

Title: linezolid (Zyvox)

Origination: 07/14/00	Revised: 08/22/07	Annual Review: 12/15/11
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summary

- Zyvox is an antibacterial agent from the oxazolidinone class used to treat infections caused by gram-positive bacteria that are resistant to other antimicrobial medications¹
- Its use should be optimized to prevent emergence of resistant organisms²
- **Oral Zyvox therapy** is the preferred route of administration in the outpatient setting
- **Intravenous Zyvox therapy** is reserved for Members who are unable to take food/medications orally

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Eligibility Criteria

- Member must be eligible for benefit coverage within the specified date(s) of service
- Members who need coverage initiated in the ambulatory setting on nights, weekends, holidays, or during an emergency (i.e., hurricane) may receive a three-day supply without prior authorization.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Procedure:

- 1.0 If the prescribing provider is an Infectious Disease (ID) Specialist or an ID specialist was consulted on member's case, request is approvable.

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Procedure, continued:

- 2.0 For Members *being discharged from the inpatient setting* with no ID specialist on the case, one (1) of the following two (2) criteria must be met:
- 2.1 Culture and sensitivity reports are provided that shows Methacillin-resistant *Staphylococcus aureus* (MRSA) or Vancomycin-resistant *Enterococcus faecium* (VRE) infections;
- OR**
- 2.1 Therapy with vancomycin or linezolid (Zyvox) was initiated in the inpatient setting. Documentation may include any one (1) of the following: discharge summary, medical administration record, or progress notes.
- 3.0 To limit potential for widespread resistance, consultation with an infectious disease specialist will be required for Members *beginning therapy in the ambulatory setting*.

References:

1. *Zyvox Package Insert*. Pharmacia & Upjohn, Kalamazoo, MI, April 2000.
2. Shales, David M., et al. "Society for Healthcare Epidemiology of America and Infectious Diseases Society of America, Joint Committee on the Prevention of Antimicrobial Resistance: Guidelines for the Prevention of Antimicrobial Resistance in Hospital." *Clinical Infectious Diseases*, 1997; 25:584-99.
3. Gorwitz, Rachel J., et al. 'Strategies for Clinical Management of MRSA in the Community: Summary of an Experts' Meeting Convened by the Centers for Disease Control and Prevention'. March 2006.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.