PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 07/03/2024

OVERVIEW

Sirturo, a diarylquinolone antimycobacterial, is indicated as part of a combination therapy in the treatment of **pulmonary tuberculosis (TB)** due to *Mycobacterium tuberculosis* resistant to at least rifampin and isoniazid in patients ≥ 5 years of age (weighing ≥ 15 kg).[1] Reserve Sirturo for use when an effective treatment regimen cannot otherwise be provided.

Limitations of use: Sirturo should not be used for the treatment of latent infections due to *Mycobacterium tuberculosis*, drug-sensitive TB, extra-pulmonary TB, and infections caused by non-tuberculous mycobacteria.

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 (2023) 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 the 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.** Approve for 9 months if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 5 years of age; AND
   - **B)** Patient weighs ≥ 15 kg; AND
   - **C)** Patient has *Mycobacterium tuberculosis* resistant to rifampin and isoniazid; 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; June 2024.
2. World Health Organization – Global Tuberculosis Report. 2023. Available at: https://iris.who.int/bitstream/handle/10665/373828/9789240083851-eng.pdf?sequence=1. . Accessed on July 1, 2024.
3. World Health Organization consolidated guidelines on tuberculosis. Module 4: Treatment - drug-resistant tuberculosis treatment. Geneva: World Health Organization. 2022. Available at: https://iris.who.int/bitstream/handle/10665/365308/9789240063129-eng.pdf?sequence=1. Accessed on July 1, 2024.