

PRIOR AUTHORIZATION CRITERIA

BRAND NAME
(generic)

(pretomanid)

Status: CVS Caremark Criteria

Type: Initial Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Limited Population: Pretomanid Tablet is indicated, as part of a combination regimen with bedaquiline and linezolid for the treatment of adults with pulmonary tuberculosis (TB) resistant to isoniazid, rifamycins, a fluoroquinolone and a second line injectable antibacterial drug OR adults with pulmonary TB resistant to isoniazid and rifampin, who are treatment-intolerant or nonresponsive to standard therapy. Approval of this indication is based on limited clinical safety and efficacy data. This drug is indicated for use in a limited and specific population of patients.

Limitations of Use:

- Pretomanid Tablets are not indicated in patients with:
 - Drug-sensitive (DS) TB
 - Latent infection due to *Mycobacterium tuberculosis*.
 - Extra-pulmonary infection due to *Mycobacterium tuberculosis*.
 - TB resistant to isoniazid and rifampin who are responsive to standard therapy and not treatment intolerant.
 - TB with known resistance to any component of the combination.
- Safety and effectiveness of Pretomanid Tablets have not been established for its use in combination with drugs other than bedaquiline and linezolid as part of the recommended dosing regimen

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The requested drug is being prescribed for pulmonary tuberculosis (TB) resistant to isoniazid, rifamycins, a fluoroquinolone and a second line injectable antibacterial drug OR TB resistant to isoniazid and rifampin, that is treatment-intolerant or nonresponsive to standard therapy

AND

- The requested drug will be prescribed as part of a combination regimen with both Sirturo (bedaquiline) and Zyvox (linezolid)

REFERENCES

1. Pretomanid [package insert]. Hyderabad, India: Mylan Laboratories Limited; December 2022.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, Ohio: UpToDate, Inc.; 2022; Accessed November 29, 2022.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com/>. Accessed November 29, 2022.