Oscar Clinical Guideline: Sirturo (bedaquiline) (PG242, Ver. 1)

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 pediatric patients 5 years and older weighing at least 15 kg. Sirturo should be used in conjunction with at least three other drugs (e.g., fluoroquinolones, linezolid, pretomanid) to which the patient's TB isolate is susceptible.

Definitions

"**Extensively drug-resistant tuberculosis (XDR-TB)**" refers to MDR-TB with additional resistance to any fluoroquinolone and at least one of three injectable second-line drugs (amikacin, capreomycin, or kanamycin).

"**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 5 years of age or older and weighs at least 15 kg; ***AND***
3. For the treatment of 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 M. tuberculosis resistant to isoniazid, rifampin, any fluoroquinolone, and at least one injectable antituberculosis agent); ***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 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.
- Treatment of drug-sensitive tuberculosis.
- Treatment of extrapulmonary tuberculosis.
- Treatment of infections caused by nontuberculous mycobacteria (NTM).

- Use in members under 5 years of age or weighing less than 15 kg.
- Use as monotherapy for MDR-TB.

References

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