CENTENE Corporation

PRIOR AUTHORIZATION GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** tedizolid (Sivextro®)
PAGE: 1 of 4	**REFERENCE NUMBER:** NH.PMN.62
EFFECTIVE DATE: 03/15	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 12/16, 10/17, 12/17
PRODUCT TYPE: Medicaid	**REVISED:** 4/16

IMPORTANT REMINDER

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of generally accepted standards of medical practice, peer-reviewed medical literature, government agency/program approval status, and other indicia of medical necessity.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based in all cases on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding results. 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.

Description: Tedizolid is a synthetic oxazolidinone antimicrobial agent. It has clinical utility in the treatment of acute bacterial skin and skin structure infections.

Brand: Tedizolid (Sivextro®): 200mg tablets

NOTE: This policy does not address intravenous linezolid.

FDA Labeled Indications: Acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria.

- *Staphylococcus aureus (Methicillin-Resistant and Methicillin-Susceptible strains)*
- *Streptococcus pyogenes*
- *Streptococcus agalactiae*
- *Streptococcus anginosus*
- *Enterocuccus faecalis*

Centene Medical Policy Statements represent technical documents developed by the Medical Management Staff. Questions regarding interpretation of these policies for the purposes of benefit coverage should be directed to a Medical Management Staff person.

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Criteria for Approval:

A. Ordered for the treatment of VRE confirmed by Culture and Sensitivity report (NOTE: tedizolid will NOT be approved as first line therapy for Ampicillin sensitive enterococcus). ***OR***

B. Ordered for the treatment of resistant gram positive infections confirmed by Culture and Sensitivity report (i.e. MRSA, S. epi., S. pneumonia (MDRSP))

C. Isolated pathogen is VRE or MRSA **AND** the pathogen is NOT susceptible to any PDL antibiotic FDA-approved for patient's diagnosis

OR

Member has failed at least TWO PDL antibiotic FDA approved for member's diagnosis, unless isolated pathogen is resistant to, or member has contraindication(s) to all PDL medications approved by the FDA for member's diagnosis.

D. Request does not exceed 1 tablet per day.

Approval: Approval: Up to a 6-day supply.

Special Instructions

- Please refer to prescribing information for dosing, precautions, and other clinical information.
- To reduce the development of drug-resistant bacteria and maintain the effectiveness of Sivextro® and other antibacterial drugs, Sivextro® should only be used to treat or prevent 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,

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local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.
- Myelosuppression and pseudomembranous colitis have been seen with Sivextro® use.
- Pregnancy Catergory C risk.
- To avoid risk of serotonin syndrome, linezolid should not be administered to patients taking: serotonin re-uptake inhibitors, tricyclic antidepressants, serotonin 5-HT1 receptor agonists (triptans), meperidine, bupropion, or buspirone.

References: 1. Clinical Pharmacology Online. Accessed 03/01/15.

Revision Log	
Revision	**Date**
Initial Guideline Creation	03/15
Increased the approval timeframe from 3 days to 6 days	07/15
Added to criteria for approval: Isolated pathogen is VRE or MRSA **AND** the pathogen is NOT susceptible to any PDL antibiotic FDA-approved for patient's diagnosis **OR** Member has failed at least TWO PDL antibiotic FDA approved for member's diagnosis, unless isolated pathogen is resistant to, or member has contraindication(s) to all PDL medications approved by the FDA for member's diagnosis. Request does not exceed 1 tablet per day.	4/16
Annual Review, No Changes	12/16

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Annual Review, No Changes	10/17
Annual Review, No Changes	12/17

POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file

V.P., Pharmacy Operations: Approval on file

Sr. V.P., Chief Medical Officer: Approval on file

NOTE: The electronic approval is retained in Compliance 360.