

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	N/A	N/A	X	NA	X	X	X	X	X	X	N/A	N/A	X

*FHK- Florida Healthy Kids

Sirturo (bedaquiline)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Sirturo (bedaquiline) tablets

APPROVAL CRITERIA

Requests for Sirturo (bedaquiline) may be approved if the following criteria are met:

- I. Individual is 18 years of age or older; **AND**
- II. Individual has a diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB); **AND**
- III. Individual is unable to use an effective regimen for treatment of MDR-TB; **AND**
- IV. Individual will use Sirturo (bedaquiline) in addition to one of the following therapies (CDC 2013):
 - A. At least 3 drugs to which the patient's multi-drug resistant tuberculosis isolate is susceptible in vitro; **OR**
 - B. At least 4 drugs to which the patient's multi-drug resistant tuberculosis isolate is likely to be susceptible if in vitro testing results are unavailable.

Sirturo (bedaquiline) **may not** be approved for the following:

- I. Latent infection due to Mycobacterium tuberculosis; **OR**
- II. Drug-sensitive tuberculosis; **OR**
- III. Extra-pulmonary tuberculosis; **OR**
- IV. Infections caused by non-tuberculosis mycobacteria.

Note: Sirturo (bedaquiline) has black box warnings for an increased risk of death and possible QT prolongation. Sirturo is to will only be used when an effective treatment regimen cannot otherwise be provided. When Sirturo is used with drugs that prolong the QT interval, the combination may cause additive QT prolongation.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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Key References:

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<http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website.

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DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.

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