

**Generic Name:** Bedaquiline

**Preferred:** N/A

**Therapeutic Class or Brand Name:** Sirturo

**Non-preferred:** N/A

**Applicable Drugs (if Therapeutic Class):** N/A

**Date of Origin:** 3/5/2021

**Date Last Reviewed / Revised:** 5/21/2025

## PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VI are met)

- I. Diagnosis of pulmonary tuberculosis due to *Mycobacterium tuberculosis* resistant to at least rifampicin and isoniazid
- II. Sirturo will be used in combination with ONE of the following, A or B:
  - A. At least three other medications that are active against patient's MDR-TB isolates *in vitro*.
  - B. At least 4 other medications that are likely to be active against patient's MDR-TB if *in vitro* testing unavailable.
- III. Minimum age requirement: 5 years old and weighing at least 15 kg.
- IV. Treatment must be prescribed by or in consultation with a pulmonologist or infectious disease specialist.
- V. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.
- VI. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

## EXCLUSION CRITERIA

- Treatment of latent, extrapulmonary or drug-sensitive tuberculosis.
- Treatment of infections caused by non-tuberculosis mycobacteria
- Clinically significant ventricular arrhythmias of QT prolongation > 500 ms

## OTHER CRITERIA

- Prior to administration, obtain ECG, liver enzymes and electrolytes (serum potassium, calcium, and magnesium), and obtain susceptibility information for the background regimen against *Mycobacterium tuberculosis* isolate if possible.
- Closely monitor when co-administered with CYP3A4 inhibitors as may increase systemic exposure of Sirturo (i.e. hepatic effects).

- Hepatic effects: Increased risk of hepatic reactions; avoid alcohol intake and other known hepatotoxic drugs, especially in patients with impaired hepatic function. Monitor AST, ALT, alkaline phosphatase, bilirubin, and symptoms of liver dysfunction (eg, fatigue, nausea, anorexia, jaundice, dark urine, liver tenderness, and hepatomegaly) at baseline and monthly during therapy, and as needed.
- Discontinue therapy in the following:
  - Transaminase elevations are accompanied by total bilirubin elevation greater than two times the upper limit of normal
  - Transaminase elevations are greater than eight times the upper limit of normal
  - Transaminase elevations are greater than five times the upper limit of normal and persist beyond two weeks
  - Evidence of clinically significant ventricular arrhythmia
- QTc interval greater than 500 ms (confirmed by repeat ECG)

## QUANTITY / DAYS SUPPLY RESTRICTIONS

- Administer Sirturo by directly observed therapy (DOT). Emphasize need for compliance with full course of therapy.
- 20 mg, 100 mg tablets: Up to 30 day supply.

## APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that therapy continued past 24-weeks is medically necessary.

## APPENDIX

- N/A

## REFERENCES

1. Sirturo. Prescriber information. Janssen Therapeutics; 2024. Accessed May 21, 2025. <https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SIRTURO-pi.pdf>
2. Nahid P, Mase SR, Migliori GB, et al. Treatment of Drug-Resistant Tuberculosis. An Official ATS/CDC/ERS/IDSA Clinical Practice Guideline [published correction appears in Am J Respir Crit Care Med. 2020 Feb 15;201(4):500-501]. *Am J Respir Crit Care Med*. 2019;200(10):e93-e142. doi:10.1164/rccm.201909-1874ST

**DISCLAIMER:** Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.