

# PRIOR AUTHORIZATION CRITERIA

**BRAND NAME**  
(generic)

**ZYVOX**  
(linezolid)

**Status: CVS Caremark Criteria**

**Type: Initial Prior Authorization**

## POLICY

### FDA-APPROVED INDICATIONS

Zyvox is indicated for the treatment of infections caused by susceptible strains of the designated microorganisms in the specific conditions listed below. Zyvox 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.

#### Pneumonia

Nosocomial pneumonia caused by *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates) or *Streptococcus pneumoniae*.

Community-acquired pneumonia caused by *Streptococcus pneumoniae*, including cases with concurrent bacteremia, or *Staphylococcus aureus* (methicillin-susceptible isolates only).

#### Skin and Skin Structure Infections

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*. Zyvox has not been studied in the treatment of decubitus ulcers.

Uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (methicillin susceptible isolates only) or *Streptococcus pyogenes*.

Vancomycin-resistant *Enterococcus faecium* Infections including cases with concurrent bacteremia.

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 or prevent 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.

The safety and efficacy of Zyvox formulations given for longer than 28 days have not been evaluated in controlled clinical trials.

### COVERAGE CRITERIA

Zyvox (linezolid) will be covered with prior authorization when the following criteria are met:

- The patient is being converted from IV linezolid (Zyvox) as prescribed or directed by an Infectious Disease specialist

**OR**

- The patient has any of the following:
  - an infection caused by vancomycin-resistant *Enterococcus faecium* including cases with concurrent bacteremia
  - a nosocomial (institution-acquired) pneumonia caused by *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates) or *Streptococcus pneumoniae*

- community-acquired pneumonia caused by *Streptococcus pneumoniae*, including cases with concurrent bacteremia, or *Staphylococcus aureus* (methicillin-susceptible isolates only)
- 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*
- 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

## **REFERENCES**

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4. Mandell L, Wunderink R, Anzueto A, et al. Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults. *Clinical Infectious Diseases* 2007;44:S27–72.
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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.
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