Linezolid
Policy Number: C8632-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DUE BY OR BEFORE
2/2019	11/18/2020	1/26/2022
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
J2020-injection, linezolid, 200mg	RxPA	Q1 2021 20210127C8632-A

PRODUCTS AFFECTED:
Linezolid

DRUG CLASS:
Oxazolidinones

ROUTE OF ADMINISTRATION:
Oral, Intravenous

PLACE OF SERVICE:
Retail Pharmacy or Buy and Bill
The recommendation is that medications in this policy will be for pharmacy benefit coverage and the IV infusion products administered in a place of service that is a non-hospital facility-based location (i.e., home infusion provider, provider's office, free-standing ambulatory infusion center) and the oral tablets for self-administration.

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%

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

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COVERAGE CRITERIA: INITIAL AUTHORIZATION

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:
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. (a) Member is not concurrently taking any of the following: monoamine oxidase (MAO) inhibitor (e.g., phenelzine, isocarboxazid), selective serotonin reuptake inhibitor (SSRI), or a selective norepinephrine reuptake inhibitor (SNRI)
   OR
   (b) Prescriber has documented that the medication regimen has been reviewed and member will be monitored for signs and symptoms for serotonin syndrome
   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

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

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

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with an infectious disease specialist

AGE RESTRICTIONS:
No restrictions

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

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

BACKGROUND:

APPENDIX:

None

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.

REFERENCES:

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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
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