

Pharmacy Medical Necessity Guidelines: Sirturo™ (bedaquiline)

Effective: March 16, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
<p>This Pharmacy Medical Necessity Guideline applies to the following:</p> <p>Tufts Health Plan Commercial Plans</p> <p><input checked="" type="checkbox"/> Tufts Health Plan Commercial Plans – large group plans</p> <p><input checked="" type="checkbox"/> Tufts Health Plan Commercial Plans – small group and individual plans</p> <p>Tufts Health Public Plans</p> <p><input checked="" type="checkbox"/> Tufts Health Direct – Health Connector</p> <p><input checked="" type="checkbox"/> Tufts Health Together – A MassHealth Plan</p> <p><input checked="" type="checkbox"/> Tufts Health RITogether – A RItE Care + Rhody Health Partners Plan</p> <p>Tufts Health Freedom Plan products</p> <p><input checked="" type="checkbox"/> Tufts Health Freedom Plan – large group plans</p> <p><input checked="" type="checkbox"/> Tufts Health Freedom Plan – small group plans</p>		<p>Fax Numbers:</p> <p>RXUM: 617.673.0988</p>	

Note: For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

OVERVIEW

FDA-APPROVED INDICATIONS

Sirturo (bedaquiline) is indicated as part of combination therapy in adult and pediatric patients (12 to less than 18 years of age and weighing at least 30 kg) with pulmonary multi-drug resistant tuberculosis (MDR-TB). Sirturo should be reserved for use when an effective treatment regimen cannot otherwise be provided.

Sirturo should not be used for the treatment of latent, extra-pulmonary or drug-sensitive tuberculosis or for the treatment of infections caused by non-tuberculous mycobacteria. Safety and efficacy of SIRTURO in HIV-infected patients with MDR-TB have not been established, as clinical data are limited.

Sirturo should be administered under directly observed therapy (DOT). Sirturo should be used in combination with at least three other drugs to which the patient's MDR-TB isolate has been shown to be susceptible in vitro. If in vitro testing results are unavailable, treatment may be initiated with Sirturo in combination with at least four other drugs to which the patient's MDR-TB isolate is likely to be susceptible.

COVERAGE GUIDELINES

The plan may authorize coverage of Sirturo (bedaquiline) for Members when **ALL** of the following criteria are met:

- 1a. Documented diagnosis of pulmonary multi-drug resistant tuberculosis
- AND**
- 1b. The Member is at least 18 years of age OR The member is 12 years of age weighing at least 30 kg
- AND**
- 1c. Sirturo should only be used in combination with at least three other drugs to which the patient's MDR-TB isolate has been shown to be susceptible in vitro. If in vitro testing results are unavailable, treatment may be initiated with Sirturo in combination with at least four other drugs to which the patient's MDR-TB isolate is likely to be susceptible.
- OR**
- 2a. Documented diagnosis of pulmonary extensively drug-resistant or treatment-intolerant or nonresponsive multi-drug resistant tuberculosis
- AND**
- 2b. Documentation that Sirturo is being used in combination with Pretomanid AND Zyvox (linezolid)

LIMITATIONS

None

CODES

None

REFERENCES

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APPROVAL HISTORY

July 9, 2013: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- August 12, 2014: No changes
- August 11, 2015: No changes
- January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
- August 9, 2016: Effective August 15, 2016, Medical Necessity Guideline applies to Tufts Health Together
- April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether
- August 8, 2017: No changes
- August 7, 2018: No changes
- November 12, 2019: Updated the criteria, in line with the FDA approved updated indication, to allow coverage for patients 12 years of age and older weighing at least 30 kg.
- March 10, 2020: Added criteria to allow coverage of Sirturo when used in combination with Pretomanid and Zyvox (linezolid) for drug-resistant or treatment-intolerant or nonresponsive multi-drug resistant tuberculosis.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). The plan makes coverage decisions on a case-by-case basis considering the individual Member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to Member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

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