

# 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

### Compendial Uses

Combination regimen with Pretomanid and linezolid for the treatment of adults with pulmonary tuberculosis (TB) resistant to isoniazid, rifamycins, a fluoroquinolone and a second line injectable antibacterial drug OR adults with pulmonary TB resistant to isoniazid and rifampin, who are treatment-intolerant or nonresponsive to standard therapy.<sup>2,4-6</sup>

### 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 tuberculosis (TB) resistant to isoniazid, rifamycins, a fluoroquinolone and a second line injectable antibacterial drug OR TB resistant to isoniazid and rifampin, that is treatment-intolerant or nonresponsive to standard therapy  
**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 29, 2023.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com>. Accessed January 29, 2023.

4. Pretomanid [package insert]. Morgantown, West Virginia: Mylan Specialty L.P.; December 2022.
5. WHO Consolidated Guidelines on Tuberculosis. Module 4: Treatment - Drug-Resistant Tuberculosis Treatment. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO. Available at: <https://www.who.int/publications/i/item/9789240007048>. Accessed February 2023.
6. WHO Consolidated Guidelines on Tuberculosis. Module 5: Management of Tuberculosis in Children and Adolescents. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO. Available at: <https://www.who.int/publications/i/item/9789240007048>. Accessed February 2023.