

Clinical Policy: Tedizolid (Sivextro)

Reference Number: PA.CP.PMN.62

Effective Date: 01/2018

Last Review Date: 07/2025

Description

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

FDA approved indication

Sivextro is indicated in adults and pediatric patients (at least 26 weeks gestational age and weighing at least 1 kg) for 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*)
- *Enterococcus faecalis*

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 infections that are 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 such data, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

Policy/Criteria

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

It is the policy of PA Health & Wellness[®] 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. If request is for pediatrics, both of the following (a and b):
 - a. Member is at least 26 weeks gestational age;
 - b. Member weighs at least 1 kg;
3. If request is for Sivextro tablets, member is ≥ 35 kg;
4. Member meets one of the following (a or b):
 - a. Request is for continuation of therapy initiated in an acute care hospital from which member was discharged;
 - b. Both of the following (i and ii):

- i. Culture and sensitivity (C&S) report for the current infection shows isolated pathogen is a gram-positive bacteria susceptible to tedizolid, unless provider submits documentation that obtaining a C&S report is not feasible;
 - ii. Member meets one of the following (a, b, or c):
 - a) Failure of ≥ 2 formulary antibiotics to which the isolated pathogen is susceptible (if available) per C&S report, unless all are contraindicated or clinically significant adverse effects are experienced;
 - b) C&S report shows resistance or lack of susceptibility of the isolated pathogen to all formulary antibiotics FDA-approved for member's diagnosis;
 - c) If provider documents that obtaining a C&S report is not feasible: Failure of ≥ 2 formulary antibiotics indicated for member's diagnosis (if available), unless all are contraindicated or clinically significant adverse effects are experienced;
5. Dose does not exceed one of the following (a or b):
 - a. For adults and pediatrics with weight ≥ 35 kg, both of the following (i and ii):
 - i. 200 mg per day;
 - ii. 1 tablet or 1 vial per day;
 - b. For pediatrics with weight < 35 kg, both of the following (i and ii):
 - i. Weight-based dosing (*see Section V below*), not to exceed 120 mg per day;
 - ii. 1 vial per day.

Approval duration: 1 month (6 doses only)

- B. Other diagnoses/indications** – Refer to PA.CP.PMN.53 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 (must meet all):

1. Member meets one of the following (a or b):
 - a. Currently receiving medication via PA Health & Wellness benefit or member has previously met initial approval criteria, or the Continuity of Care policy applies (see PA.PHARM.01);
 - b. Request is for continuation of therapy initiated in an acute care hospital from which member was discharged;
2. Member is responding positively to therapy;
3. Member has not received ≥ 6 days of therapy for current infection; If request is for a dose increase, new dose does not exceed one of the following (a or b):
 - a. For adults and pediatrics with weight ≥ 35 kg, both of the following (i and ii):
 - i. 200 mg per day;
 - ii. 1 tablet or 1 vial per day;
 - b. For pediatrics with weight < 35 kg, both of the following (i and ii):
 - i. Weight-based dosing (*see Section V below*), not to exceed 120 mg per day;
 - ii. 1 vial per day.

Approval duration: Up to 1 month (up to 6 doses only)

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

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy, or the Continuity of Care policy applies (see PA.PHARM.01); or
2. Refer to PA.CP.PMN.53 if requested indication 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.** 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 – PA.CP.PMN.53 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

MRSA: methicillin-resistant

Staphylococcus aureus

MSSA: methicillin-susceptible

Staphylococcus aureus

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 and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
Therapeutic alternatives include formulary antibiotics that are indicated for member's diagnosis and have sufficient activity against the offending pathogen at the site of the infection.		

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.

Appendix C: Contraindications/Boxed Warnings

- None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
ABSSSI	Adults and members with weight ≥ 35 kg: 200 mg once daily PO or IV over 1 hour for six days Pediatrics with weight < 35 kg: weight-based dosing below, twice daily IV administration over 1 hour for six days • 1 kg to < 2 kg: 3 mg/kg • 2 kg to < 3 kg: 6 mg	Adults and members with weight ≥ 35 kg: 200 mg/day Pediatrics with weight < 35 kg: 120 mg/day

Indication	Dosing Regimen	Maximum Dose
	3 kg to < 6 kg: 12 mg 6 kg to < 10 kg: 20 mg 10 kg to < 14 kg: 30 mg 14 kg to < 20 kg: 40 mg 20 kg to < 35 kg: 60 mg	

VI. Product Availability

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

IV. References

- Sivextro Prescribing Information. Rahway, NJ: Merck Sharp & Dohme LLC; April 2024. Available at: https://www.merck.com/product/usa/pi_circulars/s/sivextro/sivextro_pi.pdf. Accessed April 21, 2025.
- Liu, 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.
- 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. Clinical Infectious Diseases. July 2014;59(2):10-52.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J3090	Injection, tedizolid phosphate, 1 mg
J8499	Prescription drug, oral, non chemotherapeutic, nos

Reviews, Revisions, and Approvals	Date
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.	02/2018
1Q 2019 annual review: removed 7 day requirement for C&S report and replaced it with requirement that C&S report is for the current infection; added	01/2019

Reviews, Revisions, and Approvals	Date
'lack of susceptibility' as an alternative to demonstrating resistance on C&S; removed criterion allowing member to meet criteria if formulary antibiotics are not indicated for member's diagnosis, since this is incorporated into other existing criteria already; added criterion to allow member to continue treatment if it was started in an acute care hospital and member was discharged; revised cont approval duration to be up to 6 doses (1 month); added requirement for positive response to therapy; references reviewed and updated.	
1Q 2020 annual review: Removed the requirement that tedizolid be prescribed by or in consultation with an ID specialist, for consistency with policies of related drugs; references reviewed and updated.	01/2020
1Q 2021 annual review: revised lower age limit to 12 years based on newly FDA-approved pediatric indication extension, was previously approved only for use in adults; references reviewed and updated.	01/2021
1Q 2022 annual review: no significant changes; references reviewed and updated.	01/2022
1Q 2023 annual review: no significant changes; references reviewed and updated.	01/2023
Added HCPCS code J8499 for oral Sivextro; references reviewed and updated.	07/2023
3Q 2024 annual review: no significant changes; references reviewed and updated.	07/2024
3Q 2025 annual review: RT4: added pediatric extension to include use in members at least 26 weeks gestational age and weight at least 1 kg; references reviewed and updated.	07/2025