PRIOR AUTHORIZATION POLICY

POLICY: Infectious Disease – Pretomanid Prior Authorization Policy
- Pretomanid tablets (Mylan)

REVIEW DATE: 12/11/2024

OVERVIEW

Pretomanid, a nitroimidazole, is indicated as part of a combination regimen with Sirturo® (bedaquiline tablets) and linezolid tablets or oral suspension (Zyvox®, generic) for the treatment of **pulmonary extensively drug-resistant or treatment-intolerant or nonresponsive multidrug-resistant tuberculosis (TB)** in adults.[1] Approval of this indication is based on limited clinical safety and efficacy data. This drug is indicated for use in a limited and specific population of patients.

Limitation of use: Pretomanid is not indicated for use in patients with the following conditions: drug-sensitive TB, latent infection due to *Mycobacterium tuberculosis*, extra-pulmonary infection due to *M. tuberculosis*, multidrug-resistant TB that is not treatment-intolerant or nonresponsive to standard therapy. The safety and effectiveness of Pretomanid when used with drugs other than Sirturo and linezolid have not been established.

The prescribing information notes the total duration of treatment with Pretomanid, Sirturo, and linezolid to be 26 weeks.[1] The dosing of the combination regimen can be extended beyond 26 weeks.[2]

Guidelines

The World Health Organization (WHO) issued consolidated guidelines (2022) with information on the choice and design of regimens for the treatment of drug-resistant TB, including multidrug- or rifampin-resistant TB and confirmed rifampicin-susceptible, isoniazid-resistant TB.[2] Drug susceptibility tests are recommended to assist the prescriber in choosing the appropriate initial regimen. In addition, a surveillance system is recommended to determine the local prevalence of drug-resistant TB strains. The WHO notes that the duration of treatment is different for regimens containing different drugs. The duration for regimens containing Pretomanid, Sirturo, and linezolid range from 6 to 9 months.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Pretomanid. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Pretomanid as well as the monitoring required for adverse events and long-term efficacy, approval requires Pretomanid to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Pretomanid is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Tuberculosis.** Approve for 9 months if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i, ii, or iii):
     - **i.** Patient has extensively drug resistant tuberculosis; OR
     - **ii.** Patient has treatment-intolerant tuberculosis; OR
     - **iii.** Patient has nonresponsive multidrug-resistant tuberculosis; AND
   - **C)** Pretomanid is prescribed in combination with Sirturo (bedaquiline tablets) and linezolid tablets or oral suspension (Zyvox, generic); AND
   - **D)** The medication is prescribed by or in consultation with an infectious diseases specialist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Pretomanid is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Pretomanid tablets [prescribing information]. Limited Hyerabad, India: Mylan; November 2024.
2. World Health Organization consolidated guidelines on tuberculosis. Module 4: treatment - drug-resistant tuberculosis treatment, 2022. Geneva: World Health Organization. 2022. Available at: https://www.who.int/publications/i/item/9789240063129. Accessed on December 5, 2024.