UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Zyvox

Program	Prior Authorization
Medication	Zyvox (linezolid)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, South Carolina, Rhode Island
Issue Date	6/2009
Pharmacy and Therapeutics Approval Date	1/2021
Effective Date	3/2021

1. Background:

Indications

Zyvox (linezolid) is indicated for the treatment of infections caused by susceptible strains of gram-positive microorganisms in the specific conditions listed below:

1) **Nosocomial pneumonia**
   Caused by *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates) or *Streptococcus pneumoniae.*
2) **Community-acquired pneumonia**
   Caused by *Streptococcus pneumoniae*, including cases with concurrent bacteremia, or *Staphylococcus aureus* (methicillin-susceptible isolates only).
3) **Complicated skin and skin structure infections, including diabetic foot infections**
   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.
4) **Uncomplicated skin and skin structure infections**
   Caused by *Staphylococcus aureus* (methicillin-susceptible isolates only) or *Streptococcus pyogenes.*
5) **Vancomycin-Resistant *Enterococcus faecium* infection**
   Including cases with concurrent bacteremia.

Zyvox is NOT indicated for the treatment of gram-negative infections.

2. Coverage Criteria:

A. Authorization Criteria

1. **Linezolid (tablets or suspension)** will be approved based on the following:

   a. One of the following:

      (1) For continuation of therapy upon hospital discharge

      -OR-

      (2) As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication.

      -OR-

      (3) **Both** of the following:

         (a) **One** of the following diagnoses:
            - Nosocomial pneumonia
            - Community-acquired pneumonia
            - Skin and skin structure infections (complicated and uncomplicated)

         -AND-

         (b) Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Zyvox

      -OR-

      (4) Invasive infection caused by or likely to be caused by vancomycin-resistant *Enterococcus faecium* (VRE)

Authorization will be issued for 14 days. If the request is for vancomycin-resistant *Enterococcus faecium*, authorization will be issued for 28 days. If the request is for osteomyelitis, authorization will be issued for the requested duration, not to exceed 6 weeks.

B. Off-Label Uses

1. **Linezolid (tablets or suspension)** will be approved based on one of the following:

   a. For continuation of therapy upon hospital discharge

-OR-

b. As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

-OR-

c. The drug has been recognized for treatment of the indication by the Infectious Diseases Society of America (IDSA).

Authorization duration based on provider and IDSA recommended treatment durations, up to 6 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Zyvox [package insert]. New York, NY: Pfizer Inc.; October 2020.
2. Berbari EF, Kanj SS, Kowalski TJ, et al. 2015 Infectious Diseases Society of America (IDSA) clinical practice guidelines for the diagnosis and treatment of native vertebral osteomyelitis in adults, *CID*. 2015 Sept;61(6):e26-46.

Program	Prior Authorization
Change Control	
Date	Change
6/2009	Criteria taken from previously approved Unison (RX06 Zyvox) and AmeriChoice policies. Policy was reformatted.
12/2010	Annual Review.
6/2011	Annual Review
6/2012	Annual Review
3/2013	Thorough update of clinical criteria. Created sections for the following indications:

	▪ Vancomycin-resistant *Enterococcus faecium* (VRE) infection ▪ Nosocomial pneumonia ▪ Community-acquired pneumonia ▪ Complicated skin and skin structure infections ▪ Uncomplicated skin and skin structure infections ▪ Chronic osteomyelitis or prosthetic joint infection (Off-label) ▪ Nocardiosis (Off-label) ▪ Multi-drug resistant (MDR) *Enterococcus spp* urinary tract infection (Off-label) Added dosing, availability, background, and endnotes section and Updated references.
12/2015	Annual Review. Template updated to align with standard UHC current guideline template. No changes were made to the policy other than the new template format.
11/2016	Annual review, updated policy template
11/2017	Added approval criteria for transition from intravenous telavancin to nosocomial pneumonia. Removed off-label indications and added general statement about use for off-label indications needing to be recommended by IDSA or for continuation of therapy.
11/2018	Annual review. Removed off-label and empiric therapy. Combined all non-MRSA uses into one section. Updated appropriate step therapy drugs. Updated references.
7/2019	Removed step therapy agents. Removed MRSA check- there is already a question confirming organism is susceptible to Zyvox. Added osteomyelitis as an approvable condition. Updated references.
1/2020	Updated references.
1/2021	Annual review. Updated osteomyelitis authorization duration to match treatment guidelines. Updated references.