



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEDAQUILINE FUMARATE

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:**

For pediatric patients weighing 15kg to less than 30kg:

- **FIRST APPROVAL:** Approve for 4 weeks for the requested strength as follows:
 - Sirturo 20mg: #170 per 28 days
 - Sirturo 100mg: #34 per 28 days
- **SECOND APPROVAL:** Approve for 20 weeks (total fill count 5) for the requested strength as follows:
 - Sirturo 20mg: #60 per 28 days
 - Sirturo 100mg: #12 per 28 days

Please enter a start date of 3 WEEKS AFTER the START date of the first approval.
(Note: The total duration of treatment with Sirturo is 24 weeks)

For pediatric patients weighing 30kg or greater and adult patients:

- **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.
(Note: The total duration of treatment with Sirturo is 24 weeks)

If no, continue to #2.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

BEDAQUILINE FUMARATE

GUIDELINES FOR USE (CONTINUED)

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.**

(Note: The total duration of treatment with Sirturo is 26 weeks)

If no, do not approve.

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 FUMARATE (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 (MDR-TB), 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

(Denial text continued on next page)

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PRIOR AUTHORIZATION GUIDELINES

BEDAQUILINE FUMARATE

GUIDELINES FOR USE (CONTINUED)

C. If you have pulmonary extensively drug resistant tuberculosis (XDR-TB), 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

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