Clinical Policy: Tedizolid (Sivextro)

Reference Number: CP.PMN.62
Effective Date: 03.01.15
Last Review Date: 02.18
Line of Business: Health Insurance Marketplace, Medicaid

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(s)

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 (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Sivextro is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Acute Bacterial Skin and Skin Structure Infections (must meet all)**:**

1. Diagnosis of ABSSSI;
2. Prescribed by or in consultation with an infectious disease specialist;
3. Age ≥ 18 years;
4. Culture and sensitivity (C&S) report dated within the past 7 days shows isolated pathogen is a gram-positive bacteria susceptible to tedizolid, unless provider submits documentation that obtaining a C&S report is not feasible;
5. Member meets one of the following (a, b, c, or d):
   a. Failure of ≥ 2* formulary antibiotics to which the isolated pathogen is susceptible, unless all are contraindicated or clinically significant adverse effects are experienced;
   b. C&S report shows resistance of the isolated pathogen to ALL PDL antibiotics FDA-approved for member's diagnosis;
   c. Provider documents that obtaining a C&S report is not feasible, and member has tried and failed 2* formulary antibiotics indicated for member's diagnosis, unless all are contraindicated or clinically significant adverse effects are experienced;
   d. Preferred antibiotics are not indicated for member's diagnosis;
6. Dose does not exceed 200 mg/day (1 tablet/day).

Approval duration: 1 month (approve for a 6-day supply only)

Provided 2 formulary antibiotics exist to which the pathogen is susceptible and/or are indicated for member's diagnosis

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Infectious 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. Request does not exceed 200 mg/day (1 tablet/day).

Approval duration: 1 month (approve up to 6-day supply)

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. 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 policies –, HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
ABSSSI: acute bacterial skin and skin structure infections
C & S: culture and sensitivity
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
sulfamethoxazole-Trimethoprim (Bactrim®)	160/800 mg every 12 hours	20 mg/kg/day
minocycline (Minocin®)	100 mg every 12 hours	Immediate-release oral formulations: 300 mg on day 1, then 200 mg/day
doxycycline (Monodox®)	100 mg every 12 hours	300 mg/day
clindamycin (Cleocin®)	150 to 450 mg every 6 hours	1800 mg/day
vancomycin (Vancocin®)	2 g/day	2 g/day
daptomycin (Cubicin®)	6 mg/kg/dose IV	6 mg/kg/dose
Therapeutic alternatives include formulary antibiotics that are have sufficient activity against the offending pathogen at the site of the infection per the C & S.		

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
ABSSSI	200 mg once daily orally or intravenous (IV) infusion over 1 hour for six days	200 mg per day

VI. Product Availability

Tablet: 200 mg
Single-use vial: 200 mg, sterile, lyophilized powder for reconstitution

VII. References

1. Sivextro Prescribing Information. Whitehouse Station, NJ: Merck & Co., Inc.; August 2017. Available at http://www.merck.com/. Accessed November 2017.
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. In: Clinical Pharmacology. Tampa, FL: Gold Standard; 2016. Available at www.clinicalpharmacology.com. Accessed November 8, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Initial Guideline Creation	03.15	03.15
Converted into new policy template; Added that tedizolid should be prescribed by or in consultation with an ID specialist;	12.15	02.16

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added that culture and sensitivity result should show pathogen susceptibility to tedizolid and be dated within the last 7 days; Modified criteria to allow approval for any infections in which other FDA approved PDL medications are resistant; Added renewal criteria to allow for continuity of care; Deleted renewal criteria regarding empiric therapy; Changed initial approval duration to 6 days to allow a full course of treatment Added a limit of 1 tablet/day Updated references		
Converted to new integrated template; Modified requirement related to quantity limit of 1 tablet/day to the max; Removed specific number of PDL antibiotics (i.e., 2 PDL antibiotics) required for trial and failure to be in line with Zyvox criteria; Add that Sivextro will not be approved for treatment of infections/bacteria not susceptible tedizolid; added diagnosis of acute bacterial skin and skin structure infections (ABSSSI).	11.16	02.17
1Q18 Annual Review: policies combined for Medicaid and HIM lines of business. - Removed language specifying that isolated pathogen is VRE or MRSA since VRE & MRSA are gram-positive and policy now covers gram positive bacteria per indication. - Modified criteria to allow for cases in which obtaining C&S report is not feasible per documentation from the provider - Clarified requirement related to failure of formulary antibiotics by specifying 2 formulary antibiotics, provided 2 appropriate formulary antibiotics are available to which the pathogen is susceptible and/or are indicated for member's diagnosis. - Age added per safety guidance endorsed by Centene Medical Affairs - References reviewed and updated.	11.13.17	02.18

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.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.