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Section:	Prescription Drugs	**Effective Date:**	July 1, 2023
Subsection:	Anti-infective Agents	**Original Policy Date:**	August 22, 2014
Subject:	Sivextro	**Page:**	1 of 4

Last Review Date: June 15, 2023

Sivextro

Description

Sivextro (tedizolid)

Background
Sivextro is an antibiotic processed by the body to its active form tedizolid which treats specific bacterial infections. It is effective against susceptible strains of drug resistant bacteria and works by blocking protein synthesis within the bacteria causing bacterial cell death. It is chemically and clinically similar to linezolid, another antibiotic, but is effective with a shorter typical treatment duration (1).

Regulatory Status
FDA-approved indications: Sivextro is an oxazolidinone-class antibacterial drug indicated in adults and pediatric patients 12 years of age and older for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria (1).

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 bacteria (1).

The indicated species include Staphylococcus aureus (MRSA and MSSA), Streptococcus pyogenes, Streptococcus agalactiae, Streptococcus anginosus Group (including Streptococcus anginosus, Streptococcus intermedius, and Streptococcus constellatus), and Enterococcus faecalis (1).

The recommended dosage is 200mg once daily for 6 days. Due to possible hematologic changes with use longer than 6 days, Sivextro should be used beyond the recommended 6-day

duration with caution. Use of linezolid, another oxazolidinone class antibiotic for more than 28 days has been linked to peripheral and optic neuropathy (1).

The safety and effectiveness of Sivextro in pediatric patients below the age of 12 have not been established (1).

Related policies
Baxdela, Nuzyra, Xenleta, Zyvox

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Sivextro may be considered **medically necessary** if the conditions indicated below are met.

Sivextro may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 12 years of age or older

Diagnoses

Patient must have an infection caused by **OR** strongly suspected to be caused by **ONE** of the following:

Acute bacterial skin and skin structure infections (ABSSSI) caused by at least ONE of the indicated susceptible bacteria:

- Methicillin Resistant Staphylococcus Aureus (MRSA)
- Methicillin Susceptible Staphylococcus Aureus (MSSA)
- Streptococcus pyogenes
- Streptococcus agalactiae
- Streptococcus anginosus (entire group)
- Streptococcus intermedius
- Streptococcus constellatus
- Enterococcus faecalis

AND the following:

1. Inadequate treatment response, intolerance, or contraindication to a first-line antibiotic, such as a macrolide, fluoroquinolone, beta-lactam, or tetracycline

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

Duration 6 day supply every 365 days

Prior - Approval Limits

Duration 3 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Sivextro is an oxazolidinone-class antibacterial drug indicated in adults for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria. Sivextro is an antibiotic processed by the body to its active form tedizolid. It works by blocking protein synthesis within the bacteria causing bacterial cell death. The recommended dosage is 200mg once daily for 6 days. The safety and effectiveness of Sivextro in patients below the age of 12 have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Sivextro while maintaining optimal therapeutic outcomes.

References

1. Sivextro [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; July 2022.

Policy History

Date	Action
August 2014	New Policy Addition

September 2014	Annual review and update
December 2014	Annual review and update
March 2015	Annual editorial review and reference update Policy code changed from 5.03.31 to 5.01.31
December 2017	Annual editorial review and reference update
November 2018	Annual review and reference update
December 2019	Annual review and reference update
March 2020	Annual review. Revised requirement to “Patient must have an infection caused by OR strongly suspected to be caused by ONE of the following” and added requirement to t/f a first-line antibiotic per SME
July 2020	Changed age requirement from 18 and older to 12 and older
September 2020	Annual review
September 2021	Annual review and reference update
September 2022	Annual review and reference update
June 2023	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 15, 2023 and is effective on July 1, 2023.