PRIOR AUTHORIZATION POLICY

POLICY: Infectious Disease – Pretomanid Prior Authorization Policy
- Pretomanid tablets (Global Alliance for TB Drug Development/Mylan)

REVIEW DATE: 12/06/2023

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 infections 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 a 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.

- **Pretomanid tablets (Global Alliance for TB Drug Development/Mylan) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

FDA-Approved Indication

1. **Tuberculosis.** Approve for 9 months if the patient meets 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 COVERED

- **Pretomanid tablets (Global Alliance for TB Drug Development/Mylan) is(are) considered experimental, investigational or unproven for ANY other use(s).**

REFERENCES

1. Pretomanid tablets [prescribing information]. Limited Hyerabad, India: Mylan; December 2022.

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 1, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	11/16/2022
Annual Revision	No criteria changes.	12/06/2023