

AETNA BETTER HEALTH®

Coverage Policy/Guideline							
Name:	Linezolid	Page: 1 c		1 of 3			
Effective Date: 6/26/2024 Last Review Date: 6/6/2024							
Applies to:	⊠Illinois ⊠Virginia	⊠New Jersey ⊠Pennsylvania Kids	⊠Florida Kids ⊠Maryland				

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Linezolid under the patient's prescription drug benefit.

Description:

Nosocomial Pneumonia

Linezolid is indicated for the treatment of nosocomial pneumonia caused by Staphylococcus aureus (methicillin-susceptible and -resistant isolates) or Streptococcus pneumoniae.

Community-acquired Pneumonia

Linezolid is indicated for the treatment of community-acquired pneumonia caused by Streptococcus pneumoniae, including cases with concurrent bacteremia, or Staphylococcus aureus (methicillin-susceptible isolates only).

Complicated Skin and Skin Structure Infections

Linezolid is indicated for the treatment of complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis, caused by Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Streptococcus pyogenes, or Streptococcus agalactiae. Linezolid has not been studied in the treatment of decubitus ulcers.

Uncomplicated Skin and Skin Structure Infections

Linezolid is indicated for the treatment of uncomplicated skin and skin structure infections caused by Staphylococcus aureus (methicillin susceptible isolates only) or Streptococcus pyogenes.

Vancomycin-resistant Enterococcus faecium Infections

Linezolid is indicated for the treatment of vancomycin-resistant Enterococcus faecium infections, including cases with concurrent bacteremia.

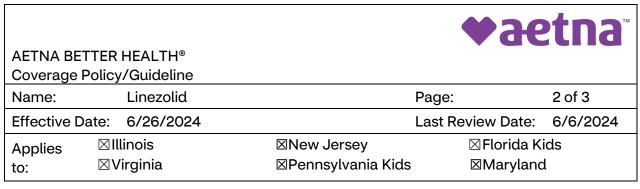
Limitations of Use

Linezolid is not indicated for the treatment of Gram-negative infections. It is critical that specific Gram-negative therapy be initiated immediately if a concomitant Gram-negative pathogen is documented or suspected.

The safety and efficacy of Linezolid formulations given for longer than 28 days have not been evaluated in controlled clinical trials.

Off Label Uses

Combination regimen for the treatment of extensively drug resistant (XDR) or treatmentintolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB).



Applicable Drug List:

Preferred Agent:

Linezolid 600mg tablets

Policy/Guideline:

Criteria for Initial Approval:

- I. The requested drug will be covered with prior authorization when the following criteria are met:
 - The patient is being converted from intravenous (IV) linezolid as prescribed or directed by an Infectious Disease specialist for a NON-Tuberculosis (TB) bacterial infection

OR

• The patient has ANY of the following: A) an infection caused by vancomycin-resistant Enterococcus faecium including cases with concurrent bacteremia, B) a nosocomial (institution-acquired) pneumonia caused by Staphylococcus aureus (methicillinsusceptible and -resistant isolates) or Streptococcus pneumoniae, C) communityacquired pneumonia caused by Streptococcus pneumoniae, including cases with concurrent bacteremia, or Staphylococcus aureus (methicillin-susceptible isolates only), D) a complicated skin and skin structure infection including diabetic foot infections, without concomitant osteomyelitis, caused by Staphylococcus aureus (methicillin-susceptible and -resistant isolates), Streptococcus pyogenes, or Streptococcus agalactiae, E) an uncomplicated skin and skin structure infection caused by Staphylococcus aureus (methicillin-susceptible isolates only) or Streptococcus pyogenes

AND

- The infection is proven or strongly suspected to be caused by susceptible bacteria AND
- The patient has experienced an inadequate treatment response, intolerance, or contraindication to alternative therapies OR the bacteria are NOT susceptible to any other antibiotics

OR

 The requested drug is being prescribed for pulmonary extensively drug resistant (XDR) or treatment-intolerant/ nonresponsive multidrug-resistant (MDR) tuberculosis

AND

• The requested drug is being prescribed as part of a combination regimen with Pretomanid and Sirturo (bedaquiline)

AND

• The patient will use the requested drug orally or intravenously



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Approval Duration and Quantity Restrictions:

Approval Duration: Requests for pulmonary extensively drug resistant (XDR) or treatment-intolerant/ nonresponsive multidrug-resistant (MDR) tuberculosis AND as part of a combination regimen with Pretomanid and Sirturo (bedaquiline): 12 months

All other approvable requests: 28 days

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

References:

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- 3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: https://www.micromedexsolutions.com/ (cited: 12/06/2023).
- 4. Diagnosis and Treatment of Adults with Community-Acquired Pneumonia. An Official Clinical Practice Guideline of the American Thoracic Society and Infectious Diseases Society of America. American Journal of Respiratory and Critical Care Medicine, Volume 200, Issue 7, 1 October 2019, Pages e45-e67.
- 5. Senneville E, Albalawi, van Asten SA, et al. IWGDF/IDSA Guidelines on the Diagnosis and Treatment
- 6. of Diabetes-related Foot Infections. *Clinical Infectious Diseases* 2023;, ciad527, https://doi.org/10.1093/cid/ciad527.
- 7. Kalil A, Metersky M, Klompas M, et al. Management of Adults With Hospital-acquired and Ventilatorassociated Pneumonia: 2016 Clinical Practice Guidelines by the Infectious Diseases Society of America and the American Thoracic Society. *Clinical Infectious Diseases* 2016;1-51.
- 8. Stevens D, Bisno A, Chambers H, et al. Practice Guidelines for the Diagnosis and Management of Skin and Soft-Tissue Infections: 2014 Update by the Infectious Diseases Society of America. *Clinical Infectious Diseases* 2014;1-43.
- 9. Pretomanid [package insert]. Hyderabad, India: Mylan Laboratories Limited for The Global Alliance for TB Drug Development (TB Alliance); April 2020.
- 10. WHO Consolidated Guidelines on Tuberculosis. Module 4: Treatment Drug-Resistant Tuberculosis Treatment. Geneva: World Health Organization; 2020. Licence: CC BY-NC-SA 3.0 IGO. Available at: https://www.who.int/publications/i/item/9789240007048. Accessed December 6, 2023.
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