

## Pharmacy Medical Necessity Guidelines: Sirturo™ (bedaquiline)

Effective: August 1, 2023

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
These pharmacy medical necessity guidelines apply to the following: <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan			<b>Fax Numbers:</b> RXUM: 617.673.0988

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

### OVERVIEW

#### FDA-APPROVED INDICATIONS

Sirturo (bedaquiline) is a diarylquinoline antimycobacterial drug indicated as part of combination therapy in adult and pediatric patients (5 years and older and weighing at least 15 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 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:

1. Member meets ALL of the following:
  - a. Documented diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB)  
**AND**
  - b. The Member is at least 5 years of age  
**AND**
  - c. Member meets ONE of the following:
    - i. Member’s MDR-TB is NOT susceptible to Sirturo (or in vitro testing results are not available) AND Sirturo will be used in combination therapy with at least four other drugs to which the patient’s MDR-TB isolate is likely to be susceptible  
**OR**
    - ii. Member’s MDR-TB isolate is susceptible to Sirturo AND Sirturo will be used in combination therapy with at least three other susceptible drugs  
**OR**
2. Member meets ALL of the following:
  - a. Documented diagnosis of pulmonary extensively drug-resistant or treatment-intolerant or nonresponsive multi-drug resistant tuberculosis  
**AND**
  - b. Documentation that Sirturo is being used in combination with Pretomanid AND linezolid

### LIMITATIONS

None

### CODES

None

### REFERENCES

1. American Lung Association. Mutidrug-resistant tuberculosis (MDR TB) fact sheet: February 2010. URL: [lung.org/lung-disease/tuberculosis/factsheets/multidrug-resistant.html](http://lung.org/lung-disease/tuberculosis/factsheets/multidrug-resistant.html). Available from Internet. Accessed 2013 Jan 28.

2. American Thoracic Society, Centers for Disease Control and Prevention, and Infectious Diseases Society of America. Treatment of Tuberculosis. *MMWR Morb Mortal Wkly Rep* 2003; 52(RR-11):1-80.
3. Capastat prescribing information. Indianapolis, IN: Eli Lilly and Company; 2008 January.
4. Center for Disease Control and Prevention. Morbidity and Mortality Weekly Report. January 2017. Drug-Resistant TB. URL: [cdc.gov/tb/topic/drtb/default.htm](http://cdc.gov/tb/topic/drtb/default.htm). Available from internet. Accessed 2017 July 19.
5. Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report. February 2009. Plan to combat extensively drug-resistant tuberculosis recommendations of the federal tuberculosis task force. URL: [cdc.gov/mmwr/preview/mmwrhtml/rr5803a1.htm](http://cdc.gov/mmwr/preview/mmwrhtml/rr5803a1.htm). Available from Internet. Accessed 2013 Jan 25.
6. Centers for Disease Control and Prevention. Morbidity and Mortality Weekly Report. December 2011. Recommendations for use of an isoniazid-rifapentine regimen with direct observation to treat latent mycobacterium tuberculosis infection. URL: [cdc.gov/mmwr/preview/mmwrhtml/mm6048a3.htm](http://cdc.gov/mmwr/preview/mmwrhtml/mm6048a3.htm). Available from Internet. Accessed 2013 Jan 25.
7. Centers for Disease Control and Prevention. Tuberculosis. Data and Statistics. 2012. URL: [cdc.gov/tb/statistics/default.htm](http://cdc.gov/tb/statistics/default.htm). Available from Internet. Accessed 2013 Jan 25.
8. Diacon AH, Pym A, Grobusch M, et al. The diarylquinoline TMC207 for multidrug resistant tuberculosis. *N Engl J Med*. 2009; 360:2397-405.
9. Diacon AH, Donald P, 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; 56(6):3271-6.
10. Isoniazid prescribing information. Laurelton, NY: Eon Labs, Inc.; 2002 March.
11. Myambutol prescribing information. Pomona, NY: Barr Laboratories, Inc.; 2007 January.
12. Mycobutin prescribing information. Kalamazoo, MI: Pharmacia & Upjohn Company; 2015 May.
13. National Institute for Health and Clinical Excellence (NICE). 2013. URL: [www.nice.org.uk/guidance/index](http://www.nice.org.uk/guidance/index). Available from Internet. Accessed 2013 January 30.
14. National Institute for Health and Clinical Excellence (NICE). March 2011. URL: [nice.org.uk/nicemedia/live/13422/53642/53642.pdf](http://nice.org.uk/nicemedia/live/13422/53642/53642.pdf). Available from Internet. Accessed 2013 January 30.
15. Paser prescribing information. Princeton, NJ: Jacobus Pharmaceutical Company, Inc.; 1996 July.
16. Priftin prescribing information. Bridgewater, NJ: Sanofi-Aventis U.S. LLC.; 2010 May.
17. Pyrazinamide prescribing information. Marietta, GA: Mikart, Inc.; 2012.
18. Rifadin prescribing information. Kansas City, MO: Aventis Pharmaceuticals, Inc.; 2016 October.
19. Rifamate prescribing information. Bridgewater, NJ: Sanofi-Aventis Pharmaceuticals U.S. LLC, Inc.; 2016 October.
20. Rifater prescribing information. Bridgewater, NJ: Sanofi-Aventis Pharmaceuticals U.S. LLC; 2010 November.
21. Cycloserine prescribing information. Indianapolis, IN: Eli Lilly and Company; 2011 October.
22. Sirturo FDA Briefing Document. 2012. TMC207 (bedaquiline): Treatment of patients with MDR-TB. URL: [fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Anti-InfectiveDrugsAdvisoryCommittee/UCM329260.pdf](http://fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/Anti-InfectiveDrugsAdvisoryCommittee/UCM329260.pdf). Available from Internet. Accessed 2013 January 25.
23. Sirturo prescribing information. Titusville, NJ: Janssen Therapeutics, Inc.; September 2021.
24. Small PM, Fujiwara PI. Management of tuberculosis in the United States. *N Engl J Med*. 2001; 345(3):189-200.
25. Streptomycin prescribing information. Northport, NY: X-Gen Pharmaceuticals, Inc.; 2011 August.
26. Trecator prescribing information. Philadelphia, PA: Wyeth Pharmaceuticals, Inc.; 2005 December.
27. World Health Organization. WHO treatment guidelines for drug-resistant tuberculosis: 2016 update. URL: [who.int/tb/areas-of-work/drug-resistant-tb/MDRTBguidelines2016.pdf](http://who.int/tb/areas-of-work/drug-resistant-tb/MDRTBguidelines2016.pdf). Available from Internet. Accessed 2017 Jul 19.

#### **APPROVAL HISTORY**

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. May 9, 2023: Effective August 1, 2023, minor verbiage changes made to the criteria.

#### **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. 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.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

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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