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5.01.31

Section:	Prescription Drugs	**Effective Date:**	January 1, 2019
Subsection:	Anti-infective Agents	**Original Policy Date:**	August 22, 2014
Subject:	Sivextro	**Page:**	1 of 4

Last Review Date: November 30, 2018

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 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 patients below the age of 18 have not been established (1).

Related policies
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** in patients 18 years of age or older for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria.

Sivextro may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have the following:

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

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

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

Duration 3 months

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 18 has 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., August 2017.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on November 30, 2018 and is effective January 1, 2019.