Linezolid (generic Zyvox)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	Pulmonary multidrug-resistant tuberculosis (MDR-TB), pulmonary extensively drug-resistant tuberculosis (XDR-TB) or non-tuberculous mycobacterial infection: 1 year All other diagnoses: 1 month

Medications	Quantity Limit
Linezolid 600mg tablets	28 tablets per fill; 1 fill per 30 days
Linezolid 100 mg/5 mL oral suspension	900 mL per fill; 1 fill per 30 days

******* If linezolid is being requested for the treatment of vancomycin-resistant Enterococcus (VRE) faecium infection; up to 56 tablets or 1,680 mL of the oral suspension may be approved per fill.

If linezolid is being requested for the treatment of pulmonary multidrug-resistant tuberculosis (MDR-TB), pulmonary extensively drug-resistant tuberculosis (XDR-TB) or non-tuberculous mycobacterial infection, may approve up to 2 tablets or 60 mL per day.

APPROVAL CRITERIA

Requests for linezolid may be approved if the following criteria are met:

I. Individual has vancomycin-resistant enterococcus (VRE) *faecium* infection***;**

OR

Individual has methicillin-resistant *Staphylococcus aureus* (MRSA) infection;

OR

II. Individual has a diagnosis of pulmonary multidrug-resistant tuberculosis (MDR-TB) or pulmonary extensively drug-resistant tuberculosis (XDR-TB) (ATS/CDC/ERS/IDSA 2019); **AND**

III. Linezolid will be used in combination with other anti-infectives (ATS/CDC/ERS/IDSA 2019);

OR

IV. Individual has a diagnosis of non-tuberculous mycobacterial infection (including but not limited to *M. fortuitum)* (ATS/CDC/ERS/IDSA 2020); **AND**

V. Linezolid will be used in combination with other anti-infectives (ATS/CDC/ERS/IDSA 2020);

OR

VI. Individual started treatment with antibiotic(s) in the hospital and requires continued outpatient therapy for an organism susceptible to linezolid.

** IDSA recommends using alternatives to vancomycin, such as linezolid, when the MRSA isolate has a vancomycin minimum inhibitory concentration (MIC) of greater than 2.

Linezolid may not be approved for the following:

I. Treatment of gram-negative infections.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: March 11, 2023.
2. Daley CL, Iaccarino JM, Lange C, et. al. Treatment of Nontuberculous Mycobacterial Pulmonary Disease: An Official ATS/ERS/ESCMID/IDSA Clinical Practice Guideline. *Clin Infect Dis*. 2020;71(4):e1-e36.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
5. Liu C, Bayer A, Cosgrove SE, et. al. Clinical Practice Guidelines by the Infectious Diseases Society of America (IDSA) for the Treatment of Methicillin-Resistant *Staphylococcus aureus* Infections in Adults and Children.*Clin Infect Dis*. 2011;52(3):e18-55.
6. 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;200(10):e93.