

Policy Name:	Sirturo (bedaquiline)	Policy #:	2045P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Sirturo.

Statement of the Policy

Health Alliance Medical Plans and Health Alliance Northwest will approve the use of Sirturo (bedaquiline) under the specialty pharmacy benefit when the following criteria have been met.

Criteria

- 1. Criteria for Coverage**
 - 1.1 Confirmed susceptibility data that indicate member has pulmonary multi-drug-resistant tuberculosis (MDR-TB). [MDR-TB refers to an isolate of *M. tuberculosis* that is resistant to at least isoniazid and rifampin, and possibly additional agents. Treatment failure refers to failure of cultures to become negative during the course of treatment, or reappearance of positive cultures after the cultures convert to negative during treatment]
 - 1.2 Prescribed by an Infectious Disease specialist or pulmonologist
 - 1.3 Age 5 years or older and weighs at least 15 kg
 - 1.4 Documentation that Sirturo will be used in combination with at least 3 other drugs to which the member's MDR-TB isolate has been shown to be susceptible in vitro OR in combination with at least 4 other drugs to which patient's MDR-TB isolate is likely to be susceptible OR documentation that Sirturo will be used in combination with pretomanid and linezolid
- 2. Exclusion Criteria**
 - 2.1 Diagnosis of latent, extra-pulmonary or drug-sensitive tuberculosis.
- 3. Managed Dose Limit**
 - 3.1 Maximum of #188 tablets over 24 weeks
- 4. Approval Period**
 - 4.1 6 months

CPT Codes

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HCPCS Codes

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References

1. Sirturo (bedaquiline) [prescribing information]. Horsham, PA: Janssen Products LP; October 2023.

2. Conradie F, Diacon AH, Ngubane N, et al; Nix-TB Trial Team. Treatment of highly drug-resistant pulmonary tuberculosis. *N Engl J Med.* 2020;382(10):893-902.
3. Nahid P, Mase SR, Migliori GB, et al. Treatment of Drug-Resistant Tuberculosis an Official ATS/CDC/ERS/IDSA Clinical Practice Guideline. *Am J Respir Crit Care Med.* 2019 Nov 15;200(10):e93-e142.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851-3379 for verification of coverage.