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: 02/01/2022**
Policy Number: PA.CP.PMN.05	**Effective Date: 01/2018** **Revision Date: 01/2022**
Policy Name: Rifapentine (Priftin)	

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 2022 annual review: references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Rifapentine (Priftin)

Reference Number: PA.CP.PMN.05
Effective Date: 02/16
Last Review Date: 01/2022

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 TB;
2. Age ≥ 12 years
3. Prescribed in combination with one or more anti-tuberculosis drugs (e.g., isoniazid, rifampin, pyrazinamide, ethambutol);
4. Member is not HIV-positive;
5. 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 LTBI ;
2. Age ≥ 2 years;
3. Prescribed in combination with isoniazid;
4. Dose 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 (4 tablets) twice weekly for 2 months;
   b. Continuation phase: 600 mg (4 tablets) 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 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 or self-administration Adults and children ≥ 12 years: Priftin (based on weight, see table below) and isoniazid 15 mg/kg (900 mg maximum) 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

Weight Range	Priftin Dose	Number of Priftin tablets
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; June 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/021024s017s018lbl.pdf. Accessed September 23, 2021.
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. Update of recommendations for use of isoniazid-rifapentine regimen to treat latent mycobacterium tuberculosis infection: United States, 2018. MMWR Morb Mortal Wkly Rep 2018; 67(25);723-726.
4. 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.
5. 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.
6. Borisov AS, Bamrah Morris S, Njie GJ, et al. Update of recommendations for use of once-weekly isoniazid-rifapentin regimen to treat latent Mycobaceterium tuberculosis Infection. MMWR. 2018;67:723-726.
7. Sterling TR, Njie G, Zenner D, et al. Guidelines for the Treatment of Latent Tuberculosis Infection: Recommendations from the National Tuberculosis Controllers Association and CDC, 2020. MMWR. February 14, 2020; 69 (1): 1-11.
8. WHO: Latent tuberculosis infection - Updated and consolidated guidelines for programmatic management. 2018. Available at: https://apps.who.int/iris/bitstream/handle/10665/260233/9789241550239-eng.pdf. Accessed September 23, 2021.

Reviews, Revisions, and Approvals	Date	Approval Date
References reviewed and updated.	02/18	
1Q 2019 annual review: references reviewed and updated.	01/19	
1Q 2020 annual review: latent tuberculosis infection dosing regimen updated to include self-administration as per updated CDC recommendations; references reviewed and updated.	01/2020	

Reviews, Revisions, and Approvals	Date	Approval Date
1Q 2021 annual review: added age limits per FDA labeling; references reviewed and updated.	01/2021	
1Q 2022 annual review: references reviewed and updated.	01/2022	