Oscar Clinical Guideline: Sirturo (bedaquiline) (PG242, Ver. 3)

Sirturo (bedaquiline)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Multidrug-resistant tuberculosis (MDR-TB) is a form of tuberculosis (TB) caused by bacteria that are resistant to at least isoniazid and rifampin, two of the most potent first-line anti-TB drugs. MDR-TB is a significant global health concern, as it is more difficult to treat and has poorer outcomes compared to drug-susceptible TB. Treatment typically requires a combination of second-line drugs for 18-24 months or longer.

Sirturo (bedaquiline) is a diarylquinoline antimycobacterial drug that inhibits mycobacterial ATP synthase. It is FDA-approved as part of combination therapy for pulmonary MDR-TB in adults and pediatrics 2 years and older weighing at least 8 kilograms (kg). Sirturo (bedaquiline) should be used in conjunction with at least three (3) other drugs (e.g., fluoroquinolones, linezolid, pretomanid) to which the individual's TB isolate is susceptible. Only use Sirturo (bedaquiline) in combination with at least 3 other drugs to which the individual's TB isolate has been shown to be susceptible in vitro. If in vitro testing results are unavailable, may initiate Sirturo (bedaquiline) in combination with at least 4 other drugs to which an individual's TB isolate is likely to be susceptible.

Definitions

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"Extensively drug-resistant tuberculosis (XDR-TB)" refers to MDR-TB with additional resistance to any fluoroquinolone (e.g., levofloxacin, moxifloxacin) and either bedaquiline or linezolid.

"Multidrug-resistant tuberculosis (MDR-TB)" is defined as tuberculosis caused by *Mycobacterium tuberculosis* strains that are resistant to at least isoniazid and rifampin.

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Clinical Review

General Medical Necessity Criteria

<u>Drug-Resistant Tuberculosis Infection</u>

The Plan considers Sirturo (bedaquiline) medically necessary when ALL of the following criteria are met:

1. The medication is prescribed by or in consultation with an infectious disease specialist, pulmonologist, or expert in the treatment of TB (e.g., state or county public health department, specialists affiliated with TB Centers of Excellence as designated by the CDC); *AND*
2. The member is 2 years of age or older*; AND*
3. The member weighs at least 8kg; *AND*
4. The member is being treated for drug-resistant tuberculosis infection, including ONE of the following[s]:
    a. Multidrug-resistant (MDR) pulmonary tuberculosis (i.e., caused by *Mycobacterium tuberculosis* resistant to isoniazid and rifampin); *or*
    b. Extensively drug resistant (XDR) pulmonary tuberculosis (i.e., caused by *Mycobacterium tuberculosis* resistant to isoniazid, rifampin, any fluoroquinolone [e.g., levofloxacin, moxifloxacin], and linezolid or a second-line injectable antituberculosis agent [e.g., amikacin, capreomycin, and kanamycin]*; or*
    c. 14 years of age or older with rifampin-resistant, fluoroquinolone-resistant TB using the bedaquiline, pretomanid, and linezolid (BPaL) regimen*; or*
    d. 14 years of age or older with rifampin-resistant, fluoroquinolone-susceptible TB using the bedaquiline, pretomanid, linezolid, and moxifloxacin (BPaLM) regimen; *AND*
5. The member has documentation of laboratory confirmed drug-resistant TB showing resistance to at least rifampin with ONE of the following:
    a. Culture based drug susceptibility testing*; or*
    b. Rapid molecular testing (e.g. Xpert MTB/RIF, Xpert MTB/XDR)*; AND*
6. Sirturo (bedaquiline) will be used as part of a combination regimen with other antituberculosis agents*; AND*
7. Sirturo (bedaquiline) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication.

<u>If the above prior authorization criteria are met, the requested product will be authorized for up to 6-months.[s]</u>

Experimental / Investigational, or unproven[s]

Sirturo (bedaquiline) for any other indication or use is considered experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Treatment of latent tuberculosis infection. Sirturo (bedaquiline) is explicitly not approved for the management of latent tuberculosis infection (listed as a limitation of use in the manufacturer's limitation of use).
- Treatment of drug-sensitive tuberculosis. Sirturo (bedaquiline) is explicitly not approved for the management of drug-sensitive tuberculosis (listed as a limitation of use in the manufacturer's limitation of use).

- Treatment of extrapulmonary tuberculosis. Sirturo (bedaquiline) is explicitly not approved for the management of extrapulmonary tuberculosis infections (listed as a limitation of use in the manufacturer's limitation of use).
- Treatment of infections caused by nontuberculous mycobacteria (NTM). Sirturo (bedaquiline) is explicitly not approved for the management of nontuberculous mycobacteria (listed as a limitation of use in the manufacturer's limitation of use).
- Use in members under 2 years of age or weighing less than 8 kg. Sirturo (bedaquiline) has only been studied in those 2 years of age and older and those weighing at least 8 kg. There is insufficient data to support the safety and efficacy of Sirturo (bedaquiline) in those less than 2 years of age and those weighing less than 8 kg.
- Use as monotherapy for MDR-TB. Sirturo (bedaquiline) was explicitly approved as a combination therapy with additional agents for the management of MDR-TB. It has only been studied in combination with at least three (3) other drug therapies; there is insufficient data to support the safety and efficacy of Sirturo (bedaquiline) as monotherapy for the management of MDR-TB.

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