

## **Clinical Policy: Rifabutin (Mycobutin)**

Reference Number: HIM.PA.12

Effective Date: 09.04.18

Last Review Date: 11.19

Line of Business: HIM

[Revision Log](#)

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

### **Description**

Rifabutin (Mycobutin<sup>®</sup>) 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 health plans affiliated with Centene Corporation<sup>®</sup> that Mycobutin is **medically necessary** when the following criteria are met:

#### **I. Initial Approval Criteria**

##### **A. *Mycobacterium avium* Complex Prophylaxis (must meet all):**

1. Prescribed by or in consultation with an HIV or infectious disease specialist;
2. Age  $\geq$  18 years;
3. Failure of azithromycin or clarithromycin, unless contraindicated or clinically significant adverse effects are experienced;
4. Dose does not exceed 300 mg per day.

**Approval duration: 12 months**

##### **B. Tuberculosis (must meet all):**

1. Diagnosis of tuberculosis infection;
2. Prescribed by or in consultation with an HIV or infectious disease specialist;
3. Documentation of current treatment with protease inhibitors or non-nucleoside reverse transcriptase inhibitors (NNRTIs) for the treatment of HIV infection;
4. Age  $\geq$  18 years;
5. Dose does not exceed 5 mg/kg per day.

**Approval duration: 12 months**

##### **C. 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): HIM.PHAR.21 for health insurance marketplace.

## II. Continued Therapy

### A. *Mycobacterium avium* Complex Prophylaxis (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 300 mg per day.

**Approval duration: 12 months**

### B. Tuberculosis (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of current treatment with protease inhibitors or non-nucleoside reverse transcriptase inhibitors (NNRTIs) for the treatment of HIV infection;
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**

### C. 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 6 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): HIM.PHAR.21 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 – HIM.PHAR.21 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
azithromycin	1,200 mg PO once weekly or 600 mg PO twice weekly	500 mg/day
clarithromycin	500 mg PO BID	1.5 g/day

*Therapeutic alternatives are listed as Brand name<sup>®</sup> (generic) when the drug is available by brand name only and generic (Brand name<sup>®</sup>) 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	5 mg/kg PO QD in combination with other agents for up to 12 months	5 mg/kg/day

**VI. Product Availability**

Capsule: 150 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](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.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	09.04.18	11.18
4Q 2019 annual review: no significant changes; references reviewed and updated.	09.03.19	11.19

**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.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note:**

**For Health Insurance Marketplace members**, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.

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