Approval Criteria Department of Pharmacy Services

Generic Name: Linezolid

Brand Name: Zyvox®

Medication Class: Anti-Infective / oxazolidinones

FDA Approved Uses
- Community-acquired pneumonia: Caused by streptococcus pneumonia (including multidrug-resistant strains), including cases with concurrent bacteremia, or staphylococcus aureus (methicillin-susceptible strains only -MSSA).
- Complicated skin and skin structure infections: Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis, caused by staphylococcus aureus (methicillin - susceptible and - resistant strains MSRA). Streptococcus pyogenes, or streptococcus agalactiae.
- Nosocomial pneumonia: caused by S. aureus (MSRA & MSSA), or S pneumonia (including multi-drug resistant strains)
- Uncomplicated skin and skin structure infections: Caused by S. Aureus (MSSA only) or S. pyogenes.
- Vancomycin-resistant enterococcal infections (VRE). Vancomycin-resistant Enterococcus faecium infections, including cases with concurrent bacteremia.

Criteria for use
- Diagnosis of FDA approved indication above, supported by any applicable labs and/or tests as evidenced by the patient’s medical record
- Must have an infectious disease consult that recommends Zyvox
  - Must include cultures & sensitivities
  - Must include patient’s type of infection as well as location of infection
- Must have cultured an organism that is susceptible to linezolid
- The patient must have failed treatment with antibiotics to which the organism is susceptible
  OR
- Patient has a severe allergy to antibiotics to which the organism is susceptible.
- Criteria for treatment duration longer than 14 days (or 28 days for VRE):
  - Patient has had a standard course of therapy of 14 to 28 days
  - Patient has had infectious disease consultation in which the specialist determines that a longer course of therapy is required
  - The duration approved is based on specialist request

Not Approved For
- Patient has any contraindication to the use of linezolid
- Patient does not meet the above stated guidelines for approval.

Required Medical Information
- Clinical Documentation of consultation with an infectious disease specialist
- Blood cultures and sensitivities
- Clinical documentation of previously tried antibiotic therapy that includes dates of treatment, doses, and outcomes.
Contraindications
- Known hypersensitivity to linezolid or any other product components.
- Use with or within 14 days of monoamine oxidase inhibitors – MAOIs [isocarboxazid (Marplan), phenelzine (Nardil), tranylcypromine (Parnate)].

Dosing
- VRE: 600 mg every 12 hours for 14 – 28 days
- Nosocomial pneumonia: 600mg 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

Authorization
- VRE: 28 days total therapy. QL = 56 doses (calculated from start of therapy. If hospitalized prior, use hospital start date)
- All Other Diagnosis: 14 days. QL = 28 doses or 900ml per fill
- See Criteria for duration extension above.

Approved by P&T: 05/27/2014

References


