Request for Prior Authorization – ZYVOX™ (linezolid)  
Website Form – www.highmarkhealthoptions.com  
Submit request via: Fax - 1-855-476-4158

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

Zyvox (linezolid) Oral Prior Authorization Criteria:

- Benefit coverage is provided for the following conditions:

- Coverage is provided for Methicillin-Resistant Staphylococcus Aureus (MRSA) skin and soft tissue infections in the presence of the following:
  - Chart information describing infection is severe and purulent, or
  - 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
  - Or culture and sensitivity reports demonstrate resistance to trimethoprim/sulfamethoxazole, clindamycin and doxycycline, and sensitivity to linezolid, or
  - Confirmed MRSA or suspected MRSA due to treatment failure with a previous trial of a penicillin antibiotic, and
  - Documented allergies or treatment failure with trimethoprim/sulfamethoxazole, clindamycin, and doxycycline, and
  - Chart information describing infection is mild to moderate and purulent

- Coverage is provided for Methicillin-Susceptible Staphylococcus Aureus (MSSA) skin and soft tissue infections in the presence of the following:
  - When the patient has allergies and/or documented intolerance to penicillins, clindamycin, doxycycline, and trimethoprim/sulfamethoxazole

- Coverage is provided for Vancomycin-Resistant Enterococcus (VRE) infections in the presence of the following:
  - Confirmed VRE based on culture and sensitivity reports, or
  - Suspected VRE based on recent course of vancomycin and no clinical improvement with or without clinical improvement from intravenous linezolid

- Coverage is provided for Pneumonia, Osteomyelitis, Endocarditis and Septic Arthritis Infections in the presence of the following:
  - When culture and sensitivity reports demonstrate sensitivity to linezolid, or
  - Chart documentation describes clinical benefit from linezolid

- Coverage Duration:
  - MRSA Skin and Soft Tissue Infections:
    - Benefit approved for the requested duration up to a maximum of 14 days as per prescribing guidelines
  - MSSA Skin and Soft Tissue Infections when allergic or intolerant to penicillins, clindamycin, doxycycline, and trimethoprim/sulfamethoxazole:
• Benefit approved for the requested duration up to a maximum of 14 days as per prescribing guidelines
  o VRE Infections:
    • Benefit approved for the requested duration up to a maximum of 28 days as per prescribing guidelines
  o Pneumococcal Infections:
    • Benefit approved for the requested duration up to a maximum of 21 days
  o Septic Arthritis Infections:
    • Benefit approved for the requested duration up to a maximum of 4 weeks
  o Osteomyelitis and Endocarditis:
    • Benefit approved for the requested duration
    • Treatment is generally a minimum of 8 weeks as per clinical guideline

• 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 non-formulary criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must over ride criteria when, in their professional judgment, the requested medication is medically necessary.

References: