MEDICATION POLICY

Generic Name: Linezolid

Therapeutic Class or Brand Name: Zyvox®

Applicable Drugs (if Therapeutic Class)**:**

Preferred: Linezolid tablets (generic), Linezolid oral suspension (generic)

Non-Preferred: Zyvox® tablets, Zyvox® oral suspension

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 12/6/17

GPI Code: 1623004000

Prior Authorization Criteria (may be considered medically necessary when criteria I through III are met):

I. Documented diagnosis of one of the following conditions A through E:
   - A. Clinically documented infection that is susceptible to linezolid if the patient has a severe allergy to beta lactamase inhibitors or any antibiotic that the organism is susceptible.
   - B. Clinically documented infection that is susceptible to linezolid if the patient has failed treatment with antibiotics that the organism is susceptible.
   - C. Clinically documented vancomycin-resistant *Enterococcus faecium* infection.
   - D. Clinically documented MRSA and the patient has failed or is intolerant to vancomycin if the organism is susceptible to vancomycin.
   - E. Patient will require continuation of therapy upon hospital discharge that has a documented diagnosis of one of the above and documented initial treatment with vancomycin or linezolid while in the hospital.

II. Linezolid is prescribed by, or after consultation with, an infectious disease physician.

III. Non-preferred products (i.e. Zyvox® tablets, Zyvox® oral suspension) require a documented clinical reason containing details as to why generic linezolid is not appropriate or is contraindicated.

Exclusion Criteria:

- Patients taking any medicinal product which inhibits monoamine oxidases A or B (i.e. phenelzine, isocarboxazid) or within two weeks of taking any such medicinal product.

Other Criteria:

- Usual Doses:

Infection	Pediatric Patients	Adults and Adolescents	Duration (days)
Nosocomial pneumonia **Community-acquired pneumonia, including concurrent bacteremia** **Complicated skin and skin structure infections**	10 mg/kg every 8 hours	600 mg every 12 hours	10 to 14
Vancomycin-resistant *Enterococcus faecium* infections, including concurrent bacteremia	10 mg/kg every 8 hours	600 mg every 12 hours	14 to 28
Uncomplicated skin and skin structure infections	Less than 5 years old: 10 mg/kg every 8 hours 5 to 11 years old: 10 mg/kg every 12 hours	Adults: 400 mg every 12 hours Adolescents: 600 mg every 12 hours	10 to 14

Quantity/Days Supply Restrictions:

- The amount needed to complete one course of therapy (see Usual Doses under Other Criteria).

Approval Length:

- **Authorization:** One time for one course of therapy (see Usual Doses under Other Criteria).
- **Re-Authorization:** N/A

Appendix:

N/A

References:

1. http://www.fchp.org/~/media/Files/FCHP/Imported/Zyvox_linezolid.pdf.ashx.
2. Medi-Span.
3. http://labeling.pfizer.com/showlabeling.aspx?id=649.

MEDICATION POLICY

<table>
<tr><td colspan="2">Historical Tracking Of Changes Made To Policy</td></tr>
<tr><td>12/6/2017</td><td>1. Policy reviewed: no changes made.</td></tr>
<tr><td>9/28/2016</td><td>1. Changed “N/A” to “Preferred: Linezolid tablets (generic), Linezolid oral suspension (generic); Non-Preferred: Zyvox® tablets, Zyvox® oral suspension” following Applicable Drugs.
2. Changed “I. E. Patient will require continuation …with vancomycin or Zyvox® …” to “I. E. Patient will require continuation …with vancomycin or linezolid …” under Prior Authorization.
3. Changed “II. Zyvox® is prescribed by…” to “II. Linezolid is prescribed by…” under Prior Authorization Criteria.
4. Added “III. Non-preferred products (i.e. Zyvox® tablets, Zyvox® oral suspension) require a documented clinical reason containing details as to why generic linezolid is not appropriate or is contraindicated” under Prior Authorization Criteria.
5. Removed “http://www.connecticare.com/provider/PDFs/Pharmacy/Zyvox.pdf” from References (link no longer valid).</td></tr>
<tr><td>3/27/2015</td><td>1. Changed “Usual Doses: Vancomycin-resistant Enterococcus faecium infections: 600 mg every 12 hours for 14-28 days; Nosocomial pneumonia: 600 mg every 12 hours for 10-14 days; Complicated skin and skin structure infections: 600 mg every 12 hours for 10-14 days; Uncomplicated skin and skin structure infections: 400 mg every 12 hours for 10-14 days; Community-acquired pneumonia: 600 mg every 12 hours for 10-14 days” to “Usual Doses:
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</table>
” under Other Criteria.</td></tr>
<tr><td>12/3/2013</td><td>1. Adapted policy to new format.
2. Added GPI Code.
3. Changed “Clinically documented MRSA and has failed or is intolerant to vancomycin if the organism is susceptible to vancomycin” to “Clinically documented MRSA and the patient has failed or is intolerant to vancomycin if the organism is susceptible to vancomycin” under Prior Authorization Criteria.
4. Added “Patients taking any medicinal product which inhibits monoamine oxidases A or B (i.e. phenelzine, isocarboxazid) or within two weeks of taking any such medicinal product” under Exclusion Criteria.
5. Added “The amount needed to complete one course of therapy (see Usual Doses under Other Criteria)” under Quantity/Days Supply Restrictions.
6. Updated references to include Medi-Span.</td></tr>
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MEDICATION POLICY

Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.