

# Pharmacy

## PRIOR AUTHORIZATION FORM

For Prior Authorization, please fax toll-free (877) 974-4411, or local number (616) 942-8206

This form applies to:  Commercial Plan  Medicaid Plan  Medicare Plan

# Zyvox<sup>®</sup> (linezolid)

**URGENT** (life threatening)

**Non-Urgent** (standard review)

A claim involving "urgent care" applies when the standard review time will seriously jeopardize the life or health of the member, or subject the member to severe pain that cannot be managed without the care or treatment requested in the subject of this request. **Priority Health averages between 1 and 3 business days for our standard review response time.**

### Member Information

Member Name:	Member No.:
DOB:	Gender:
Member's PCP:	

### Provider Information

Provider Name:	
Office Contact Name:	Provider Phone:
Provider NPI:	Provider Fax:
Provider Address:	

\_\_\_\_\_  
Provider Signature

\_\_\_\_\_  
Date

Is this provider an infectious disease specialist?  Yes  No

If no, has an infectious disease specialist been consulted?  Yes  No

**WARNING:** Zyvox<sup>®</sup> is a reversible, nonselective inhibitor of monoamine oxidase. Therefore, linezolid has the potential for interaction with adrenergic and serotonergic agents. Because there is limited experience with administration of linezolid and serotonergic agents, physicians should be alert to the possibility of signs and symptoms of serotonin syndrome (e.g. hyperpyrexia, cognitive dysfunction) in patients receiving concomitant therapy.

Myelosuppression (including anemia, leucopenia, pancytopenia, and thrombocytopenia) may develop in patients receiving Zyvox<sup>®</sup> for more than 14 days.

### PRIORITY HEALTH PRECERTIFICATION REQUIREMENTS

Authorization for Zyvox<sup>®</sup> (linezolid) requires the following information to certify:

1. Patient must be started on Zyvox oral or IV therapy in the hospital, or other inpatient setting and will be continuing therapy outpatient.
2. Patient has Vancomycin-resistant *Enterococcus faecium* infection.
3. Patient has a documented methicillin-resistant *Staphylococcus aureus* (MRSA) infection.

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**PRODUCT INFORMATION**

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- Zyvox<sup>®</sup> 600 mg tablet  
 Zyvox<sup>®</sup> 100 mg/5 mL oral suspension  
 Zyvox<sup>®</sup> 200 mg/100 mL injection

Dose: \_\_\_\_\_

Start Date: \_\_\_\_\_

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**BILLING INFORMATION (for intravenous route of administration only)**

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**Place of administration:**

- Provider's Office  
 Outpatient Infusion Center  
Center Name: \_\_\_\_\_  
 Home Infusion  
Agency Name: \_\_\_\_\_

**Billing Options:**

- Physician buy and bill  
 Preferred Specialty Vendor  
 Other: \_\_\_\_\_

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**PRIORITY HEALTH PRECERTIFICATION DOCUMENTATION**

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Authorization for Zyvox<sup>®</sup> (linezolid) requires the following information to certify:**A. What is the patient's diagnosis?**

- a.  Vancomycin-Resistant *Enterococcus faecium* infection  
b.  Nosocomial pneumonia  
c.  Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis  
d.  Uncomplicated skin and skin structure infections  
e.  Community-acquired pneumonia  
f.  Other: \_\_\_\_\_

Rationale for use: \_\_\_\_\_

Note: Authorization for indications not approved by the Food and Drug Administration (FDA) or recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, and also Clinical Pharmacology for oncology indications only) require supporting evidence for coverage. Please provide two published peer-reviewed literature articles supporting the drug's use for the identified indication.

