



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: April 18, 2014 Original Effective Date: Revision Date:	April 18, 2014

Sirturo® (bedaquiline)

THERAPY LENGTH OF AUTHORIZATION: 24 weeks

REVIEW CRITERIA (ALL OF THE FOLLOWING MUST BE TRUE):

- Patient must be ≥ 18 years old
- Patient must have a diagnosis of multidrug-resistant tuberculosis (MDR-TB); resistant to at least isoniazid and rifampin
- Bedaquiline must be used in combination with ≥ 3 drugs to which the organism is susceptible or ≥ 4 drugs to which it is likely to be susceptible if test results are unavailable

DOSING & ADMINISTRATION:

- Dosage: The recommended dosage of bedaquiline is 400 mg (4 tablets) once daily with food for weeks 1 and 2, followed by 200 mg (2 tablets) three times per week with food for weeks 3 through 24. The total duration of bedaquiline therapy is 24 weeks. The tablets should be swallowed whole with water. The dose should be administered by directly observed therapy (DOT). Alcohol should be avoided throughout the treatment period.
- Dosage Form: 100 mg tablet