

**Pretomanid (safinamide)**  
**Effective 01/01/2023**

<b>Plan</b>	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
<b>Specialty Limitations</b>	N/A		
<b>Contact Information</b>	<b>Medical and Specialty Medications</b>		
	All Plans	Phone: 877-519-1908	Fax: 855-540-3693
<b>Exceptions</b>	<b>Non-Specialty Medications</b>		
	All Plans	Phone: 800-711-4555	Fax: 844-403-1029

### Overview

Pretomanid is an antimycobacterial drug that kills actively replicating *Mycobacterium tuberculosis* by inhibiting mycolic acid biosynthesis, blocking cell wall production. Against nonreplicating bacteria, under anaerobic conditions, Pretomanid acts as a respiratory poison following nitric oxide release.

### Coverage Guidelines

Authorization may be granted for members new to the plan who are currently receiving treatment with and is stable on Pretomanid 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:

1. The member is  $\geq 18$  years old
2. The member has a diagnosis of pulmonary extensively drug resistant, treatment-intolerant or nonresponsive multidrug-resistant tuberculosis
3. Member is using Pretomanid in combination with bedaquiline and linezolid

### Continuation of Therapy

Reauthorization requires physician documentation of improvement of member's condition.

### Limitations

Initial approvals will be for 6 months.

### References

1. Pretomanid tablet [prescribing information]. New York, NY: The Global Alliance for TB Drug Development; August 2019

**Review History**

07/22/2020 – Reviewed P&T Mtg. Effective 09/01/2020

09/21/2022 –Reviewed at Sept P&T; Separated Comm/Exch vs MH policies; no clinical updates. Effective 01/01/2023

