Effective Date: 07/01/2016
Last P&T Approval/Version: 01/26/2022
Next Review Due By: 01/2023
Policy Number: C9353-A

Sivextro (tedizolid)

PRODUCTS AFFECTED

Sivextro (tedizolid)

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:
acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria

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

A. ACUTE BACTERIAL SKIN AND SKIN STRUCTURE INFECTION:
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. Documentation of inadequate treatment response, intolerance, contraindication or non-susceptibility to a first-line antibiotic treatment: [acute bacterial skin and skin structure infections-(e.g. IV/PO linezolid, IV vancomycin, PO TMP/SMX, PO doxycycline, PO nafcillin, IV cefazolin, PO clindamycin, PO dicloxacillin or PO cephalexin, PO penicillin)]
AND
4. FOR IV REQUESTS ONLY: Member must have medical documentation of medically necessary use of IV Sivextro (tedizolid) for the current active infection instead of oral Sivextro (tedizolid).

CONTINUATION OF THERAPY:
NA

DURATION OF APPROVAL:
Initial authorization: 6 days, subsequent approval will require a new authorization

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:
12 years of age and older

QUANTITY:
Up to 6 tablets
J3090 – 200 units/dose (200 mg) every 24 hours x 6 = Total 1200 units

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 or Intravenous

DRUG CLASS:
Oxazolidinones

FDA-APPROVED USES:
SIVEXTRO is indicated in adult and pediatric patients 12 years of age and older for:

- treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria.

To reduce the development of drug-resistant bacteria and maintain the effectiveness of SIVEXTRO and other antibacterial drugs, SIVEXTRO should be used only to treat or prevent infections that are

proven or strongly suspected to be caused by susceptible bacteria

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Sivextro (tedizolid) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Sivextro (tedizolid) are not present at this time.

OTHER SPECIAL CONSIDERATIONS:
To reduce the development of bacterial resistance and maintain effectiveness of Sivextro (tedizolid), Sivextro should only be used to treat ABSSSI 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 culture and susceptibility information, local epidemiology and susceptibility patterns may contribute to empiric selection of therapy

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

HCPCS CODE	DESCRIPTION
J3090	injection, tedizolid phosphate, 1mg
C9446	injection, tedizolid phosphate,1mg

AVAILABLE DOSAGE FORMS:
Sivextro 200mg tab, 200mg Inj

REFERENCES

1. Sivextro (tedizolid) [prescribing information]. Whitehouse Station, NJ: Merck; October2020.
2. Prokocimer P, De Anda C, Fang E, et al. Tedizolid phosphate vs. linezolid for treatment of acute bacterial skin and skin structure infections. The ESTABLISH-1 randomized trial.JAMA. 2013;309:559-569.
3. Urbina O, Ferrandez O, Espona M, et al. Potential role of tedizolid phosphate in the treatment of acute bacterial skin infections. Drug Design Dev and Ther. 2013;7:243-265
4. Kisgen JJ, Mansour H, Unger NR, et al. Tedizolid: a new oxazolidinone antimicrobial. AmJHealthSys Pharm. 2014;71:621-633.