



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Linezolid

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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 treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB).



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### 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* (methicillin-susceptible and -resistant isolates) or *Streptococcus pneumoniae*, C) community-acquired 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:

1. Zyvox [package insert]. New York, NY: Pharmacia & Upjohn Company LLC a subsidiary of Pfizer Inc; August 2023.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2023. <https://online.lexi.com>. Accessed December 6, 2023.
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 Ventilator-associated 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.
11. WHO Consolidated Guidelines on Tuberculosis. Module 5: Management of Tuberculosis in Children and Adolescents.
12. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO. Available at: <https://www.who.int/publications/i/item/9789240007048>. Accessed December 6, 2023.