Updated: 09/2018
PARP Approved: 09/2018

Gateway Health
Prior Authorization Criteria
Zyvox (linezolid oral)

All requests for Zyvox (linezolid oral) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Zyvox (linezolid oral) Prior Authorization Criteria:
For all requests for Zyvox (linezolid) oral all of the following criteria must be met:

- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- If member is requests a continuation of therapy from hospital discharge, chart documentation of intended treatment duration must be provided. Zyvox will be approved for the remaining duration of treatment.

Coverage may be provided with a diagnosis of Methicillin-Resistant Staphylococcus Aureus (MRSA) skin and soft tissue infections and the following criteria is met:

- Must provide documentation of one of the following:
    - Culture and sensitivity reports confirming purulent MRSA
    - Suspected MRSA due to:
        - Chart information describing infection is severe and purulent
        - Treatment failure with a previous trial of penicillin antibiotic
        - Member has risk factors for multi-drug resistant bacteria, which include:
            - Resident of a long-term care facility
            - Uncontrolled diabetes
            - History of recurrent infections to the same site as the current request
            - Cystic fibrosis with pulmonary manifestations
- Must provide documentation of the following:
    - Member has tried and failed (which will be verified via pharmacy claims if available), has an intolerance, has a contraindication, or has culture and sensitivity reports demonstrating resistance to all of the following:
        - Trimethoprim/sulfamethoxazole
        - Clindamycin
        - Minocycline
        - Doxycycline
    - If a culture and sensitivity report is provided, it must also show sensitivity to linezolid
- **Duration of Approval:** 14 days

Coverage may be provided with a diagnosis of Methicillin-Susceptible Staphylococcus Aureus (MSSA) skin and soft tissue infections and the following criteria is met:

- Must provide documentation of the following:

    - Member has tried and failed (which will be verified via pharmacy claims if available) has an intolerance, has a contraindication, or has culture and sensitivity reports demonstrating resistance to all of the following:
        - Penicillins
        - Clindamycin
        - Cephalexin
        - Doxycycline
        - Minocycline
        - Trimethoprim/sulfamethoxazole
    - If a culture and sensitivity report is provided, it must also show sensitivity to linezolid
- **Duration of Approval:** 14 days

Coverage may be provided with a diagnosis of Vancomycin-Resistant Enterococcus (VRE) infections and the following criteria is met:

- Must provide documentation of one of the following:
    - Confirmed VRE based on culture and sensitivity reports
    - Suspected VRE based on recent course of vancomycin and no clinical improvement with or without clinical improvement from intravenous linezolid
- **Duration of Approval:** 28 days

Coverage may be provided with a diagnosis of osteomyelitis and the following criteria is met:

- Must provide documentation of one of the following:
    - Member has tried and failed (which will be verified via pharmacy claims if available), has an intolerance, has a contraindication, or has culture and sensitivity reports demonstrating resistance to all of the following:
        - Trimethoprim/sulfamethoxazole
        - Clindamycin
    - If a culture and sensitivity report is provided, it must also show sensitivity to linezolid
- **Initial Duration of Approval:** Benefit approved for the requested duration. Treatment is generally a minimum of 8 weeks as per clinical guideline.
- **Reauthorization criteria**
    - Must provide chart documentation of clinical improvement
- **Reauthorization Duration of Approval:** Benefit approved for the requested duration.

Coverage may be provided with a diagnosis of pneumonia and the following criteria is met:

- Must provide culture and sensitivity report demonstrating sensitivity to linezolid
- **Duration of Approval:** 21 days

Coverage may be provided with a diagnosis of endocarditis and the following criteria is met:

- Must provide culture and sensitivity report demonstrating sensitivity to linezolid
- **Initial Duration of Approval:** Benefit approved for the requested duration. Treatment is generally a minimum of 6 weeks as per clinical guideline.
- **Reauthorization criteria**
    - Must provide chart documentation of clinical improvement

- **Reauthorization Duration of Approval:** Benefit approved for the requested duration.

Coverage may be provided with a diagnosis of septic arthritis and the following criteria is met:

- Must provide culture and sensitivity report demonstrating sensitivity to linezolid
- **Duration of Approval:** 21 days

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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LINEZOLID (ZYVOX)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

1. Member's Diagnosis: _____
2. Has the infection been confirmed with culture and sensitivity reports? (If yes, please provide them).
   ☐ Yes ☐ No
3. If not confirmed, is MRSA skin and soft tissue infection suspected due to:
   a. Severity and purulence
   b. Treatment failure with a previous trial of penicillin antibiotic
   c. Risk of multi-drug resistant bacteria due to uncontrolled diabetes, residence at a long-term care facility, history of recurrent infections to the same site as the current request, or cystic fibrosis with pulmonary manifestations?

   ☐ Yes ☐ No
4. If not confirmed, is VRE suspected due to a recent course of vancomycin and no clinical improvement with or without clinical improvement from intravenous linezolid? ☐ Yes ☐ No

5. Please provide the intended duration of treatment: _____

MEDICATION ALLERGIES

Drug Name	Outcome

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LINEZOLID (ZYVOX)
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

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PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

MEMBER INFORMATION

Member Name:	DOB:
Gateway ID:	Member weight: _____pounds or _____kg

MEDICATION ALLERGIES

Drug Name	Outcome

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

REAUTHORIZATION

Has the member experienced a significant improvement with treatment? ☐ Yes ☐ No
Please describe: _____
_____
_____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date