Description
Linezolid (Zyvox®) is a synthetic antibacterial agent of the oxazolidinone class.

FDA approved indication
Zyvox is indicated in adults and children for the treatment of the following infections caused by susceptible Gram-positive bacteria:

- 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.

Policy/Criteria
*Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria*

It is the policy of health plans affiliated with Centene Corporation® that Zyvox tablets and/or oral suspension are medically necessary when the following criteria are met:

I. Initial Approval Criteria (must meet all):
   A. Infections Caused by Susceptible Gram-positive Bacteria (must meet all):
      1. Prescribed by or in consultation with an infectious disease specialist;
      2. Isolated pathogen is VRE or susceptible gram positive bacteria (e.g., MRSA, S. pneumoniae [including multi-drug resistant strains, MDRSP], S. pyogenes) confirmed by culture and sensitivity report;
      3. Culture and sensitivity report (dated within the past 7 days) shows isolated pathogen is susceptible to linezolid;
      4. Member meets one of the following (a or b):
         a. Culture and sensitivity report shows resistance of the isolated pathogen to ALL formulary antibiotics FDA-approved for member’s diagnosis;
b. Member has failed treatment with formulary antibiotics to which the isolated pathogen is susceptible, unless contraindicated, intolerant, or agents are not indicated for member’s diagnosis;
5. Prescribed dose does not exceed 1200 mg/day.

Approval duration: Up to a 14-day supply

B. Other diagnoses/indications – Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

II. Continued Therapy
A. Infections Caused by Susceptible Gram-positive Bacteria (must meet all):
   1. Currently receiving medication via Centene benefit;
   2. Member has not received ≥ 28 days of therapy for current infection;
   3. If request is for a dose increase, new dose does not exceed 1200 mg/day.

Approval duration: Up to an additional 14-day supply (28 days of therapy total)

B. Other diagnoses/indications (must meet 1 or 2):
   1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy; or
   2. Refer to CP.PMN.53 if requested indication is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:
A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy - CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information
Appendix A: Abbreviation Key
MDRSP: multidrug-resistant Streptococcus pneumoniae
MRSA: methicillin-resistant Staphylococcus aureus
VRE: vancomycin-resistant enterococci

V. Dosage and Administration

<table>
<thead>
<tr>
<th>Infection</th>
<th>Dosage, Route, and Frequency of Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pediatric Patients</td>
</tr>
<tr>
<td>Nosocomial pneumonia</td>
<td>10 mg/kg oral every 8 hours</td>
</tr>
<tr>
<td>Community-acquired pneumonia, including concurrent bacteremia</td>
<td></td>
</tr>
<tr>
<td>Complicated skin and skin structure infections</td>
<td></td>
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</tbody>
</table>
Vancomycin-resistant Enterococcus faecium infections, including concurrent bacteremia

<table>
<thead>
<tr>
<th>Condition</th>
<th>Children (10 mg/kg)</th>
<th>Adults (600 mg)</th>
<th>Adolescents (600 mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Uncomplicated skin and skin structure infections</td>
<td>&lt; 5 years: 10 mg/kg oral every 8 hours 5–11 years: 10 mg/kg oral every 12 hours</td>
<td>Adults: 400 mg oral every 12 hours</td>
<td>Adolescents: 600 mg oral every 12 hours</td>
</tr>
</tbody>
</table>

VI. Product Availability

- Tablet: 600 mg linezolid;
- Oral suspension: 100 mg of linezolid per each 5 mL.

VII. Workflow Document

CP.PMN.27.linezolid
(Zyvox)workflow.Q42016.docx

VIII. References


Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.
The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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