

PRIOR AUTHORIZATION CRITERIA

BRAND NAME*
(generic)

ZYVOX
(linezolid)

Status: CVS Caremark Criteria
Type: Initial Prior Authorization

Ref # 263-A

* Drugs that are listed in the target drug box include both brand and generic and all dosage forms and strengths unless otherwise stated

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

The requested drug 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

RATIONALE

The intent of the criteria is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. 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.

- 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).
- 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.

Zyvox (linezolid) will be approved if being requested for a patient converted from intravenous (IV) Zyvox as prescribed or directed by an Infectious Disease specialist.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Zyvox (linezolid) and other antibacterial drugs, Zyvox (linezolid) 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. Prescribing Zyvox (linezolid) in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug-resistant bacteria.¹⁻⁸ To limit potential for widespread resistance, clinicians should consider reserving linezolid for use in more severe infections in consultation with an infectious disease specialist.⁸

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

REFERENCES

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 Reviewed: CRC 05/2000, 09/2003, Medicals Affairs (MM) 04/2005, 06/2005, 01/2006; (WF) 02/2007, 03/2008, 03/2009; (KP) 01/2010, 10/2010, 12/2011, 12/2012; (DC) 12/2013; (LCB) 12/2014; (JG) 12/2016
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CRITERIA FOR APPROVAL

1	Is the patient being converted from intravenous (IV) linezolid (Zyvox) as prescribed or directed by an Infectious Disease specialist? [If yes, then no further questions.]	Yes	No
2	Does the patient have any of the following: A) an infection caused by vancomycin-resistant <i>Enterococcus faecium</i> including cases with concurrent bacteremia, B) a nosocomial (institution-acquired) pneumonia caused by <i>Staphylococcus aureus</i> (methicillin-susceptible and -resistant isolates) or <i>Streptococcus pneumoniae</i> , C) community-acquired pneumonia caused by <i>Streptococcus pneumoniae</i> , including cases with concurrent bacteremia, or <i>Staphylococcus aureus</i> (methicillin-susceptible isolates only), D) a complicated skin and skin structure infection including diabetic foot infections, without concomitant osteomyelitis, caused by <i>Staphylococcus aureus</i> (methicillin-susceptible and -resistant isolates), <i>Streptococcus pyogenes</i> , or <i>Streptococcus agalactiae</i> , E) an uncomplicated skin and skin structure infection caused by <i>Staphylococcus aureus</i> (methicillin-susceptible isolates only) or <i>Streptococcus pyogenes</i> ?	Yes	No
3	Is the infection proven or strongly suspected to be caused by susceptible bacteria?	Yes	No
4	Has the patient experienced an inadequate treatment response, intolerance, or contraindication to alternative therapies OR are the bacteria NOT susceptible to any other antibiotics?	Yes	No

Mapping Instructions

DENIAL REASONS – DO NOT USE FOR MEDICARE PART D

	Yes	No	
1.	Approve, 28 days	Go to 2	
2.	Go to 3	Deny	Your plan covers this drug when all of these conditions apply: - You have an infection that is caused by bacteria - The bacteria are susceptible to the drug Your use of this drug does not meet the requirement. This is based on the

			information we have.
3.	Go to 4	Deny	<p>Your plan covers this drug when all of these conditions apply:</p> <ul style="list-style-type: none"> - Tests show or strongly suggest you have an infection - This infection is caused by bacteria - The bacteria are susceptible to the drug <p>Your use of this drug does not meet the requirements. This is based on the information we have.</p>
4.	Approve, 28 days	Deny	<p>Your plan covers this drug when you meet one of these conditions:</p> <ul style="list-style-type: none"> - You have tried other drugs and they either did not work for you or you cannot use them - The bacteria are not susceptible to any other drugs <p>Your use of this drug does not meet the requirements. This is based on the information we have.</p>