Commercial/Healthcare Exchange PA Criteria

Effective: August 11, 2020

Prior Authorization: Sirturo

Products Affected: Sirturo (bedaquiline fumarate) 20 mg oral tablets

Medication Description: Sirturo is a diarylquinoline antimycobacterial, that inhibits the proton transfer chain of mycobacterial ATP synthase required for energy generation in M. tuberculosis. Sirturo (bedaquiline) is indicated as part of combination therapy in adult and pediatric patients with pulmonary multi-drug resistant tuberculosis (MDR-TB). Sirturo should be reserved for use when an effective treatment regimen cannot otherwise be provided.

Covered Uses: Pulmonary multidrug resistant tuberculosis (MDR-TB)

Exclusion Criteria:

1. Latent infection due to Mycobacterium tuberculosis
2. Drug-sensitive tuberculosis
3. Extra-pulmonary tuberculosis
4. Infections caused by non-tuberculous mycobacteria
5. HIV-infected patients with multi-drug resistant tuberculosis (MDR-TB)

Required Medical Information:

1. Diagnosis
2. Current therapy regimen
3. Patient weight

Age Restrictions: 5 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, infectious disease specialist or pulmonologist.

Coverage Duration: 24 weeks

Other Criteria:

Pulmonary multidrug resistant tuberculosis

A. Sirturo will be used as one of the following:
    i. In combination with at least 3 other drugs to which the patient's MDR-TB isolate has been shown to be susceptible in vitro; OR
    ii. In combination with at least 4 other drugs to which patient's MDR-TB isolate is likely to be susceptible, if in vitro testing results are unavailable; AND
B. Patient weighs at least 15kg or greater

References:

1. Sirturo prescribing information. Titusville, NJ: Janssen Therapeutics, Inc.; 2019 August

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	8/11/2020