

Reference number(s)
1161-A

Initial Prior Authorization

Sivextro

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Sivextro	tedizolid

Indications

FDA-Approved Indications

Acute Bacterial Skin and Skin Structure Infections

Sivextro is indicated for the 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), and Enterococcus faecalis, in adult and pediatric patients (at least 26 weeks gestational age and weighing at least 1 kg).

Usage to Reduce Development of Drug-Resistant Bacteria

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 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, local epidemiology and susceptibility patterns may contribute to the empiric selection of therapy.

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Coverage Criteria

Authorization may be granted for the requested drug when the following criteria is met:

- The patient is being converted from IV (intravenous) Sivextro (tedizolid) as prescribed by or in consultation with an Infectious Disease specialist

Acute Bacterial Skin and Skin Structure Infection (ABSSI)

Authorization may be granted when the requested drug is being prescribed for the treatment of acute bacterial skin and skin structure infection (ABSSI) when ALL of the following criteria are met:

- The requested drug is being prescribed for a patient at least 26 weeks gestational age or older AND weighing at least 1 kg
- The infection is caused by susceptible isolates of ANY 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
- The infection is proven or strongly suspected to be caused by susceptible bacteria based on culture and susceptibility OR local epidemiology and susceptibility patterns
- The patient meets ONE of the following:
 - The patient has experienced an inadequate treatment response, intolerance, or contraindication to alternative therapies
 - The bacteria are NOT susceptible to any other antibiotics

Duration of Approval (DOA)

- 1161-A: DOA: 6 days

References

1. Sivextro [package insert]. Rahway, NJ: Merck Sharp & Dohme LLC; April 2025.
2. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Waltham, MA: UpToDate, Inc.; 2025. <https://online.lexi.com>. Accessed February 4, 2025.
3. Micromedex (electronic version). Merative, Ann Arbor, Michigan, USA. Available at: <https://www.micromedexsolutions.com/> (cited: 02/04/2025).

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4. 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 2014;59(2):e10-52.