Pharmacy Drug Policy & Procedure

Policy Name:	Pretomanid	Policy #:	2729P

Purpose of the Policy

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

Statement of the Policy

Health Alliance Medical Plans will approve the use of pretomanid under the pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria

1.1 Treatment of pulmonary tuberculosis (TB) that is resistant to isoniazid, rifamycins, a fluoroquinolone and an alternative injectable antibiotic OR pulmonary TB resistant to isoniazid and rifampin

1.2 Member is treatment intolerant or non-responsive to standard therapy. [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]

1.3 Age 18 years or older

1.4 Prescribed by or in consultation with an Infectious Disease specialist or pulmonologist (lung doctor)

1.5 Documentation that pretomanid will be used in combination with Sirturo (bedaquiline) and linezolid

2. Exclusion Criteria

2.1 Not to be used in those who have a contraindication to bedaquiline ane/or linezolid

2.2 Drug-sensitive tuberculosis

2.3 Latent infection due to Mycobacterium tuberculosis

2.4 Extra-pulmonary infection (infection outside of the lungs) due to Mycobacterium tuberculosis

2.5 Multi-drug resistant tuberculosis in patients who are responsive to standard therapy and are not treatment intolerant

3. Managed Dose Limit

3.1 #30 tablets/30 days

4. Approval Period

4.1 Initial: 26 weeks

4.2 Initial authorization may be extended but re-treatment with pretomanid has not been studied and is considered experimental at this time

CPT Codes

HCPCS Codes

References

1. Pretomanid [prescribing information]. Morgantown, WV: Mylan Specialty LP; November 2024.

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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