Prior Authorization Review Panel

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CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2020**
Policy Number: PA.CP.PMN.223	**Effective Date: 01/15//2020** **Revision Date: 01/15/2020**
Policy Name: Rifabutin (Mycobutin), Rifabutin/Omeprazole/Amoxicillin (Talicia)	

Type of Submission – Check all that apply:

- ✓ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

New Policy Created

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Rifabutin (Mycobutin), Rifabutin/Omeprazole/Amoxicillin (Talicia)

Reference Number: PA.CP.PMN.223
Effective Date: 01/2020
Last Review Date: 01/2020

Revision Log

Description
Rifabutin (Mycobutin®) is a derivative of rifamycin, an antimycobacterial agent.

Rifabutin/omeprazole/amoxicillin (Talicia®) is a three-drug combination of rifabutin; omeprazole, a proton pump inhibitor; and amoxicillin, a penicillin-class antibacterial.

FDA Approved Indication(s)
Mycobutin is indicated for the prevention of disseminated *Mycobacterium avium* complex (MAC) disease in patients with advanced HIV infection.

Talicia is indicated for the treatment of *Helicobacter pylori* infection in adults.

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 PA Health & Wellness® that Mycobutin and Talicia are **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. *Mycobacterium avium* Complex Prophylaxis (must meet all)**:**
1. Request is for Mycobutin;
2. Prescribed by or in consultation with an HIV or infectious disease specialist;
3. Age ≥ 18 years;
4. Failure of azithromycin or clarithromycin, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 300 mg (2 capsules) per day.

Approval duration: 12 months

B. *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 ≥ 18 years;
4. Failure of a first-line treatment regimen (see *Appendix B*), unless contraindicated or clinically significant adverse effects are experienced or culture and sensitivity report shows resistance or lack of susceptibility of *H. pylori* to all first-line treatment regimens;

5. For Mycobutin requests, prescribed in combination with amoxicillin and a proton pump inhibitor;
6. For Talicia requests, medical justification supports inability to use the individual components (i.e., generic rifabutin, amoxicillin, omeprazole) concurrently (e.g., contraindications to the excipients);
7. Dose does not exceed one of the following (a or b):
   a. Mycobutin: 300 mg (2 capsules) per day;
   b. Talicia: 150 mg rifabutin (12 capsules) per day.

Approval duration:
Mycobutin – 10 days
Talicia – 14 days

C. Tuberculosis (off-label) (must meet all)**:**
1. Diagnosis of tuberculosis infection;
2. Request is for Mycobutin;
3. Prescribed by or in consultation with an HIV or infectious disease specialist;
4. Documentation of current treatment with protease inhibitors, non-nucleoside reverse transcriptase inhibitors (NNRTIs), or maraviroc for the treatment of HIV infection, or if medical justification supports intolerance to use rifampin;
5. Age ≥ 18 years;
6. Dose does not exceed 5 mg/kg per day.

Approval duration: 12 months

D. Other diagnoses/indications
1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. *Mycobacterium avium* Complex Prophylaxis (must meet all)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 300 mg (2 capsules) per day.

Approval duration: 12 months

B. *Helicobacter pylori* Infection
1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

C. Tuberculosis (must meet all):
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;

2. Documentation of current treatment with protease inhibitors, non-nucleoside reverse transcriptase inhibitors (NNRTIs), or maraviroc for the treatment of HIV infection, or if medical justification supports intolerance to use rifampin;
3. If request is for a dose increase, new dose does not exceed 5 mg/kg per day.

Approval duration: Up to a total duration of 12 months

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

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 – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
NNRTI: non-nucleoside reverse transcriptase inhibitors

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
azithromycin	**MAC:** 1,200 mg PO once weekly or 600 mg PO twice weekly	500 mg/day
clarithromycin	**MAC:** 500 mg PO BID	1.5 g/day
clarithromycin triple regimen	***H. pylori* infection:** 14 days: PPI (standard or double dose) BID; Clarithromycin 500 mg; Amoxicillin 1,000 mg or metronidazole 500 mg TID (if penicillin allergy)	See dosing regimen
bismuth quadruple regimen	***H. pylori* 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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
concomitant regimen	***H. pylori* infection:** 10-14 days: PPI (standard dose) BID; Clarithromycin 500 mg; Amoxicillin 1,000 mg; Metronidazole or tinidazole 500 mg	See dosing regimen
sequential regimen	***H. pylori* infection:** 5-7 days of BID PPI (standard dose) + amoxicillin 1,000 mg; followed by 5-7 days of BID PPI, clarithromycin 500 mg + metronidazole/tinidazole	See dosing regimen
hybrid regimen	***H. pylori* infection:** 7 days of BID PPI (standard dose) + amoxicillin 1,000 mg; followed by 7 days of BID PPI, amoxicillin + clarithromycin 500 mg + metronidazole/tinidazole	See dosing regimen
levofloxacin triple regimen	***H. pylori* infection:** 10-14 days: PPI (standard dose) BID; levofloxacin 500 mg QD; amoxicillin 1,000 mg BID	See dosing regimen
levofloxacin sequential regimen	***H. pylori* infection:** 5-7 days of BID PPI (standard dose) + amoxicillin 1,000 mg; followed by 5-7 days of BID PPI, amoxicillin + metronidazole/tinidazole + QD levofloxacin 500 mg	See dosing regimen
rifabutin triple	***H. pylori* 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):
  - Mycobutin: clinically significant hypersensitivity to rifabutin or to any other rifamycins
  - Talicia: hypersensitivity to the components of Talicia; patients receiving rilpivirine-containing products, delavirdine or voriconazole
- Boxed warning(s): none reported

Appendix D: General Information

- There is no evidence that rifabutin is an effective prophylaxis against Mycobacterium tuberculosis.

V. Dosage and Administration

Drug Name	Indication	Dosing Regimen	Maximum Dose
Rifabutin (Mycobutin)	MAC prophylaxis	300 mg PO QD or 150 mg PO BID	300 mg/day
	Tuberculosis infection in patients co-infected with HIV	5 mg/kg PO QD in combination with other agents for up to 12 months	5 mg/kg/day
	H. pylori infection	300 mg PO QD with amoxicillin 1 g PO BID and proton pump inhibitor PO BID	300 mg/day
Rifabutin/ omeprazole/ amoxicillin (Talicia)	*H. pylori* infection	Four capsules PO Q8H	150 mg rifabutin (12 capsules)/day

VI. Product Availability

Drug Name	Availability
Rifabutin (Mycobutin)	Capsule: 150 mg
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. Mycobutin Prescribing Information. New York, New York: Pharmacia & Upjohn Co; May 2015. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2015/050689s022lbl.pdf Accessed August 22, 2019.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/. Accessed August 22, 2019.
3. U.S. Department of Health and Human Services. Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents. Available at: https://aidsinfo.nih.gov/guidelines/html/4/adult-and-adolescent-opportunistic-infection/354/primary-prophylaxis. Accessed August 22, 2019.
4. Talicia Prescribing Information. Raleigh, NC: RedHill Biopharma Inc.; November 2019. Available at: https://www.redhillbio.com/talicia. Accessed November 6, 2019.
5. Chey WD, Leontiadis GI, Howden CW, et al. ACG Clinical Guideline: Treatment of Helicobacter pylori Infection. American Journal of Gastroenterology: 2017 January 10; doi: 10.1038/ajg.2016.563.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01/2020	