Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

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 confirmed vancomycin-resistant enterococcus (VRE) *faecium* infection***;

OR

II. Individual has confirmed methicillin-resistant *Staphylococcus aureus* (MRSA) infection;
AND
III. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one alternative antibiotic that the organism is susceptible to examples of alternative antibiotics may include, but are not limited to: vancomycin, TMP-SMX, clindamycin, doxycycline, tetracycline (IDSA, 2011);

OR

IV. Isolates of MRSA have a vancomycin minimum inhibitory concentration (MIC) of greater then 2** (IDSA, 2011);

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

OR

V. Individual has a diagnosis of pulmonary multidrug-resistant tuberculosis (MDR-TB) or pulmonary extensively drug-resistant tuberculosis (XDR-TB) (WHO 2019); **AND**
VI. Linezolid will be used in combination with other anti-infectives (WHO 2019);

OR

VII. Individual has a diagnosis of non-tuberculous mycobacterial infection (including but not limited to *M. fortuitum)* (ATS/IDSA 2007); **AND**
VIII. Linezolid will be used in combination with other anti-infectives (ATS/IDSA 2007);

OR

IX. 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 13, 2020.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Griffith DE, Aksamit T, Brown-Elliott BA, et. al. An Official ATS/IDSA Statement: Diagnosis, Treatment, and Prevention of Nontuberculous Mycobacterial Diseases. *Am J Respir Crit Care Med*. 2007;175: 367-416.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; 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 Feb 1;52(3):e18-55. doi: 10.1093/cid/ciq146.
6. Schluger NW, Heysell SK, Friedland G. Treatment of drug-resistant pulmonary tuberculosis in adults. Last updated: March 11, 2020. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: March 14, 2020.
7. World Health Organization. WHO consolidated guidelines on drug-resistant tuberculosis treatment. 2019. Available at: https://apps.who.int/iris/bitstream/handle/10665/311389/9789241550529-eng.pdf?ua=1. Accessed: March 14, 2020.

Market Applicability							
Market	**DC**	**GA**	**KY**	**MD**	**NJ**	**NY**	**WA**
Applicable	X	X	X	X	X	X	NA

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.