**Effective Date** ..... **12/1/2022**
**Next Review Date…** ..... **12/1/2023**
**Coverage Policy Number** ..... **IP0494**

# Bedaquiline

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## Related Coverage Resources

***INSTRUCTIONS FOR USE***
*The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.*

## Overview

This policy supports medical necessity review for bedaquiline (**Sirturo**®).

Receipt of sample product does not satisfy any criteria requirements for coverage.

## Medical Necessity Criteria

**Bedaquiline (Sirturo) is considered medically necessary when the following are met:**

1. **Multidrug-Resistant Tuberculosis (Pulmonary).** Individual meets **ALL** of the following criteria (A, B, and C):
   A. Individual is 5 years of age or older
   B. Individual weighs 15 kg or more
   C. The medication is prescribed by, or in consultation with, an infectious diseases specialist

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

## Reauthorization Criteria

Bedaquiline (Sirturo) is considered medically necessary for continued use when initial criteria are met AND there is documentation of beneficial response.

## Authorization Duration

Initial approval duration: up to 9 months
Reauthorization approval duration: up to 9 months

## Conditions Not Covered

Any other use is considered experimental, investigational or unproven.

## Background

**OVERVIEW**
Sirturo, a diarylquinolone antimycobacterial, is indicated as part of a combination therapy in the treatment of patients ≥ 5 years of age (weighing ≥ 15 kg) with **pulmonary multidrug-resistant tuberculosis (TB)**.[1] Sirturo should be used when an effective treatment regimen cannot otherwise be provided. This indication is approved under accelerated approval based on time to sputum culture conversion. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

**Limitations of use:** Sirturo should not be used for latent infections due to *Mycobacterium tuberculosis*, drug-sensitive TB, extra-pulmonary TB, and infections caused by non-tuberculous mycobacteria. The safety and efficacy of Sirturo in the treatment of patients infected with human immunodeficiency virus (HIV) with multidrug-resistant TB have not been established as clinical data are limited.

The prescribing information notes the total duration of treatment with Sirturo to be 24 weeks (adults and pediatric patients).[1]

**Guidelines**
The WHO issued an operational handbook (2020) with information on the choice and design of regimens for the treatment of drug-resistant TB, including multidrug- or rifampin-resistant TB and confirmed rifampicin-susceptible, isoniazid-resistant TB.[2] Drug susceptibility tests are recommended to assist the prescriber in choosing the appropriate initial regimen. In addition, a surveillance system is recommended to determine the local prevalence of drug-resistant TB strains. There are different regimens that include Sirturo and other drugs (e.g., rifampicin, ethambutol, levofloxacin/moxifloxacin, pretomanid, linezolid, clofazimine). Sirturo is used for 6 to 9 months, whereas the other drugs in the regimen may be used for different duration.

## References


1. Sirturo® tablets [prescribing information]. Titusville, NJ: Janssen; May 2020.
2. World Health Organization – Global Tuberculosis Report. 2020. Available at: https://apps.who.int/iris/bitstream/handle/10665/336069/9789240013131-eng.pdf?ua=1. Accessed on October 20, 2021.
3. World Health Organization operational handbook on tuberculosis. Module 4: Treatment - drug-resistant tuberculosis treatment. Geneva: World Health Organization. 2020. Available at: https://www.who.int/publications/i/item/9789240006997. Accessed on October 20, 2021.