

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Zyvox (linezolid)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 fill per 30 days

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

*** If Zyvox (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.

APPROVAL CRITERIA

Requests for Zyvox (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 of or has contraindications* to an alternative antibiotic that the organism is susceptible to (*depending on manifestation, severity of infection and culture or local sensitivity patterns, examples of alternative antibiotics may include, but are not limited to: vancomycin, TMP-SMX, clindamycin, doxycycline, tetracycline (based on 2011 IDSA MRSA guideline recommendations)*);

OR

- IV. Isolates of MRSA have a vancomycin minimum inhibitory concentration (MIC) of greater than 2**;

OR

- V. Individual started treatment with intravenous antibiotic(s) in the hospital and requires continued outpatient therapy for an organism susceptible to Zyvox.

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.

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Note: To reduce the development of drug-resistant bacteria and maintain the effectiveness of Zyvox and other antibacterial drugs, Zyvox should be used only to treat infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy

*Contraindications may include but are not limited to; adverse events, allergic reaction, lack of venous access or complications from venous access devices (for IV antibiotics).

** 2011 IDSA guidelines for MRSA recommend linezolid as a viable alternative for treatment of isolates with vancomycin MIC greater than 2.

Zyvox (linezolid) may **not** be approved for the following:

- I. Treatment of gram-negative infections.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.

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