**B. Was a culture completed?**

- a.  Yes  
b.  No

**C. Was antibiotic susceptibility determined?**

- a.  Yes (fax results along with this prior authorization request; required for authorization)  
Note: susceptibility results must show infection is not susceptible to alternative antibiotics (e.g. high dose ampicillin for *Enterococcus faecium*).  
b.  No

**D. Was Zyvox<sup>®</sup> started in the hospital?**

- a.  Yes – Number of days of treatment patient received in the hospital: \_\_\_\_\_  
b.  No

**E. What other antibiotics were previously used that were not successful in treating the patient's current infection?**

- a.  Yes, other drugs used include:  
 Drug: \_\_\_\_\_ Date: \_\_\_\_\_ Outcome: \_\_\_\_\_  
 Drug: \_\_\_\_\_ Date: \_\_\_\_\_ Outcome: \_\_\_\_\_  
 Drug: \_\_\_\_\_ Date: \_\_\_\_\_ Outcome: \_\_\_\_\_
- b.  No other antibiotics have been used for the patient's current infection

**F. Does the patient have a documented MRSA infection?**

- a.  Yes – one of the following criteria is required for authorization:
- i.  Patient has a documented therapeutic trial and clinical failure with intravenous vancomycin. The recommended trough level with vancomycin is 15 to 20 mcg/mL. (Note: Intravenous vancomycin is covered under the patient's medical benefit and no prior authorization is required. If home healthcare is needed, contact the Priority Health medical department for authorization.)
  - ii.  Patient has history of severe intolerance to vancomycin, as defined by one of the following:
    1.  Hypersensitivity rash determined to be directly related to vancomycin administration.
    2.  Red-man's syndrome (histamine-mediated), refractory to traditional counter measures (e.g. prolonged intravenous infusion, premedicated with diphenhydramine).
  - iii.  MRSA isolates have a vancomycin MIC  $\geq$  2 mcg/mL. Fax a copy of the susceptibility results.
  - iv.  Patient has severe renal insufficiency. The patient's serum creatinine level is: \_\_\_\_\_mg/dL
- b.  No, patient has Vancomycin-Resistant *Enterococcus faecium* infection
- c.  No, patient has other infection

**G. If the patient is female, is she pregnant?**

- a.  Yes  
 b.  No

**H. Does the patient have an allergy to alternative antibiotic therapies?**

- a.  Yes (describe reaction)  
 Drug: \_\_\_\_\_ Reaction: \_\_\_\_\_  
 Drug: \_\_\_\_\_ Reaction: \_\_\_\_\_  
 Drug: \_\_\_\_\_ Reaction: \_\_\_\_\_  
 Drug: \_\_\_\_\_ Reaction: \_\_\_\_\_
- b.  No

**I. Is the patient taking any medications that interact with or are contraindicated when used with Zyvox<sup>®</sup>**

- Yes (authorization will not be given for patients taking any medications below that interact with or are contraindicated with Zyvox<sup>®</sup>):
- dopamine
  - bupropion
  - buspirone
  - MAOI (e.g. Nardil, tranylcypromine, Marplan)
  - meperidine
  - SNRI (e.g. venlafaxine, Cymbalta, Pristiq)
  - SSRI (e.g. fluoxetine, paroxetine, citalopram, sertraline, Lexapro)
  - sympathomimetic agents (e.g. pseudoephedrine, phenylephrine)
  - tricyclic antidepressant (e.g. doxepin, amitriptyline, clomipramine, nortriptyline)
  - triptans (e.g. sumatriptan, naratriptan, Frova, Maxalt, Relpax, Zomig)
- b.  No

**I. Please provide any additional information you feel is necessary for review of this request: \_\_\_\_\_**

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**DURATION OF THERAPY**

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If approved, authorization will be for a maximum of 14 days. Authorization may be extended for up to a maximum of 28 days when treating Vancomycin-Resistant *Enterococcus faecium* infection.

The safety and efficacy of Zyvox given for greater than 28 days has not been evaluated in controlled clinical trials.

Review of precertification requests for indications and/or duration of therapy in the above criteria will be reviewed by a clinical pharmacist and/or medical director.

**\*\*\* All fields must be complete and legible for Prior Authorization Review\*\*\***

**Please fax this request to: (877)974-4411 toll free or (616)942-8206**

**YOUR OFFICE WILL RECEIVE A RESPONSE VIA FAX**