 - b. Pylera: 12 capsules per day for 10 days;
 - c. Talicia: 150 mg rifabutin (12 capsules) per day for 14 days.

Approval duration:

Omeclamox-Pak, Pylera – 10 days

Talicia – 14 days

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, CP.PMN.53 for Medicaid, and HIM.PA.154 for health insurance marketplace.

II. Continued Therapy

A. *Helicobacter pylori* Infection

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, CP.PMN.53 for Medicaid, and HIM.PA.154 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, CP.PMN.53 for Medicaid, and HIM.PA.154 for health insurance marketplace, or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
clarithromycin triple regimen	<i>H. pylori</i> infection: 14 days: PPI (standard or double dose) BID; Clarithromycin 500 mg BID; Amoxicillin 1,000 mg BID or metronidazole 500 mg TID (if penicillin allergy)	See dosing regimen
bismuth quadruple regimen	<i>H. pylori</i> infection: 10-14 days: PPI (standard dose) BID; bismuth subcitrate (120-300 mg) or subsalicylate (300 mg) QID; tetracycline 500 mg QID; metronidazole 250 mg QID or 500 mg TID-QID	See dosing regimen
concomitant regimen	<i>H. pylori</i> infection: 10-14 days: PPI (standard dose) BID; Clarithromycin 500 mg BID; Amoxicillin 1,000 mg BID; Metronidazole or tinidazole 500 mg BID	See dosing regimen
sequential regimen	<i>H. pylori</i> infection: 5-7 days of BID PPI (standard dose) + amoxicillin 1,000 mg BID; followed by 5-7 days of BID PPI, clarithromycin 500 mg BID + metronidazole/tinidazole 500 mg BID	See dosing regimen
hybrid regimen	<i>H. pylori</i> infection: 7 days of BID PPI (standard dose) + amoxicillin 1,000 mg BID; followed by 7 days of BID PPI, amoxicillin 1,000 mg BID + clarithromycin 500 mg BID + metronidazole/tinidazole 500 mg BID	See dosing regimen
levofloxacin triple regimen	<i>H. pylori</i> infection: 10-14 days: PPI (standard dose) BID; levofloxacin 500 mg QD; amoxicillin 1,000 mg BID	See dosing regimen
levofloxacin sequential regimen	<i>H. pylori</i> infection: 5-7 days of BID PPI (standard dose) + amoxicillin 1,000 mg BID; followed by 5-7 days of BID PPI, amoxicillin 1,000 mg BID + metronidazole/tinidazole 500 mg BID + QD levofloxacin 500 mg	See dosing regimen
rifabutin triple	<i>H. pylori</i> infection: 10 days of BID PPI (standard dose) + amoxicillin 1,000 mg BID + rifabutin 300 mg QD	See dosing regimen

Therapeutic alternatives are listed as Brand name[®] (generic) when the drug is available by brand name only and generic (Brand name[®]) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Omeclamox-Pak: known hypersensitivity to omeprazole, any macrolide antibiotic, any penicillin, or any component of the formulations, coadministration with pimozide, ergotamine or dihydroergotamine.
 - Pylera: concurrent usage of methoxyflurane, disulfiram usage within the last two weeks, alcoholic beverage consumption for at least three days during or after therapy, patients with Cockayne syndrome, severe renal impairment, women who are pregnant, known hypersensitivity to product components
 - Talicia: hypersensitivity to the components of Talicia; patients receiving rilpivirine-containing products, delavirdine or voriconazole
- Boxed warning(s): none reported

V. Dosage and Administration

Drug Name	Dosing Regimen	Maximum Dose
Omeprazole/clarithromycin/amoxicillin (Omeclamox-Pak)	omeprazole 20 mg plus clarithromycin 500 mg plus amoxicillin 1000 mg, each given PO BID for 10 days	See dosing regimen
Bismuth subcitrate potassium/metronidazole/tetracycline hydrochloride (Pylera)	Three capsules PO QID for 10 days with omeprazole 20 mg BID	See dosing regimen
Rifabutin/ omeprazole/ amoxicillin (Talicia)	Four capsules PO Q8H for 14 days	150 mg rifabutin (12 capsules)/day

VI. Product Availability

Drug Name	Availability
Omeprazole/clarithromycin/amoxicillin (Omeclamox-Pak)	Pack of 10 daily administration cards for morning and evening dosing, each containing: <ul style="list-style-type: none"> • Two 20 mg omeprazole delayed-release capsules • Two 500 mg clarithromycin tablets • Four 500 mg amoxicillin capsules
Bismuth subcitrate potassium/metronidazole/tetracycline hydrochloride (Pylera)	Each capsule contains: 140 mg of bismuth subcitrate potassium, 125 mg metronidazole, 125 mg of tetracycline hydrochloride
Rifabutin/omeprazole/ amoxicillin (Talicia)	Delayed-release capsule: omeprazole 10 mg, (equivalent to 10.3 mg of omeprazole magnesium), amoxicillin 250 mg, and rifabutin 12.5 mg

VII. References

1. Omeclamox-Pak Prescribing Information. Nashville, TN: Cumberland Pharmaceuticals Inc.; November 2020. Available at: <https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=9e52c29a-fdbe-4a4d-b280-d700eba5b94f>. Accessed February 21, 2022.
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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created per February SDC and prior clinical guidance (Talicia removed from CP.PMN.223).	02.17.22	05.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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