Sivextro (tedizolid)
Policy Number: C9353-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DUE BY OR BEFORE
7/1/2016	11/18/2020	1/26/2022
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL/VERSION**
J3090-injection, tedizolid phosphate, 1mg C9446-injection, tedizolid phosphate,1mg	RxPA	Q1 2021 20210127C9353- A

PRODUCTS AFFECTED:
Sivextro (tedizolid)

DRUG CLASS:
Oxazolidinones

ROUTE OF ADMINISTRATION:
Oral or Intravenous

PLACE OF SERVICE:
Retail Pharmacy (oral) or Buy and Bill (IV)
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)
The recommendation is that ORAL Sivextro (tedizolid) will be for pharmacy benefit coverage and self-administered

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

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

COVERAGE CRITERIA: INITIAL AUTHORIZATION

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

REQUIRED MEDICAL INFORMATION:
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. linezolid, vancomycin, TMP/SMX, doxycycline, nafcillin, cefazolin, clindamycin, dicloxacillin or cephalexin, 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).

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

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

PRESCRIBER REQUIREMENTS:
Prescribed by or in consultation with an infectious disease specialist. If prescribed in consultation, consultation notes must be submitted.

AGE RESTRICTIONS:
12 years of age and older

CONTINUATION OF THERAPY:
NA

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

BACKGROUND:
None

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:
1. Sivextro (tedizolid) [prescribing information]. Whitehouse Station, NJ: Merck; October 2020.
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. Am J HealthSys Pharm. 2014;71:621-633.