Prior Authorization Review Panel

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: 02/01/2025**
Policy Number: PA.CP.PMN.223	**Effective Date: 01/2020** **Revision Date: 01/2025**
Policy Name: Rifabutin (Mycobutin)	

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:

1Q 2025 annual review: no significant changes; references reviewed and updated.

Name of Authorized Individual (Please type or print): **Craig A. Butler, MD MBA**	**Signature of Authorized Individual:**

Clinical Policy: Rifabutin (Mycobutin)

Reference Number: PA.CP.PMN.223
Effective Date: 01/2020
Last Review Date: 01/2025

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

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

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 PA Health & Wellness® that Mycobutin and rifabutin 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 MAC prophylaxis in member with HIV;
2. Prescribed by or in consultation with an HIV or infectious disease specialist;
3. Failure of azithromycin or clarithromycin, unless clinically significant adverse effects are experienced or both are contraindicated;
4. If request is for brand Mycobutin, member must use generic rifabutin 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)**:**

** For Talicia® requests, see PHW.PDL.001 H. Pylori Treatments*

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, 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 (off-label) requests, prescribed in combination with amoxicillin and a proton pump inhibitor;
6. If request is for brand Mycobutin, member must use generic rifabutin unless contraindicated or clinically significant adverse effects are experienced;
7. Dose does not exceed 300 mg (2 capsules) per day;

Approval duration: 10 days

C. Tuberculosis (off-label) (must meet all)**:**
1. Diagnosis of tuberculosis infection in member with HIV;
2. Prescribed by or in consultation with an HIV or infectious disease specialist;
3. Documentation of current or anticipated 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;
4. If request is for brand Mycobutin, member must use generic rifabutin unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed one of the following (a or b):
   a. 300 mg (2 capsules) per day;
   b. 600 mg (4 capsules) per day and member is being treated with efavirenz.

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.PHARM.01) applies;
2. Member is responding positively to therapy;
3. If request is for brand Mycobutin, member must use generic rifabutin unless contraindicated or clinically significant adverse effects are experienced;
4. 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 (off-label) (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.PHARM.01) applies;
2. Member has not received more than 12 months of therapy;
3. Documentation of current treatment with protease inhibitors, non-nucleoside reverse transcriptase inhibitors (NNRTIs), or integrase strand transfer inhibitors (INSTIs) other than elvitegravir for the treatment of HIV infection;
4. If request is for brand Mycobutin, member must use generic rifabutin unless contraindicated or clinically significant adverse effects are experienced;
5. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. 300 mg (2 capsules) per day;

b. 600 mg (4 capsules) per day and member is being treated with efavirenz.

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.PHARM.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
INSTIs: integrase strand transfer
MAC: *Mycobacterium avium* complex
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 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
concomitant regimen	***H. pylori* infection:** 10-14 days: PPI (standard dose) BID; Clarithromycin 500 mg;	See dosing regimen

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	Amoxicillin 1,000 mg; Metronidazole or tinidazole 500 mg	
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

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): clinically significant hypersensitivity to rifabutin or to any other rifamycins
- 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

Indication	Dosing Regimen	Maximum Dose
MAC prophylaxis	300 mg PO QD or 150 mg PO BID	300 mg/day
Tuberculosis infection in patients co-infected with HIV	300 mg (approximately 5 mg/kg) PO QD in combination with other agents for up to 12 months	300 mg/day (600 mg/day if treatment with efavirenz)
H. pylori infection *(off-label)*	300 mg PO QD with amoxicillin 1 g PO BID and proton pump inhibitor PO BID	300 mg/day

VI. Product Availability

Capsule: 150 mg

VII. References

1. Mycobutin Prescribing Information. New York, New York: Pharmacia & Upjohn Co; September 2021. Available at: labeling.pfizer.com/ShowLabeling.aspx?id=635. Accessed October 22, 2024.
2. Clinical Pharmacology [database online]. Elsevier, Inc. Updated periodically. Available at: https://www.clinicalkey.com/pharmacology/. Accessed October 30, 2024.
3. U.S. Department of Health and Human Services. Guidelines for the Prevention and Treatment of Opportunistic Infections in HIV-Infected Adults and Adolescents. Reviewed October 29, 2024. Available at: https://clinicalinfo.hiv.gov/en/guidelines/hiv-clinical-guidelines-adult-and-adolescent-opportunistic-infections/whats-new. Accessed October 30, 2024.
4. 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.Chey, WD, Howden, CW, Moss, SF, et al. ACG Clinical Guideline: Treatment of Helicobacter pylori Infection. The American Journal of Gastroenterology. September 2024. 119(9): 1730-1753.

Reviews, Revisions, and Approvals	Date
Policy created	01/2020
1Q21 annual review: removed Talicia from policy as this was added to the Pennsylvania Medical Assistance Program's Statewide Preferred Drug List; added "off-label" for Mycobutin for *H. pylori* infection; added redirection to generic rifabutin in initial and continuation criteria; references reviewed and updated.	01/2021
1Q 2022 annual review: modified medical justification language to member must use language per updated template; clarified tuberculosis off-label criteria set apples to members with HIV; references reviewed and updated.	01/2022
1Q 2023 annual review: no significant changes; references reviewed and updated.	01/2023
1Q 2024 annual review: added specific requirement that "request is for MAC prophylaxis in member with HIV" to support labeled indication; for off-label use in tuberculosis, added to continuation of therapy the following to support existing approval duration: "member has not received more than 12 months of therapy"; for added clarity with requests for H.pylori added the following note "for Talicia requests, see PHW.PDL.001 H. Pylori Treatments"; reviewed and updated.	01/2024
1Q 2025 annual review: no significant changes; references reviewed and updated.	01/2025