# Pharmacy Medical Necessity Guidelines:
# Sivextro (tedizolid)

*Effective: March 1, 2026*

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| Prior Authorization Required | √ | Type of Review – Care Management | |
| Not Covered | | Type of Review – Clinical Review | √ |
| Pharmacy (RX) or Medical (MED) Benefit | RX | Department to Review | RXUM |
| These pharmacy medical necessity guidelines apply to the following:<br>☒ Tufts Health RITogether – A Rhode Island Medicaid Plan | | **Fax Numbers:**<br>RXUM: 617.673.0939 | |

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

## OVERVIEW

**FDA-APPROVED INDICATIONS**

**Sivextro (tedizolid)** is an oxazolidinone-class antibacterial drug indicated in adults and pediatric patients (at least 26 weeks gestational age and weighing at least 1 kg) for the treatment of acute bacterial skin and skin structure infections (ABSSSI) caused by designated susceptible bacteria.

Susceptible isolates of gram-positive bacteria include: *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.*

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.

Sivextro tablets are not recommended in pediatric patients weighing less than 35 kg. Sivextro is also available as intravenous infusion indicated for adults and pediatric patients who are at least 26 weeks gestational age and weighing at least 1 kg.

## COVERAGE GUIDELINES

The plan may authorize coverage of Sivextro (tedizolid) for Members when **ALL** the following criteria are met and limitations do not apply:

**Initial:**

1. Diagnosis of an acute bacterial skin and skin structure infections (ABSSI) caused by susceptible bacteria

**AND**

2. Member meets **ONE** of the following:
    a. Member failed other antibiotics to which the organism is susceptible OR provider submits a clinical rationale why the Member is unable to take other antibiotics to which the organism is susceptible

**OR**

    b. The Member is continuing treatment Sivextro upon discharge from a facility

**AND**

3. The medication is prescribed following consult with an infection disease specialist or upon discharge from an inpatient setting

**Reauthorization:**

1. The Member has been re-assessed for this condition, and continued therapy with this medication is considered medically necessary

## LIMITATIONS

1. The length of approval will be for 6 days; subsequent approval will require a new authorization.

## CODES

None

## REFERENCES


1. Sivextro (tedizolid) [prescribing information]. Rahway, NJ: Merck Sharpe and Dohme LLC;April 2025.
2. Kisgen JJ, Mansour H, Unger NR, et al. Tedizolid: a new oxazolidinone antimicrobial. *Am J Health-Sys Pharm*. 2014;71:621-633.

## APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. May 9, 2023: No changes.
2. February 13, 2024: Effective March 1, 2024, updated reauthorization criteria to remove office visit requirement. Updated fax number for RxUM.
3. February 11, 2025: No changes
4. February 10, 2026: Effective March 1, 2026, administrative update to overview section for expanded indication in pediatric patients at least 26 weeks gestational age and weighing at least 1 kg. No criteria changes.

## BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.