Clinical Policy: Tedizolid (Sivextro)
Reference Number: HIM.PA.118
Effective Date: 05/17
Last Review Date: 01/17
Line of Business: Health Insurance Marketplace

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Tedizolid (Sivextro®) is an oxazolidinone class antibacterial agent.

FDA approved indication
Sivextro is indicated in adults:

- 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

Policy/Criteria
** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria **

I. Initial Approval Criteria

A. Acute Bacterial Skin and Skin Structure Infections Caused by Susceptible Gram-Positive Bacteria (must meet all):

1. Diagnosis of acute bacterial skin and skin structure infections (ABSSSI);
2. Prescribed by or in consultation with an infectious disease specialist;
3. Culture and sensitivity (C&S) report (dated within past 7 days) shows isolated pathogen is susceptible to tedizolid, unless provider submits documentation that obtaining a C&S report is not feasible;
4. Member meets one of the following: (a, b, or c):
   a. Isolated pathogen is a gram-positive bacteria and is NOT susceptible to any formulary antibiotic FDA approved for member's diagnosis;
   b. Failure of formulary antibiotics to which the isolated pathogen is susceptible, unless contraindicated or clinically significant adverse effects are experienced;
   c. Provider indicates obtaining a C&S report is not feasible, and member has tried and failed 2 formulary antibiotics indicated for member's diagnosis, unless contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed 200 mg per day (1 tablet per day).

Approval duration: 6 days

B. Other diagnoses/indications - Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Acute Bacterial Skin and Skin Structure Infections Caused by Susceptible Gram-Positive Bacteria (must meet all):
1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member has not received ≥ 6 days of therapy for current infection;
3. Dose does not exceed 200 mg per day (1 tablet per day).

Approval duration: Allow no more than 6 days of total therapy

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy;
2. Refer to off-label use policy: HIM.PHAR.21 for diagnosis is NOT listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: No more than 6 days of total therapy or duration of request, whichever is less

III. Diagnoses/Indications for which coverage is NOT authorized:
A. Treatment of infections/bacteria not susceptible to tedizolid;
B. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy - HIM.PHAR.21 or evidence of coverage documents.

IV. Appendices/General Information
Appendix A: Abbreviation Key
ABSSSI: acute bacterial skin and skin structure infections
C&S: culture and sensitivity
FDA: Food and Drug Administration

V. References
1. Sivextro Prescribing Information. Whitehouse Station, NJ: Merck & Co., Inc.; October 2016. Available at http://www.merck.com/. Accessed November 2016.
2. Lui, 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. Clin Infect Dis. 2011 Feb;52:1-38. Clinical Infectious Diseases; 2011;52:1-38.
3. Tedizolid Drug Monograph. Clinical Pharmacology. Accessed January 2017. http://www.clinicalpharmacology-ip.com

Reviews, Revisions, and Approvals	Date	Approval Date
Policy created.	01/17	

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted

standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence.

Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.