Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Sirturo (bedaquiline)

Effective: July 14, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – 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 tuberculosis (TB) due to *Mycobacterium tuberculosis* resistant to at least rifampin and isoniazid.

Clinical Guideline Coverage Criteria

Sirturo (bedaquiline)

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

1. 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. All of the following:
    a. Documented diagnosis of pulmonary extensively drug resistant (XDR) or treatment-intolerant/nonresponsive multidrug-resistant (MDR) tuberculosis

    AND

    b. Prescribed by infectious disease specialist or pulmonologist

    AND

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

Limitations

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

Codes

None

References

1. Sirturo (bedaquiline) [prescribing information]. Titusville, NJ: Janssen Therapeutics; July 2025.
2. Conradie F, Diacon AH, Ngubane N, et al; Nix-TB Trial Team. Treatment of highly drug-resistant pulmonary tuberculosis. N

Engl J Med. 2020;382(10):893-902. doi:10.1056/NEJMoa1901814.
3. 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.
4. World Health Organization. *WHO consolidated guidelines on tuberculosis. Module 4: treatment-drug-resistant tuberculosis treatment, 2022 update*. World Health Organization, 2022.

Approval And Revision History

September 2022: Reviewed by the Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

- July 11, 2023: no changes
- 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.
- July 8, 2025: Administrative update to Sirturo's full FDA-approved indication within overview section.
- July 14, 2026: Administrative update to overview with Sirturo's expanded indication in pediatric patients 2 years and older and weighing at least 8 kg. Administrative update to remove CareLink from the Medical Necessity Guideline template.

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.