Pharmacy Medical Necessity Guidelines: Sirturo™ (bedaquiline)

Effective: March 1, 2026

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: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

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 (2 years and older and weighing at least 8 kg) with pulmonary multi-drug resistant tuberculosis (MDR-TB). Sirturo should be reserved for use when an effective treatment regimen cannot otherwise be provided.

COVERAGE GUIDELINES

The plan may authorize coverage of Sirturo (bedaquiline) for Members when 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. Prescribed by infectious disease specialist or pulmonologist

    AND

    c. One of the following:
        i. Sirturo will be used in combination therapy with at least three other antitubercular drugs
        ii. Sirturo will be used in combination therapy with Pretomanid and Zyvox (linezolid)

OR

2. Member meets **ALL** of the following:
    a. Documented diagnosis of pulmonary extensively drug-resistant (XDR) or treatment-intolerant or nonresponsive multi-drug resistant (MDR) tuberculosis

    AND

    b. Prescribed by infectious disease specialist or pulmonologist

    AND

    c. Sirturo (bedaquiline) will be used in combination with Pretomanid AND Zyvox (linezolid)

LIMITATIONS

1. Approval of Sirturo (bedaquiline) will be limited to 6 months.

CODES

None

REFERENCES

1. 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.
2. Capastat prescribing information. Indianapolis, IN: Eli Lilly and Company; 2008 January.
3. Center for Disease Control and Prevention. Morbidity and Mortality Weekly Report. January 2017. Drug-Resistant TB. URL: cdc.gov/tb/topic/drtb/default.htm. Available from internet. Accessed 2017 July 19.
4. 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. Available from Internet. Accessed 2013 Jan 25.
5. 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. Available from Internet. Accessed 2013 Jan 25.

6. Centers for Disease Control and Prevention. Tuberculosis. Data and Statistics. 2012. URL: cdc.gov/tb/statistics/default.htm. Available from Internet. Accessed 2013 Jan 25.
7. Diacon AH, Pym A, Grobusch M, et al. The diarylquinolines TMC207 for multidrug resistant tuberculosis. *N Engl J Med*. 2009; 360:2397-405.
8. 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.
9. Isoniazid prescribing information. Laurelton, NY: Eon Labs, Inc.; 2002 March.
10. Myambutol prescribing information. Pomona, NY: Barr Laboratories, Inc.; 2007 January.
11. Mycobutin prescribing information. Kalamazoo, MI: Pharmacia & Upjohn Company; 2015 May.
12. National Institute for Health and Clinical Excellence (NICE). 2013. URL: www.nice.org.uk/guidance/index. Available from Internet. Accessed 2013 January 30.
13. National Institute for Health and Clinical Excellence (NICE). March 2011. URL: nice.org.uk/nicemedia/live/13422/53642/53642.pdf. Available from Internet. Accessed 2013 January 30.
14. Paser prescribing information. Princeton, NJ: Jacobus Pharmaceutical Company, Inc.; 1996 July.
15. Priftin prescribing information. Bridgewater, NJ: Sanofi-Aventis U.S. LLC.; 2010 May.
16. Pyrazinamide prescribing information. Marietta, GA: Mikart, Inc.; 2012.
17. Rifadin prescribing information. Kansas City, MO: Aventis Pharmaceuticals, Inc.; 2016 October.
18. Rifamate prescribing information. Bridgewater, NJ: Sanofi-Aventis Pharmaceuticals U.S. LLC, Inc.; 2016 October.
19. Rifater prescribing information. Bridgewater, NJ: Sanofi-Aventis Pharmaceuticals U.S. LLC; 2010 November.
20. Cycloserine prescribing information. Indianapolis, IN: Eli Lilly and Company; 2011 October.
21. Saukkonen JJ, Duarte R, Munsiff SS, et al. Updates on the Treatment of Drug-Susceptible and Drug-Resistant Tuberculosis: An Official ATS/CDC/ERS/IDSA Clinical Practice Guideline. *Am J Respir Crit Care Med*. 2025;211(1):15-33.
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. Available from Internet. Accessed 2013 January 25.
23. Sirturo prescribing information. Horsham, PA: Janssen Therapeutics, Inc.;July 2025.
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. Update of WHO guidelines on the programmatic management of drug resistant TB. Geneva: World Health Organization; 2019. https://apps.who.int/iris/bitstream/handle/10665/311389/9789241550529-eng.pdf?ua=18. Accessed June 9, 2021.
28. World Health Organization. WHO consolidated guidelines on tuberculosis. Module 4: treatment-drug-resistant tuberculosis treatment, 2022 update. World Health Organization, 2022.

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.
2. February 13, 2024: Updated fax number for RxUM.
3. July 9, 2024: Effective October 1, 2024, removed age requirement and updated combination therapy requirement to MDR-TB criteria. Prescriber requirement added to all diagnoses. Approval duration limited to 6 months. Administrative updates to overview section.
4. February 11, 2025: No changes
5. February 10, 2026: Effective March 1, 2026, administrative updates to overview section for expanded indication in pediatric patients for 2 years of age and older and weighing at least 8 kg. Updated references. No criteria changes.

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.

Provider Services