# Clinical Policy: Rifapentine (Priftin)

Reference Number: PA.CP.PMN.05
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Coding Implications
Revision Log

**Description**
Rifapentine (Priftin®) is a cyclopentyl rifamycin antimycobacterial agent.

**FDA approved indication**
Priftin is indicated for:

- Patients 12 years of age and older for the treatment of active pulmonary tuberculosis (TB) caused by Mycobacterium tuberculosis (*M. tuberculosis*) in combination with one or more anti-tuberculosis drugs to which the isolate is susceptible
- The treatment of latent tuberculosis infection (LTBI) caused by *M.tuberculosis* in combination with isoniazid in patients 2 years of age and older at high risk of progression to TB disease.

Limitation(s) of use:

- Do not use Priftin monotherapy in either the initial or the continuation phases of active antituberculous treatment. Priftin should not be used once-weekly in the continuation phase regimen in combination with isoniazid in HIV-infected patients with active TB because of a higher rate of failure and/or relapse with rifampin-resistant organisms. Priftin has not been studied as part of the initial phase treatment regimen in HIV-infected patients with active pulmonary tuberculosis
- Active tuberculosis disease should be ruled out before initiating treatment for latent tuberculosis infection. Priftin must always be used in combination with isoniazid as a 12-week once-weekly regimen for the treatment of latent tuberculosis infection. Priftin in combination with isoniazid is not recommended for individuals presumed to be exposed to rifamycin- or - isoniazid resistant *M. tuberculosis*.

**Policy/Criteria**
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria **

It is the policy of Pennsylvania Health and Wellness® that Priftin is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Active Pulmonary Tuberculosis Infection** (must meet all)**:**

1. Diagnosis of pulmonary tuberculosis;
2. Prescribed in combination with one or more anti-tuberculosis drugs (e.g., isoniazid, rifampin, pyrazinamide, ethambutol);
3. Member is not HIV-positive;
4. Dose does not exceed the following:

a. Induction phase of treatment: 600 mg twice weekly for 2 months;
b. Continuation phase: 600 mg once weekly for 4 months.

**Approval duration: 6 months**

**B. Latent Tuberculosis Infection** (must meet all)**:**
1. Diagnosis of latent tuberculosis infection;
2. Failure of ≥ 9 month trial of isoniazid at maximally indicated doses;
3. Prescribed in combination with isoniazid;
4. Request does not exceed 900 mg weekly (6 tablets/week).

**Approval duration: 12 weeks**

**C.** Other diagnoses/indications – Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

## II. Continued Therapy

**A. Active Pulmonary Tuberculosis** (must meet all)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member has not received up to 6 months of therapy;
3. Prescribed in combination with one or more anti-tuberculosis drugs (e.g. isoniazid, rifampin, pyrazinamide, ethambutol);
4. If request is for a dose increase, new dose does not exceed the following:
   a. Induction phase of treatment: 600 mg twice weekly for 2 months;
   b. Continuation phase: 600 mg once weekly for 4 months.

**Approval duration: Approve up to 6 months of total treatment**

**B. Latent Tuberculosis Infection** (must meet all):
1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member has not yet received 12 weeks of therapy;
3. Prescribed in combination with isoniazid;
4. Dose does not exceed 900 mg weekly (6 tablets/week).

**Approval duration: Up to 12 weeks of total treatment**

**C. Other diagnoses/indications** (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellnessbenefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

**Approval duration: 3 months or duration of request (whichever is less)**

## 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 policy – PA.CP.PMN.53 or evidence of coverage documents

## IV. Appendices/General Information

*Appendix A: Abbreviation/Acronym Key*

FDA: Food and Drug Administration
HIV: human immunodeficiency virus
INH: isoniazid
LTBI: latent tuberculosis infection
*M. tuberculosis*: *Mycobacterium tuberculosis*
DOT: directly observed therapy
RIF: rifampin

*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 |
|---|---|---|
| isoniazid | 5 mg/kg up to 300 mg daily in a single dose or 15 mg/kg up to 900 mg/day, two or three times/week PO or IM | 300 mg/day daily or 900 mg/day for twice weekly therapy |

*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): history of hypersensitivity of rifamycins
- Boxed warning(s): none reported

## V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|---|---|---|
| Active Pulmonary Tuberculosis | Initial: 600 mg twice weekly for two months as directly observed therapy (DOT), with no less than 72 hours between doses, in combination with other anti- tuberculosis drugs for 2 months<br><br>Continuation: 600 mg once-weekly for 4 months as DOT with isoniazid or another appropriate anti- tuberculosis agent for 4 months | 900 mg/dose |
| Latent Tuberculosis Infection | In combination with isoniazid once-weekly for 12 weeks as directly observed therapy.<br>Adults and children ≥ 12 years: Priftin (based on weight, see table below) and isoniazid 15 mg/kg (900 mg maximum)<br>Children 2–11 years: Priftin (based on weight, see table below) and isoniazid 25 mg/kg (900 mg maximum) | 900 mg/dose |

| Weight Range | Priftin Dose | Number of Priftin tablets |
|---|---|---|
| 10–14 kg | 300 mg | 2 |
| 14.1–25 kg | 450 mg | 3 |
| 25.1– 32 kg | 600 mg | 4 |
| 32.1–50 kg | 750 mg | 5 |
| > 50 kg | 900 mg | 6 |

## VI. Product Availability

Tablet: 150 mg

## VII. References

1. Priftin Prescribing Information. Bridgewater, NJ: Sanofi-Aventis U.S. LLC; August 2017. Available at: http://products.sanofi.us/. Accessed October 2018.
2. Centers for Disease Control and Prevention. Recommendations for use of isoniazid-rifapentine regimen with direct observation to treat latent mycobacterium tuberculosis infection: United States, 2011.MMWR Morb Mortal Wkly Rep 2011;60(48);1650-1653.
3. Centers for Disease Control and Prevention. Treatment of tuberculosis, American Thoracic Society, CDC, and Infectious Diseases Society of America. MMWR 2003;52(No. RR-11):1-77.
4. Nahid P, Dorman SE, Alipanah N et al. Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis. Clin Infect Dis. 2016 Oct 1;63(7):e147-95. doi: 10.1093/cid/ciw376. Epub 2016 Aug 10.

| Reviews, Revisions, and Approvals | Date | Approval Date |
|---|---|---|
| References reviewed and updated. | 02/18 | |
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