

Pharmacy

PRIOR AUTHORIZATION FORM

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

This form applies to: Commercial Plan Medicaid Plan Medicare Plan

Zyvox[®] (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

PRIORITY HEALTH PRECERTIFICATION REQUIREMENTS

Authorization for Zyvox[®] (linezolid) requires the following information to certify:

1. Must be prescribed by an infectious disease specialist or an infectious disease specialist must be consulted
2. Patient has an FDA-approved diagnosis, or a medically accepted indication determined by a CMS approved compendia
3. Culture and sensitivity report must be submitted with request, with antibiotic susceptibility results for alternative antibiotic therapies for diagnosis
4. Patient must not be receiving an interacting or contraindicated medication concurrently with Zyvox

PRODUCT INFORMATION

- Zyvox[®] 600 mg tablet
- Zyvox[®] 100 mg/5 mL oral suspension
- Zyvox[®] 200 mg/100 mL injection

Dose: _____

Start Date: _____

BILLING INFORMATION (for intravenous route of administration only)

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: _____

PRIORITY HEALTH PRECERTIFICATION DOCUMENTATION

 Authorization for Zyvox[®] (linezolid) requires the following information to certify:

A. Is the prescriber an infectious disease specialist?

- a. Yes
- b. No – If not, has an infectious disease specialist been consulted?
- i. Yes
- ii. No – Rationale for use: _____

B. What is the patient's diagnosis?

- a. Community-acquired pneumonia
- b. Complicated skin and skin structure infections
- c. Uncomplicated skin and skin structure infections
- d. Nosocomial pneumonia
- e. Vancomycin-Resistant *Enterococcus faecium* infection
- f. Bacteremia associated with intravascular line
- i. Confirmed ampicillin- and vancomycin-resistant *Enterococcus faecium* infection
- g. Febrile neutropenia
- h. Infection of bone due to disorder of joint
- i. Infective endocarditis
- j. Other: _____
- Rationale for use: _____

Note: Authorization for indications not approved by the Food and Drug Administration (FDA) must be recognized in CMS-accepted compendia (e.g. DrugDex, AHFS, U.S. Pharmacopeia, and also Clinical Pharmacology for oncology indications only).

C. Was a culture completed?

- a. Yes
- b. No

D. 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

E. Was Zyvox[®] started in the hospital?

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

F. 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

G. 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

I. Is the patient taking any medications that interact with or are contraindicated when used with Zyvox[®]

Yes (authorization will not be given for patients taking any medications below that interact with or are contraindicated with Zyvox[®]):

- 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)

- d. No

H. Please provide any additional information you feel is necessary for review of this request: _____

DURATION OF THERAPY

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.

WARNING: Zyvox[®] 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[®] for more than 14 days.

PRIORITY MEDICARE PLANS

Note: Priority Health Medicare applies CMS national and local coverage determination criteria when available for Part B drugs. If no national determination criteria or local coverage determination criteria is available for the state in which the member is receiving the services, the above prior authorization criteria must be met.

FOR MEDICARE ONLY

If none of the above precertification criteria is applicable to this member, please check off which, if any, of the following apply:

1. All covered Part D drugs on any tier of a plan's formulary would not be as effective for the enrollee as the non-formulary drug, and/or would have adverse effects
2. The number of doses available under a dose restriction for the prescription drug:
 - a. Has been ineffective in the treatment of the enrollee's disease or medical condition, or
 - b. Based on sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.
3. The prescription drug alternative(s) listed on the formulary or required to be used in accordance with step therapy requirements:
 - a. Has been ineffective in the treatment of the enrollee's disease or medical condition, or
 - b. Based on sound clinical evidence and medical and scientific evidence, the known relevant physical or mental characteristics of the enrollee, and known characteristics of the drug regimen, is likely to be ineffective or adversely affect the drug's effectiveness or patient compliance.
 - c. Has caused or, based on sound clinical evidence and medical and scientific evidence, is likely to cause an adverse reaction or other harm to the enrollee.
4. None of the above apply

****If you selected 1, 2, or 3 above, supporting evidence/documentation is required for review. If no supporting evidence/documentation is provided, this request will not be approved.**

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

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YOUR OFFICE WILL RECEIVE A RESPONSE VIA FAX