



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Linezolid

Page: 1 of 3

Effective Date: 5/25/2023

Last Review Date: 3/9/2023

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> New Jersey
	<input checked="" type="checkbox"/> Maryland	<input checked="" type="checkbox"/> Florida Kids	<input checked="" type="checkbox"/> Pennsylvania Kids
	<input type="checkbox"/> Michigan	<input checked="" type="checkbox"/> Virginia	

### 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).



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Linezolid

Page: 2 of 3

Effective Date: 5/25/2023

Last Review Date: 3/9/2023

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> New Jersey
	<input checked="" type="checkbox"/> Maryland	<input checked="" type="checkbox"/> Florida Kids	<input checked="" type="checkbox"/> Pennsylvania Kids
	<input type="checkbox"/> Michigan	<input checked="" type="checkbox"/> Virginia	

### Applicable Drug List:

Preferred: 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



AETNA BETTER HEALTH®  
Coverage Policy/Guideline

Name: Linezolid

Page: 3 of 3

Effective Date: 5/25/2023

Last Review Date: 3/9/2023

Applies to:	<input checked="" type="checkbox"/> Illinois	<input type="checkbox"/> Florida	<input checked="" type="checkbox"/> New Jersey
	<input checked="" type="checkbox"/> Maryland	<input checked="" type="checkbox"/> Florida Kids	<input checked="" type="checkbox"/> Pennsylvania Kids
	<input type="checkbox"/> Michigan	<input checked="" type="checkbox"/> Virginia	

### 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 Co Division of Pfizer Inc; November 2021.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, Ohio: UpToDate, Inc.; 2021; Accessed December 2021.
3. Micromedex (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com/>. Accessed December 2021.
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. Lipsky B, Berendt A, Cornia P, et al. 2012 Infectious Diseases Society of America Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Infections. *Clinical Infectious Diseases* 2012; 54(12):132-173.
6. 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.
7. 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.
8. Gorwitz RJ, Jernigan DB, Powers JH, Jernigan JA, and Participants in the CDC Convened Experts' Meeting on Management of MRSA in the Community. Strategies for clinical management of MRSA in the community: Summary of an experts' meeting convened by the Centers for Disease Control and Prevention. 2006. Available at <https://www.cdc.gov/mrsa/pdf/MRSA-Strategies-ExpMtgSummary2006.pdf>. Accessed December 2021.
9. Pretomanid [package insert]. Hyderabad, India: Mylan Laboratories Limited for The Global Alliance for TB Drug Development (TB Alliance); April 2020.
10. WHO Global Tuberculosis Report 2020. Geneva: World Health Organization; 2020. <https://apps.who.int/iris/bitstream/handle/10665/336069/9789240013131-eng.pdf>. Accessed December 2021.