



**Antitubercular Agents  
Pretomanid (safinamide)  
Sirturo® (bedaquiline)  
Effective 01/01/2023**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth UPPL <input type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Specialty Limitations</b>			
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
Exchange	Phone: 855-582-2022	Fax: 855-245-2134	
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>	N/A		

**Overview**

Pretomanid is an antitubercular agent indicated as part of a combination regimen with bedaquiline and linezolid for the treatment of adults with pulmonary extensively drug resistant (XDR) or treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB).

Sirturo® (bedaquiline) is an antitubercular agent indicated as part of combination therapy in the treatment of adult and pediatric patients (5 years and older and weighing at least 15 kg) with pulmonary multi-drug resistant tuberculosis (MDR-TB).

No PA	Drugs that require PA
cyclosporine	pretomanid
Myambutol® # (ethambutol)	Sirturo® (bedaquiline)
Mycobutin® (rifabutin)*	
Paser® (aminosalicylic acid)	
Priftin® (rifapentine)	
pyrazinamide	
Rifadin® # (rifampin)	
Trecator (ethionamide)	

# This is a brand-name drug with FDA “A”-rated generic equivalents. PA is required for the brand, unless a particular form of that drug (for example, tablet, capsule, or liquid) does not have an FDA “A”-rated generic equivalent.

\*Authorized generic available



### Coverage Guidelines

Authorization may be reviewed on a case by case basis for members who are new to the plan currently receiving treatment with requested medication excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

#### OR

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

#### Non-responsive MDR-TB, Pulmonary extensively drug resistant (XDR) tuberculosis, Treatment-intolerant tuberculosis

##### **pretomanid**

Prescriber provides documentation of **ALL** of the following:

1. Appropriate diagnosis
2. Requested agent will be used in combination with Sirturo and linezolid
3. Quantity does not exceed 1 tablet/day

#### Multi-drug resistant tuberculosis (MDR-TB)

##### **Sirturo® (bedaquiline)**

1. Member meets **ONE** of the following diagnoses:
  - a. Multi-drug resistant tuberculosis
  - b. Pulmonary extensively drug resistant tuberculosis in combination with pretomanid
  - c. Treatment-intolerant tuberculosis in combination with pretomanid
2. Member meets **ONE** of the following:
  - a. Requested agent will be used in combination with at least three other antitubercular agents
  - b. Requested agent will be used in combination with pretomanid and linezolid

#### Continuation of Therapy

Reauthorization requires physician attestation of a positive response to therapy.

#### **Limitations**

1. Initial approvals and reauthorizations will be granted for 6 months.
2. The following quantity limits apply:

pretomanid	30 tablets per 30 days
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#### **References**

1. Sirturo® [package insert]. Titusville (NJ): Janssen Therapeutics; 2020 May.
2. Pretomanid [package insert]. Morgantown (WV): Mylan Specialty L.P.; 2020 Apr
3. Centers for Disease Control and Prevention. Tuberculosis (TB) [webpage on the Internet]. Atlanta (GA): Centers for Disease Control and Prevention; Dec 2018 [cited 2021 Jul 18]. Available from: <http://www.cdc.gov/tb>.
4. Schluger NW, Heysell SK, Friedland G. Treatment of drug-resistant pulmonary tuberculosis in adults. In Basow DS (Ed). UpToDate [database on the Internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Jul 18]. Available from: <http://www.uptodate.com/utd/index.do>.
5. Avom J. Approval of a tuberculosis drug based on a paradoxical surrogate measure. JAMA. 2013 Apr; 309(13):1349-50.

6. TMC207 (bedaquiline). Briefing Document for Anti-infective Advisory Committee Meeting: NDA No. 204- 384. Rockville (MD): Food and Drug Administration: 2012 Nov [cited 2021 Jul 18].
7. Diacon AH, Pym A, Grobusch M, Patientia R, Rustomjee R, Page-Shipp L, et al. The diarylquinoline TMC207 for Multidrug-Resistant Tuberculosis. *N Engl J Med* . 2009;360(23):2397-2405.
8. World Health Organization (WHO). Guidelines for the treatment of drug-susceptible tuberculosis and patient care 2017 update [guideline on the internet]. Geneva, Switzerland: World Health Organization; 2017 [cited 2021 Jul 18]. Available from: <https://apps.who.int/iris/bitstream/handle/10665/255052/9789241550000-eng.pdf?sequence=1>.
9. World Health Organization (WHO). WHO treatment guidelines for multidrug- and rifampicin-resistant tuberculosis, 2018 update [guideline on the internet]. Geneva, Switzerland: World Health Organization; 2018 [cited 2021 Jul 18]. Available from: <https://www.who.int/tb/publications/2018/WHO.2018.MDR-TB.Rx.Guidelines.prefinal.text.pdf>
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12. Nahid P, Dorman SE, Alipanah N, Barry PM, Brozek JL, Cattamanchi A et al. Official American Thoracic Society/Centers for Disease Control and Prevention/Infectious Diseases Society of America Clinical Practice Guidelines: Treatment of Drug-Susceptible Tuberculosis. *Clin Infect Dis*. 2016 Oct 1;63(7):e147-e195.
13. Nahid P, Mase SR, Migliori GB, Sotgiu G, Bothamley GH, Brozek JL 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.
14. World Health Organization (WHO). WHO Consolidated Guidelines on Tuberculosis, Module 4: Treatment - Drug-Resistant Tuberculosis Treatment. Geneva, Switzerland: World Health Organization; 2020 [cited 2021 Jul 18]. Available from: <https://www.who.int/publications/i/item/9789240007048>.
15. Bedaquiline: drug information. In: Basow DS (Ed). UpToDate[database on the Internet]. Waltham (MA): UpToDate; 2021 [cited 2021 Jul 18]. Available from: <http://www.utdol.com/utd/index.do>.

## Review History

09/21/22 – Reviewed and Created for Sept P&T; matched MH UPPL. Effective 01/01/2023

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