Oscar Clinical Guideline: Sirturo (bedaquiline) (PG242, Ver. 2)

Sirturo (bedaquiline)

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.

Definitions

"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.

Medical Necessity Criteria for Authorization

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 or pulmonologist; *AND*
2. The member is 2 years of age or older and weighs at least 8kg; *AND*
3. The member is being treated for drug-resistant tuberculosis infection, including:
    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 at least one injectable antituberculosis agent [e.g., linezolid]); *AND*
4. The member has documentation of culture and susceptibility testing showing resistance to at least isoniazid and rifampin; *AND*
5. Will be used as part of a combination regimen with other antituberculosis agents.

If the above prior authorization criteria are met, the requested product will be authorized for up to 6-months.

Experimental or Investigational / Not Medically Necessary

Sirturo (bedaquiline) for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be 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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