Pharmacy Medical Necessity Guidelines:
Pretomanid Tablet

Effective: February 10, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

Pretomanid is an antimycobacterial indicated, as part of a combination regimen with bedaquiline and linezolid for the treatment of adults with:

- Pulmonary tuberculosis (TB) that is resistant to isoniazid, rifamycins, a fluoroquinolone and a second line injectable antibacterial drug, OR
- Pulmonary TB resistant to isoniazid and rifampin, who are treatment-intolerant or nonresponsive to standard therapy.

Pretomanid is not indicated for patients with:

- Drug-sensitive (DS) tuberculosis
- Latent infection due to *Mycobacterium tuberculosis*
- Extra-pulmonary infection due to *Mycobacterium tuberculosis*
- TB resistant to isoniazid and rifampin, who are responsive to standard therapy and not treatment-intolerant
- TB with known resistance to any component of the combination

Safety and effectiveness of pretomanid have not been established for its use in combination with drugs other than bedaquiline and linezolid as part of the recommended dosing regimen.

COVERAGE GUIDELINES

The plan may authorize coverage of Pretomanid for Members when **ALL** of the following criteria are met:

1. The Member was started on Pretomanid in the inpatient setting

OR

1. The Member has one of the following diagnoses
   a. Pulmonary tuberculosis that is resistant to isoniazid, rifamycins, a fluoroquinolone and a second line injectable antibacterial drug
   b. Pulmonary tuberculosis resistant to isoniazid and rifampin that is treatment-intolerant or nonresponsive to standard therapy

AND

2. Pretomanid will be used in combination with bedaquiline and linezolid

LIMITATIONS

None

CODES

None

REFERENCES

1. Pretomanid tablet [prescribing information]. Morgantown, WV: Mylan Specialty LP;November 2024.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. May 9, 2023: Effective August 1, 2023, updated the diagnostic criteria to align with the new FDA-approved indication.
2. February 13, 2024: Effective May 1, 2024, updated criteria to clarify both approvable diagnoses. Updated fax number for RxUM.
3. February 11, 2025: No changes
4. February 10, 2026: No changes.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services