Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2020**
Policy Number: PA.CP.PMN.62	**Effective Date: 01/01/2018** **Revision Date: 01/15/2020**
Policy Name: Tedizolid (Sivextro)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

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

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:**

Clinical Policy: Tedizolid (Sivextro)

Reference Number: PA.CP.PMN.62
Effective Date: 01/18
Last Review Date: 01/2020 Revision Log

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 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 ABSSSI 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 Pennsylvania Health and 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. Age ≥ 18 years;
3. 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;

4. Dose does not exceed 200 mg (1 tablet or 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 Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria, or the Continuity of Care policy applies (*see PA.LTSS.PHAR.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;
4. Request does not exceed 200 mg (1 tablet or 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 Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy, or the Continuity of Care policy applies (*see PA.LTSS.PHAR.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 for all relevant lines of business 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	200 mg once daily PO or IV over 1 hour for six days	200 mg/day

VI. Product Availability

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

Injection: 200 mg, sterile, lyophilized powder in single-use vial for reconstitution for intravenous infusion

VII. References

1. Sivextro Prescribing Information. Whitehouse Station, NJ: Merck & Co., Inc.; September 2019. Available at: https://www.merck.com/product/usa/pi_circulars/s/sivextro/sivextro_pi.pdf. Accessed October 30, 2019.
2. 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.
3. 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. April 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

Reviews, Revisions, and Approvals	Date	Approval 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.	02/18	
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 '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.	01/19	
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	