

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

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 6 years of age or older (WHO 2019); **AND**
- II. Individual has a diagnosis of pulmonary multi-drug resistant tuberculosis (MDR-TB) or pulmonary extensively drug-resistant tuberculosis (XDR-TB); **AND**
- III. Individual will use Sirturo (bedaquiline) in combination with other anti-infectives (WHO 2019).

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.

An increased risk of death was seen with Sirturo in one placebo-controlled trial. Sirturo can prolong the QT interval. When Sirturo is used in combination with other drugs that prolong the QT interval, the combination may cause additive QT prolongation. Monitor ECGs and discontinue Sirturo if significant ventricular arrhythmia or QT prolongation of greater than 500 ms develops.

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Applicable	X	X	X	X	X	X	NA

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: October 6, 2019.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2019; Updated periodically.
4. Schluger NW, Heysell SK, Friedland G. Treatment of drug-resistant pulmonary tuberculosis in adults. Last updated: September 18, 2019. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: October 7, 2019.
5. World Health Organization. WHO consolidated guidelines on drug-resistant tuberculosis treatment. 2019. Available at: <https://apps.who.int/iris/bitstream/handle/10665/311389/9789241550529-eng.pdf?ua=1>. Accessed: October 6, 2019.

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.