STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEDAQUILINE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
BEDAQUILINE FUMARATE	SIRTURO	39895		GPI-10 (0900001510)	

GUIDELINES FOR USE

1. Does the patient have a diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB) (i.e., an isolate of M. tuberculosis that is resistant to at least isoniazid and rifampin) and meet **ALL** of the following criteria?
   - The patient meets ONE of the following:
     - The patient is 5 to less than 18 years of age **AND** weighs at least 15kg
     - The patient is 18 years of age or older
   - Sirturo will be used in combination with at least 3 other antibiotics

   If yes, **approve for a total of 24 weeks by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve for 4 weeks for the requested strength as follows:**
     - **Sirturo 20mg: #340 per 28 days.**
     - **Sirturo 100mg: #68 per 28 days.**
   - **SECOND APPROVAL: Approve for 20 weeks (total fill count 5) for the requested strength as follows:**
     - **Sirturo 20mg: #120 per 28 days.**
     - **Sirturo 100mg: #24 per 28 days.**

     Please enter a start date of 3 WEEKS AFTER the START date of the first approval.

   If no, continue to #2.

2. Does the patient have a diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB) (i.e., an isolate of M. tuberculosis that is resistant to at least isoniazid and rifampin) **OR** pulmonary extensively drug resistant tuberculosis (XDR-TB) (i.e., an isolate of M. tuberculosis that is resistant to at least isoniazid, rifampin, a fluoroquinolone, and an aminoglycoside) and meet **ALL** of the following criteria?
   - The patient is 18 years of age or older
   - Sirturo will be used in combination with pretomanid and linezolid

   If yes, **approve for a total of 26 weeks for Sirturo 100mg by GPID or GPI-14 as follows:**
   - **FIRST APPROVAL: Approve for 4 weeks with a quantity limit of #68 per 28 days.**
   - **SECOND APPROVAL: Approve for 22 weeks (total fill count 6) with a quantity limit of #24 per 28 days. Please enter a start date of 3 WEEKS AFTER the START date of the first approval.**

   If no, do not approve.
   DENIAL TEXT: See the denial text at the end of the guideline.

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BEDAQUILINE

GUIDELINES FOR USE (CONTINUED)

DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **BEDAQUILINE (Sirturo)** requires the following rule(s) be met for approval:

A. You have ONE of the following diagnoses:
   1. Pulmonary multi-drug resistant tuberculosis (MDR-TB: tuberculosis bacteria in lungs does not respond to multiple drugs, including at least isoniazid and rifampin)
   2. Pulmonary extensively drug resistant tuberculosis (XDR-TB: tuberculosis bacteria is resistant to at least isoniazid, rifampin, a fluoroquinolone [type of antibiotic], and an aminoglycoside [a type of antibiotic])

B. **If you have pulmonary multi-drug resistant tuberculosis, approval also requires ONE of the following:**
   1. You are 5 years to less than 18 years of age AND weigh at least 15 kg (33 lbs), AND will be using Sirturo in combination with at least 3 other antibiotics
   2. You are 18 years of age, AND will be using Sirturo in combination with at least 3 other antibiotics
   3. You are 18 years of age, AND will be using Sirturo in combination with pretomanid and linezolid

C. **If you have pulmonary extensively drug resistant tuberculosis, approval also requires:**
   1. You are 18 years of age or older
   2. You will be using Sirturo in combination with pretomanid and linezolid

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Sirturo.

REFERENCES

- Sirturo [Prescribing Information]. Titusville, NJ: Janssen Therapeutics; May 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 12/01/21
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P&T Approval: 07/20