

**HARVARD PILGRIM HEALTH CARE
RECOMMENDED MEDICATION REQUEST GUIDELINES**

BEDAQUILINE (SIRTURO)

| Generic | Brand | HICL | GCN | Exception/Other |
|-------------------------|---------|-------|-----|-----------------|
| BEDAQUILINE FUMARATE | SIRTURO | 39895 | | |

GUIDELINES FOR USE

1. Does the patient have a diagnosis of multi-drug resistant tuberculosis?

If yes, continue to #2.

If no, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your health plan's Sirturo (bedaquiline) guideline, this medication is only covered for members with multi-drug resistant tuberculosis. Your provider did not indicate that you have multi-drug resistant tuberculosis and therefore your request was not approved.

2. Is the patient 18 years of age or older?

If yes, continue to #3.

If no, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your health plan's Sirturo (bedaquiline) guideline, this medication is only covered for members 18 years of age and older. Your provider indicated that you are under the age of 18 and therefore your request was not approved.

3. Has this drug been prescribed by or in consultation with a specialist (e.g., pulmonologist, infectious disease)?

If yes, continue to #4.

If no, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your health plan's Sirturo (bedaquiline) guideline, this medication is only covered when prescribed by or in consultation with a specialist (e.g., pulmonologist, infectious disease). Your provider did not indicate that he or she specializes in one of these areas or has consulted with a specialist and therefore your request was not approved.

4. Has the patient's MDR-TB isolate been shown to be susceptible to Sirturo?

If yes, continue to #5.

If no, continue to #6.

5. Will Sirturo be used in combination therapy with at least 3 other susceptible drugs?

If yes, continue to #7.

If no, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your health plan's Sirturo (bedaquiline) guideline, this medication is only covered for member's whose MDR-TB isolate has been shown to be susceptible to Sirturo when used in combination therapy with at least 3 other susceptible drugs. Your provider did not indicate that Sirturo would be used in combination therapy with at least 3 other susceptible drugs and therefore your request was not approved.

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GUIDELINES FOR USE (CONTINUED)

6. Will Sirturo be used in combination therapy with at least 4 other drugs to which the patient's MDR-TB isolate is likely to be susceptible?

If yes, continue to #7.

If no, do not approve. Please use status code #238 and the denial text provided.

DENIAL TEXT: Per your health plan's Sirturo (bedaquiline) guideline, this medication is only covered Sirturo will be used in combination therapy with at least 4 other drugs to which the patient's MDR-TB isolate is likely to be susceptible. Your provider did not indicate that Sirturo would be used in combination therapy with at least 4 other drugs to which your MDR-TB isolate is likely to be susceptible and therefore your request was not approved.

7. **Please approve for 24 weeks by HICL.** Please use status code #057 and the approval text provided.

APPROVAL TEXT: Your request for Sirturo has been approved for a 24 week period.

RATIONALE

To ensure appropriate use aligned with FDA approved indication.

FDA APPROVED INDICATIONS

SIRTURO is a diarylquinoline antimycobacterial drug indicated as part of combination therapy in the treatment of adults (18 years and older) with pulmonary multi-drug resistant tuberculosis (MDR-TB). Reserve SIRTURO for use when an effective treatment regimen cannot otherwise be provided. Administer SIRTURO by directly observed therapy (DOT).

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-tuberculosis mycobacteria

REFERENCES

- Janssen Therapeutics. Sirturo package insert. Titusville, NJ. December 2012.

Created: 09/16

Effective: 10/01/18

Client Approval: 07/18/18

P&T Approval: 09/27/18