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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)

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. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a mandatory generic and that generic drugs will be dispensed whenever available.

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
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, serious side effects, contraindication or non-susceptibility to a first-line antibiotic treatment for the site of infection such as a beta-lactam, tetracycline, clindamycin, trimethoprim-sulfamethoxazole, or fluoroquinolone, or vancomycin
   AND
4. FOR IV REQUESTS ONLY: Documentation of medically necessary use of IV Sivextro (tedizolid) for the current active infection instead of oral Sivextro (tedizolid).

CONTINUATION OF THERAPY:
N/A

DURATION OF APPROVAL:
Initial authorization: 6 days, subsequent approval will require a new authorization, Continuation of therapy: N/A

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

AGE RESTRICTIONS:
12 years of age and older

QUANTITY:
200 mg IV or orally once daily

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

FDA-APPROVED USES:
Indicated in adult and pediatric patients 12 years of age and older for the 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.

Sivextro is an oxazolidinone-class antibacterial indicated in adult and pediatric patients 12 years of age and older for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by susceptible isolates of the following Gram-positive microorganisms: Staphylococcus aureus (including methicillin-resistant [MRSA] and methicillin-susceptible [MSSA] isolates), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), and Enterococcus faecalis.

COMPENDIAL APPROVED OFF-LABELED USES:
None

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
Tedizolid phosphate is an oxazolidinone antibiotic approved for the treatment of acute bacterial skin and skin structure infections caused by susceptible bacteria. It is the second oxazolidinone-class antibacterial (linezolid is the first). Tedizolid is similar to linezolid spectrum of activity, mechanism of action, and pharmacology. It is bacteriostatic against staphylococci (including MRSA and Staph. epidermidis), streptococci (S. pyogenes, S. agalactiae, and S. anginosus group), and enterococci (including vancomycin-resistant enterococci). It was found to be non-inferior to linezolid in clinical trials. Tedizolid is a weak monoamine oxidase inhibitor and could increase the risk of the serotonin syndrome if combined with serotonin uptake inhibitors. Patients requiring concomitant therapy with other monoamine oxidase inhibitors or serotonergic agents (SSRIs) were excluded from clinical trials.

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) include: No labeled contraindications.

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.

Clostridioides difficile-associated diarrhea (CDAD) has been reported for nearly all systemic antibacterial agents including SIVEXTRO, with severity ranging from mild diarrhea to fatal colitis. Treatment with antibacterial agents can alter the normal flora of the colon and may permit overgrowth of C. difficile. C. difficile produces toxins A and B which contribute to the development of CDAD. Hypertoxin producing strains of C. difficile cause increased morbidity and mortality, as these infections can be refractory to antibacterial therapy and may require colectomy. CDAD must be considered in all patients who present with diarrhea following antibacterial drug use. Careful medical history is necessary because CDAD has been reported to occur more than two months after the administration of antibacterial agents. If CDAD is suspected or confirmed, antibacterial use not directed against C. difficile should be discontinued, if possible. Appropriate measures such as fluid and electrolyte management, protein supplementation, antibacterial treatment of C. difficile, and surgical evaluation should be instituted as clinically indicated.

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

AVAILABLE DOSAGE FORMS:
Sivextro TABS 200MG
Sivextro SOLR 200MG single dose vial

REFERENCES

1. Sivextro (tedizolid) [prescribing information]. Whitehouse Station, NJ: Merck; March 2023.
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 JHealthSys Pharm. 2014;71:621-633.
5. 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. ClinInfect Dis 2014; Jul 15;59(2):147-59.

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Background Other Special Considerations References	Q1 2024
REVISION- Notable revisions: Diagnosis Required Medical Information Duration of Approval Prescriber Requirements Quantity FDA-Approved Uses Contraindications/Exclusions/Discontinuation HCPCS Code and Description Available Dosage Forms References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file