

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	March 30, 2022, September 8, 2022

### Sirturo® (bedaquiline fumarate)

**LENGTH OF AUTHORIZATION:** 6 months

**REVIEW CRITERIA:**

- Patient must be  $\geq 5$  years of age and  $\geq 15$  kg.
- Patient must have a diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB).
- **Documentation confirming** that Sirturo will be co-administered with at least 3 other drugs proven to be effective against the patient's M. tuberculosis isolate.
- Submission of susceptibility testing.
- Prior to treatment baseline liver enzymes, ECG, and electrolytes have been obtained. (*Official lab results must be provided*).

**DOSING AND ADMINISTRATION:**

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as 20 mg and 100mg tablets.