

make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Sirturo (bedaquiline), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by or in consultation with an infectious disease specialist or pulmonologist
- Must be age 18 years or older
- Must have a diagnosis of multi-drug resistant pulmonary tuberculosis (TB)
- Must have previously had an inadequate response to at least one first line TB regimen containing isoniazid and rifampin OR have documentation of susceptibility testing of Mycobacterium tuberculosis isolates demonstrating resistance to isoniazid and rifampin
- Must be used in combination with at least three drugs active against specific TB
- Must indicate that the member understands the importance of compliance to the full medication regimen

Reauthorization Criteria:

All prior authorization renewals are reviewed on a case-by-case basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 6-month intervals based upon:

- Documentation of the member's initial response to therapy and clinical rationale for continuation of treatment or re-treatment
- Documentation that member was compliant with previous course of therapy
- Documentation of susceptibility testing of Mycobacterium tuberculosis isolates demonstrating continued susceptibility to bedaquiline

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 6 months
Reauthorization	Up to 6 months



If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Sirturo [package insert]. Titusville, NJ: Janssen Therapeutics. December 2012.
2. Diacon AH, Donald PR, Pym A, et al. Randomized pilot trial of eight weeks of bedaquiline (TMC207) treatment for multidrug-resistant tuberculosis: long-term outcome, tolerability, and effect on emergence of drug resistance. *Antimicrob Agents Chemother.* 2012 Jun;56(6):3271-3276.
3. Diacon AH, Pym A, Grobusch M, et al. The diarylquinoline TMC207 for multidrug-resistant tuberculosis. *N Engl J Med* 2009;360(23):2397-2405.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
<i>Annual review</i>	<i>02/17, 02/18</i>

