



Effective Date: 02/2019
Last P&T Approval/Version: 01/26/2022
Next Review Due By: 01/2023
Policy Number: C8632-A

Linezolid

PRODUCTS AFFECTED

Zyvox (linezolid)

COVERAGE POLICY

Coverage for services, procedures, medical devices, and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines

Documentation Requirements:

Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational, or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive

DIAGNOSIS:

Nosocomial pneumonia, Community-acquired pneumonia, Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis, Uncomplicated skin and skin structure infections, Vancomycin-resistant Enterococcus faecium infections, Anthrax, systemic infection; CNS infection, health care-associated (e.g., cerebrospinal fluid shunt infection); Cystic fibrosis, acute pulmonary exacerbation, moderate to severe; Endocarditis, treatment, native or prosthetic valve; Intracranial abscess (brain abscess, intracranial epidural abscess) and spinal epidural abscess; Meningitis, bacterial; Osteomyelitis and/or discitis; Prosthetic joint infection; Septic arthritis; Toxic shock syndrome; Tuberculosis, drug-resistant

REQUIRED MEDICAL INFORMATION:

This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by-case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review

Drug and Biologic Coverage Criteria

A. FOR ALL INDICATIONS:

1. Documentation member has an infection caused by or strongly suspected to be caused by a type of pathogen and site of infection within the FDA label or compendia supported
AND
2. Prescriber attests that they have reviewed the members medication profile and the member is not concurrently taking any of the following: A) monoamine oxidase (MAO) inhibitor (e.g., phenelzine, isocarboxazid), B) selective serotonin reuptake inhibitor (SSRI), C) selective norepinephrine-reuptake inhibitor (SNRI) OR the member will discontinue the concurrent interacting medication and be monitored.
AND
3. FOR IV LINEZOLID REQUESTS: Documentation that the member is converting from IV linezolid to oral linezolid OR documentation of medical necessity for continued IV therapy

CONTINUATION OF THERAPY:

A. FOR INDICATIONS WITH COMPENDIA APPROVED TREATMENT > 4WEEKS:

1. Documentation member is not experiencing hematologic or neurotoxic adverse effects.
AND
2. Prescriber attests that member is being monitored for myelosuppression and changes in vision

DURATION OF APPROVAL:

Initial authorization: 28 days; Continuation of Therapy: 2 months

**** Linezolid is not a preferred agent for the treatment of infections requiring prolonged therapy as the risk of serious hematologic and neurologic toxicity increases after >2 weeks and >4 weeks of therapy, respectively**

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with an infectious disease specialist. [If prescribed in consultation, consultation notes must be submitted within initial request and reauthorization requests]

AGE RESTRICTIONS:

No restrictions

QUANTITY:

Dosage, frequency, and total treatment duration must be supported by FDA label or compendia supported dosing for prescribed indication

PLACE OF ADMINISTRATION:

The recommendation is that oral medications in this policy will be for pharmacy benefit coverage and patient self-administered.

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Oral, Intravenous

DRUG CLASS:

Oxazolidinones

Drug and Biologic Coverage Criteria

FDA-APPROVED USES:

ZYVOX is indicated in adults and children for the treatment of the following infections caused by susceptible Gram-positive bacteria:

- Nosocomial pneumonia
- Community-acquired pneumonia
- Complicated skin and skin structure infections, including diabetic foot infections, without concomitant osteomyelitis
- Uncomplicated skin and skin structure infections
- Vancomycin-resistant *Enterococcus faecium* infections.

Limitations of Use: ZYVOX is not indicated for the treatment of Gram-negative infections. The safety and efficacy of ZYVOX formulations given for longer than 28 days have not been evaluated in controlled clinical trials.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of ZYVOX formulations and other antibacterial drugs, ZYVOX should be used only to treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

COMPENDIAL APPROVED OFF-LABELED USES:

Anthrax, systemic infection; CNS infection, health care-associated (e.g., cerebrospinal fluid shunt infection); Cystic fibrosis, acute pulmonary exacerbation, moderate to severe; Endocarditis, treatment, native or prosthetic valve; Intracranial abscess (brain abscess, intracranial epidural abscess) and spinal epidural abscess; Meningitis, bacterial; Osteomyelitis and/or discitis; Prosthetic joint infection; Septic arthritis; Toxic shock syndrome; Tuberculosis, drug-resistant

APPENDIX

APPENDIX:

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of linezolid are considered experimental/investigational and therefore, will follow Molina's Off-Label policy.

OTHER SPECIAL CONSIDERATIONS:

None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPSC CODE	DESCRIPTION
J2020	injection, linezolid,200mg

AVAILABLE DOSAGE FORMS:

Zyvox tablets 600mg, Linezolid tablets 600 MG, Zyvox For Susp 100 MG/5 ML, Linezolid For Susp 100 MG/5ML, Zyvox IV solution 600mg/300mL, Linezolid IV Soln 600 MG/300ML (2 MG/ML), Linezolid in Sodium Chloride IV Soln 600 MG/300ML-0.9%

REFERENCES

1. Zyvox (linezolid) [prescribing information]. New York, NY: Pharmacia and Upjohn; September 2021
2. O'Driscoll T, Crank C. Vancomycin-resistant enterococcal infections: epidemiology, clinical manifestations, and optimal management. *Inf and Drug Res.* 2015;8:217-230.
3. Stevens DL, Bisno AL, Chambers HF, et al. Practice guidelines for the diagnosis and management of skin and soft tissue infections: 2014 update by the infectious diseases society of America. *Clin Infect Dis* 2014; Jul 15;59(2):147-59.
4. Ament PW, Jamshed, N., Horne JP. Linezolid: Its Role in the Treatment of Gram-Positive, DrugResistant Bacterial Infections. *Am Fam Physician.* 2002 Feb 15;65(4):663-671. www.aafp.org/afp/20020215/663.html.
5. Liu C, Bayer A, Cosgrove SE, et al. Clinical practice guidelines by the Infectious Diseases Society of America for the treatment of methicillin-resistant *Staphylococcus aureus* infections in adults and children: executive summary. *Clin Infect Dis.* 2011;52(3):285-292. doi:10.1093/cid/cir034
6. Baddour LM, Wilson WR, Bayer AS, et al; American Heart Association Committee on Rheumatic Fever, Endocarditis, and Kawasaki Disease of the Council on Cardiovascular Disease in the Young, Council on Clinical Cardiology, Council on Cardiovascular Surgery and Anesthesia, and Stroke Council. Infective endocarditis in adults: diagnosis, antimicrobial therapy, and management of complications: a scientific statement for healthcare professionals from the American Heart Association. *Circulation.* 2015;132(15):1435-1486.
7. Berbari EF, Kanj SS, Kowalski TJ, et al; Infectious Diseases Society of America. 2015 Infectious Diseases Society of America (IDSA) clinical practice guidelines for the diagnosis and treatment of native vertebral osteomyelitis in adults. *Clin Infect Dis.* 2015;61(6):e26-e46. doi:10.1093/cid/civ482
8. Metlay JP, Waterer GW, Long AC, et al. 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. *Am J Resp Crit Care Med.* 2019;200(7):e45-e67. doi:10.1164/rccm.201908-1581ST