MEDICATION POLICY:
Sirturo®

Generic Name: Bendaquiline

Therapeutic Class or Brand Name: Sirturo

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 3/5/2021

Date Last Reviewed / Revised: 1/17/2023

PRIOR AUTHORIZATION CRITERIA

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

I. Diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB).

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 is 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.

OTHER CRITERIA

- Prior to administration, obtain ECG, liver enzymes and electrolytes, and obtain susceptibility information for the background regimen against Mycobacterium tuberculosis isolate if possible.
- Arrhythmias: [US Boxed Warning]: May prolong QTc interval. Use with drugs that prolong the QTc interval may cause additive prolongation. Monitor ECGs at baseline, and at least 2, 12, and 24 weeks of treatment. Monitor ECG frequently with concurrent administration of other medications known to prolong the QTc interval.
- Discontinue therapy (and all other QT prolonging drugs) if patient develops confirmed QTcF interval of >500 msec (confirmed by repeat ECG) or ventricular arrhythmia and monitor ECG to confirm return to baseline.

- 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.

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**: 24 Weeks
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

- N/A

REFERENCES

1. Sirturo. Prescriber information. Janssen Therapeutics; 2021. Accessed January 6, 2023. https://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SIRTURO-pi.pdf
2. Schluger NW, Heysell SK, Friedland G. Treatment of drug-resistant pulmonary tuberculosis in adults. In: Bernardo J, Baron EL, ed. *UpToDate*. UpToDate; 2022. Accessed January 9, 2022. https://www.uptodate.com/contents/treatment-of-drug-resistant-pulmonary-tuberculosis-in-adults?search=2.%09Treatment%20of%20drug-resistant%20pulmonary%20tuberculosis%20in%20adults&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1