

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

SIRTURO
(bedaquiline)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Sirturo is a diarylquinoline antimycobacterial drug indicated as part of combination therapy in the treatment of adult and pediatric patients (5 years and older and weighing at least 15 kg) with pulmonary multi-drug resistant tuberculosis (MDR-TB). Reserve Sirturo for use 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:

- Do not use Sirturo for the treatment of:
 - Latent infection due to *Mycobacterium tuberculosis*
 - Drug-sensitive tuberculosis
 - Extra-pulmonary tuberculosis
 - Infections caused by non-tuberculous mycobacteria
- The safety and efficacy of Sirturo in the treatment of HIV infected patients with MDR-TB have not been established as clinical data are limited

Off Label Uses

Combination regimen with pretomanid and linezolid for the treatment of pulmonary extensively drug resistant (XDR) or treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB)^{5,6}

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed as part of combination therapy in a patient with pulmonary multi-drug resistant tuberculosis (MDR-TB)

AND

- Another effective treatment regimen cannot be used instead of Sirturo (bedaquiline)

OR

- The requested drug is being prescribed for pulmonary extensively drug resistant (XDR) or treatment-intolerant/nonresponsive multidrug-resistant (MDR) tuberculosis

AND

- The requested drug is being prescribed as part of a combination regimen with Pretomanid and Zyvox (linezolid)

REFERENCES

1. Sirturo [package insert]. Titusville, New Jersey: Janssen Therapeutics; September 2021.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online, Hudson, Ohio: UpToDate, Inc.; 2022; Accessed January 27, 2022.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed January 27, 2022.

4. Centers for Disease Control and Prevention. Provisional CDC Guidelines for the Use and Safety Monitoring of Bedaquiline Fumarate (Sirturo) for the Treatment of Multidrug-Resistant Tuberculosis. *MMWR*. Oct 2013; 62(9):1-12.
5. Pretomanid [package insert]. Morgantown, West Virginia: Mylan Specialty L.P.; April 2020.
6. Update of WHO guidelines on the programmatic management of drug resistant TB. Geneva: World Health Organization; 2019. https://www.who.int/tb/features_archive/Update-WHO-guidelines-programmatic-management-of-drug/en/. Accessed February 2022.
7. WHO consolidated guidelines on drug-resistant tuberculosis treatment. Geneva: World Health Organization; 2019. <https://apps.who.int/iris/bitstream/handle/10665/311389/9789241550529-eng.pdf?ua=1>. Accessed February 2022.
8. Rapid communication: key changes to treatment of drug-resistant tuberculosis. Geneva: World Health Organization; December 2019. https://www.who.int/tb/publications/2019/WHO_RapidCommunicationMDRTB2019.pdf?ua=1. Accessed February 2022.
9. WHO Global Tuberculosis Report 2020. Geneva: World Health Organization; 2020. <https://apps.who.int/iris/bitstream/handle/10665/336069/9789240013131-eng.pdf>. Accessed February 2022.