Drug Coverage Policy

Effective Date.....09/01/2024
Coverage Policy Number.....IP0494
Policy Title.....Sirturo

Infectious Disease – Sirturo

- Sirturo® (bedaquiline fumarate tablets – Janssen)

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. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. 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 Healthcare Coverage Policy

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 (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. 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.

Medical Necessity Criteria

Sirturo is considered medically necessary when the following criteria are met:

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.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (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.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	No criteria changes	7/1/2024
Selected Revision	**Tuberculosis: Updated** the criterion, "Patient has multidrug-resistant tuberculosis" to "Patient has *Mycobacterium tuberculosis* resistant to rifampin and isoniazid." **Overview: Removed** the statement regarding accelerated approval as Sirturo has received traditional approval from the FDA. **Updated** the indication for use from "Sirturo is indicated as part of a combination therapy in the treatment of pulmonary multidrug-resistant tuberculosis (TB) in patients ≥ 5 years of age (weighing ≥ 15 kg)" to "Sirturo 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)." **Removed** the statement about limited data on safety and efficacy in HIV patients with multidrug resistant TB.	09/01/2024

The policy effective date is in force until updated or retired.