

**Zyvox (linezolid) tablets
Linezolid oral suspension**
Effective 11/26/2018

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A		
Contact Information	Medical Benefit Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

Linezolid is an antibiotic that fights bacteria in the body. Linezolid is also a MAO (monoamine oxidase) inhibitor. Linezolid is used to treat different types of bacterial infections, such as pneumonia, skin infections, and infections that are resistant to other antibiotics.

Coverage Guidelines

Authorization may be granted for members when ANY of the following criteria are met, and documentation is provided:

1. Member was started on linezolid therapy in the hospital or another inpatient facility.
2. Member has a documented blood, sputum, tissue or urine culture positive for vancomycin-resistant Enterococcus (VRE).
3. Member has a documented blood, sputum, tissue or urine culture positive for methicillin-resistant Staphylococcus (MRSA) and treatment with vancomycin is not an option (e.g. lack of IV access, etc.).
4. Member currently has a complicated skin or skin structure infection with no concomitant osteomyelitis where a culture cannot be obtained (e.g. closed wound infections, diabetic foot infections, cellulitis infections, etc.) and patient has a history of MRSA infections.
5. Member has hospital-acquired or healthcare-associated pneumonia caused by *S. aureus* (methicillin-susceptible and -resistant isolates), or *S. pneumoniae*.
6. Member has uncomplicated skin and skin structure infections caused by *S. aureus* (methicillin-susceptible isolates) or *S. pyogenes*.

Limitations

1. Approvals for the following will be granted for 28 days:
 - a. Therapy has been started in a hospital/inpatient facility,
 - b. Blood, sputum, tissue or urine culture positive for VRE/MRSA,
 - c. Hospital-acquired or healthcare-associated pneumonia caused by *S. aureus* or *S. pneumoniae*.
2. Approvals for the following will be granted for 14 days:
 - a. Complicated skin or skin structure infection with no concomitant osteomyelitis and a history of MRSA infections.

- b. Uncomplicated skin and skin structure infection cause by *S.aureus* or *S. pyogenes*
- 3. For treatment duration exceeding 2 weeks, weekly monitoring of patient's complete blood count (CBC) is required.
- 4. The following quantity limits apply:

Linezolid 600mg tablets	56 tablets per 90 days
Linezolid oral suspension	1800mL (12 bottles) per 90 days

References

1. Zyvox (linezolid) [prescribing information]. New York, NY: Pharmacia & Upjohn Co; July 2018.
2. Stevens DL, Bisno AL, Chambers HF, Everett ED, Dellinger P, Goldstein EJC, et al. Practice Guidelines for the Diagnosis and Management of Skin and Soft-Tissue Infections. IDSA Guidelines. CID. 2005; 41:1373-406.
3. Lipsky BA, Berendt AR, Cornia PB, Pile JC, Peters EJG, Armstrong DG, et al. 2012 IDSA Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Infections. CID. 2012;54(12):132-73.
4. Mandell LA, Wunderink RG, Anzueto A, Bartlett JG, Douglas Campbell G, Dean NC, et al. IDSA/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults. CID. 2007;44: S27-72.
5. Liu C, Bayer A, Cosgrove SE, Datum RS, Fridkin SK, Gorwitz RJ, et al. Clinical practice guidelines by the Infectious Diseases Society of America for the treatment of methicillin-resistant *staphylococcus aureus* infections in adults and children. CID. 2011; 52:1-38.
6. Yue J, Dong BR, Yang M, Chen X, Wu T, Liu GJ. Linezolid versus vancomycin for skin and soft tissue infections. *Cochrane Database Syst Rev*. 2016;1:CD008056.[\[PubMed 26758498\]](#)[\[10.1002/14651858.CD008056.pub3\]](#)
7. Itani KM, Dryden MS, Bhattacharyya H, Kunkel MJ, Baruch AM, Weigelt JA. Efficacy and safety of linezolid versus vancomycin for the treatment of complicated skin and soft-tissue infections proven to be caused by methicillin-resistant *Staphylococcus aureus*. *Am J Surg*. 2010;199(6):804-816.[\[PubMed 20227056\]](#)
8. Pea F, Cojutti PG, Baraldo M. A 10-year experience of therapeutic drug monitoring (TDM) of linezolid in a hospital-wide population of patients receiving conventional dosing: is there enough evidence for suggesting TDM in the majority of patients? *Basic Clin Pharmacol Toxicol*. 2017;121(4):303-308.[\[PubMed 28419737\]](#)[\[10.1111/bcpt.12797\]](#)

Review History

12/09/05 – Reviewed
 11/27/06 – Reviewed
 11/26/07 – Reviewed
 11/24/08 – Reviewed
 11/23/09 – Reviewed and revised
 11/22/10 – Reviewed
 11/28/11 – Reviewed and revised
 11/26/12 – Reviewed and revised
 11/25/13 – Reviewed
 11/24/14 – Reviewed
 11/2016 – Reviewed
 11/27/17 – Reviewed in P&T Meeting
 11/26/18 – Reviewed and revised in P&T Meeting
 01/22/2020 – Reviewed P&T Mtg.

