PRIOR AUTHORIZATION POLICY

POLICY: Infectious Disease – Sirturo Prior Authorization Policy
- Sirturo® (bedaquiline fumarate tablets – Janssen)

REVIEW DATE: 11/16/2022

OVERVIEW

Sirturo, a diarylquinolone antimycobacterial, is indicated as part of a combination therapy in the treatment of patients ≥ 5 years of age (weighing ≥ 15 kg) with **pulmonary multidrug-resistant tuberculosis (TB)**.[1] Reserve Sirturo for use when an effective treatment regimen cannot otherwise be provided. This indication is approved under accelerated approval based on time to sputum culture conversion. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Limitations of use: Sirturo should not be used for latent infections due to *Mycobacterium tuberculosis*, drug-sensitive TB, extra-pulmonary TB, and infections caused by non-tuberculous mycobacteria. The safety and efficacy of Sirturo in the treatment of patients infected with human immunodeficiency virus (HIV) with multidrug-resistant TB have not been established as clinical data are limited.

The prescribing information notes the total duration of treatment with Sirturo to be 24 weeks (adults and pediatric patients).[1]

Guidelines

The World Health Organization issued an operational handbook (2020) 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. There are different regimens that include Sirturo and other drugs (e.g., rifampicin, ethambutol, levofloxacin/moxifloxacin, pretomanid, linezolid, clofazimine). Sirturo is used for 6 to 9 months, whereas the other drugs in the regimen may be used for different duration.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Sirturo. All approvals are provided for the duration noted below. In cases where 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 Sirturo as well as monitoring required for adverse events and long-term efficacy, approval requires Sirturo to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Tuberculosis (Pulmonary).** Approve for 9 months if the patient meets the following criteria (A, B, C, D, and E):
   - **A)** Patient is ≥ 5 years of age; AND
   - **B)** Patient weighs ≥ 15 kg; AND
   - **C)** Patient has multidrug-resistant tuberculosis; AND
   - **D)** Sirturo is prescribed as part of a combination regimen with other anti-tuberculosis agents; AND
   - **E)** The medication is prescribed by or in consultation with an infectious diseases specialist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Sirturo 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. Sirturo® tablets [prescribing information]. Titusville, NJ: Janssen; September 2021.
2. World Health Organization – Global Tuberculosis Report. 2020. Available at: https://apps.who.int/iris/bitstream/handle/10665/336069/9789240013131-eng.pdf?ua=1. Accessed on November 8, 2022.
3. World Health Organization operational handbook on tuberculosis. Module 4: Treatment - drug-resistant tuberculosis treatment. Geneva: World Health Organization. 2020. Available at: https://www.who.int/publications/i/item/9789240006997. Accessed on November 8, 2022.