

SIVEXTRO (tedizolid)

## RATIONALE FOR INCLUSION IN PA PROGRAM

# **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 antibacterial indicated for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible microorganisms in adult and pediatric patients (at least 26 weeks gestational age and weighing at least 1 kg) (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 susceptible 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).

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 less than 26 weeks gestational age and weighing less than 1 kg have not been established (1).

#### **Summary**

Sivextro is an oxazolidinone-class antibacterial drug indicated for the treatment of acute bacterial



# SIVEXTRO

eral Employee Program。 (tedizolid)

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 safety and effectiveness of Sivextro in patients less than 26 weeks gestational age and weighing less than 1 kg 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]. Rahway, NJ: Merck & Co., Inc.; April 2025.