

Initial Prior Authorization

Zyvox

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Zyvox	linezolid

Indications

FDA-approved Indications

Nosocomial Pneumonia

Zyvox is indicated for the treatment of nosocomial pneumonia caused by *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates) or *Streptococcus pneumoniae*.

Community-acquired Pneumonia

Zyvox is indicated for the treatment of 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

Zyvox is indicated for the treatment of 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

Zyvox is indicated for the treatment of uncomplicated skin and skin structure infections caused by *Staphylococcus aureus* (methicillin susceptible isolates only) or *Streptococcus pyogenes*.

Vancomycin-resistant *Enterococcus faecium* Infections

Zyvox is indicated for the treatment of vancomycin-resistant *Enterococcus faecium* infections, including cases with concurrent bacteremia.

Limitations of Use

- Zyvox is not indicated for the treatment of Gram-negative infections. It is critical that specific Gram-negative therapy be initiated immediately if a concomitant Gram-negative pathogen is documented or suspected.
- The safety and efficacy of Zyvox formulations given for longer than 28 days have not been evaluated in controlled clinical trials.

Usage

To reduce the development of drug-resistant bacteria and maintain the effectiveness of Zyvox and other antibacterial drugs, Zyvox should be used only to treat or prevent infections that are proven or strongly suspected to be caused by susceptible bacteria. When culture and susceptibility information are available, they should be considered in selecting or modifying antibacterial therapy. In the absence of such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Off Label Uses

Combination regimen with Pretomanid and linezolid for the treatment of adults with pulmonary tuberculosis (TB) resistant to isoniazid, rifamycins, a fluoroquinolone and a second line injectable antibacterial drug OR adults with pulmonary TB resistant to isoniazid and rifampin, who are treatment-intolerant or nonresponsive to standard therapy.^{2, 9, 10}

Coverage Criteria

Community-Acquired Pneumonia, Complicated Skin and Skin Structure Infections, Nosocomial Pneumonia, Uncomplicated Skin and Skin Structure Infections, Vancomycin-Resistant *Enterococcus faecium* Infections

Authorization may be granted for the requested drug when ALL of the following criteria are met:

- The patient has ANY of the following:
 - An infection caused by vancomycin-resistant *Enterococcus faecium* including cases with concurrent bacteremia.
 - A nosocomial (institution-acquired) 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).
 - A complicated skin and skin structure infection including diabetic foot infections, without concomitant osteomyelitis, caused by *Staphylococcus aureus* (methicillin-susceptible and -resistant isolates), *Streptococcus pyogenes*, or *Streptococcus agalactiae*.
 - An uncomplicated skin and skin structure infection caused by *Staphylococcus aureus* (methicillin-susceptible isolates only) or *Streptococcus pyogenes*.
- The infection is proven or strongly suspected to be caused by susceptible bacteria.
- The patient will use the requested drug orally or intravenously.

Non-Tuberculosis (TB) Bacterial Infection

Authorization may be granted when the requested drug is being prescribed for a NON-Tuberculous (TB) bacterial infection when ALL of the following criteria are met:

- The patient is being converted from intravenous (IV) linezolid (Zyvox).
- The requested drug is being prescribed or directed by an Infectious Disease specialist.
- The patient will use the requested drug orally or intravenously.

Tuberculosis (TB)

Authorization may be granted when the requested drug is being prescribed for pulmonary tuberculosis (TB) resistant to isoniazid, rifamycins, a fluoroquinolone and a second line injectable antibacterial drug OR TB resistant to isoniazid and rifampin, that is treatment-intolerant or nonresponsive to standard therapy when ALL of the following criteria are met:

- The requested drug is being prescribed as part of a combination regimen with Pretomanid AND Sirturo (bedaquiline).
- The patient will use the requested drug orally or intravenously.

Duration of Approval (DOA)

- 495-A:
 - Non-Tuberculosis bacterial infection DOA: 28 days
 - Pulmonary tuberculosis (TB) DOA: 12 months

References

1. Zyvox [package insert]. New York, NY: Pharmacia & Upjohn Company LLC a subsidiary of Pfizer Inc; June 2024.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2024. <https://online.lexi.com>. Accessed December 2, 2024.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 12/02/2024).
4. Diagnosis and Treatment of Adults with Community-Acquired Pneumonia. An Official Clinical Practice Guideline of the American Thoracic Society and Infectious Diseases Society of America. American Journal of Respiratory and Critical Care Medicine, Volume 200, Issue 7, 1 October 2019, Pages e45-e67.
5. Senneville E, Albalawi, van Asten SA, et al. IWGDF/IDSA Guidelines on the Diagnosis and Treatment of Diabetes-related Foot Infections. Clinical Infectious Diseases 2023;; ciad527, <https://doi.org/10.1093/cid/ciad527>.
6. Kalil A, Metersky M, Klompas M, et al. Management of Adults With Hospital-acquired and Ventilator-associated Pneumonia: 2016 Clinical Practice Guidelines by the Infectious Diseases Society of America and the American Thoracic Society. Clinical Infectious Diseases 2016;1-51.
7. Stevens D, Bisno A, Chambers H, et al. Practice Guidelines for the Diagnosis and Management of Skin and Soft-Tissue Infections: 2014 Update by the Infectious Diseases Society of America. Clinical Infectious Diseases 2014;1-43.
8. Pretomanid [package insert]. Hyderabad, India: Mylan Laboratories Limited for The Global Alliance for TB Drug Development (TB Alliance); December 2022.
9. WHO Consolidated Guidelines on Tuberculosis. Module 4: Treatment - Drug-Resistant Tuberculosis Treatment, 2022 Update. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO. Available at: <https://www.who.int/publications/i/item/9789240063129>. Accessed December 2, 2024.
10. WHO Consolidated Guidelines on Tuberculosis. Module 5: Management of Tuberculosis in Children and Adolescents. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO. Available at: <https://www.who.int/publications/i/item/9789240046764>. Accessed December 2, 2024.