

Generic Name: Bedaquiline

Therapeutic Class or Brand Name: Sirturo[®]

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 090000151003

Preferred: N/A

Non-preferred: N/A

Date of Origin: 3/5/2021

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I – IV are met)

- I. Diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB).
- II. Used in combination with criteria A or B:
 - A. At least three other medications that is active against patient's MDR-TB isolates *in vitro*.
 - B. At least 4 other medications that is likely to be active against patient's MDR-TB if *in vitro* testing unavailable.
- III. Age \geq 18 years for adults or pediatrics age \geq 5 years and weighing at least 15 kg.
- IV. Prescribed by or in consultation with a pulmonologist or infectious disease specialist.

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- 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

- 20 mg, 100 mg tablets: Up to 30day 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® (Bedaquiline) [package insert]. Titusville, NJ: Janssen Therapeutics; May 2020. Available at: <http://www.janssenlabels.com/package-insert/product-monograph/prescribing-information/SIRTURO-pi.pdf>.
2. Medispan.
3. Treatment of drug-resistant pulmonary tuberculosis in adults. <http://www.Uptodate.com>