

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

## Sivextro (tedizolid)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 month

Medications	Quantity Limit
Sivextro (tedizolid) tablets	6 tablets per fill; 1 fill per 30 days

### APPROVAL CRITERIA

Requests for Sivextro (tedizolid) may be approved for individuals who meet the following criteria:

- I. Individual has been diagnosed with acute bacterial skin and skin structure infection (ABSSSI) defined as one of the following (FDA, 2013):
    - A. Cellulitis/erysipelas; **OR**
    - B. Wound infection; **OR**
    - C. Major cutaneous abscess;

**AND**
  - II. Individual has at least one regional or one systemic sign of infection as defined by:
    - A. Lymphadenopathy; **OR**
    - B. Oral temperature greater than or equal to 38 degrees Celsius; **OR**
    - C. White blood cell count greater than or equal to 10,000 per microliter; **OR**
    - D. White blood cell count less than 4000 per microliter; **OR**
    - E. Greater than 10% of immature neutrophils;

**AND**
  - III. Infection is caused by methicillin-resistant *Staphylococcus aureus* [MRSA]; **AND**
  - IV. Individual has had a trial (medication samples/coupons/discount cards are excluded from consideration as a trial) and inadequate response or intolerance to one alternative antibiotic that the organism is susceptible to (examples of alternative antibiotics may include, but are not limited to: TMP/SMX, doxycycline, vancomycin, daptomycin, televancin, clindamycin) (IDSA 2014);
- OR**
- V. Individual started treatment with antibiotic(s) in the hospital and requires continued outpatient therapy for an organism susceptible to Sivextro (tedizolid).

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Applicable	X	X	X	X	X	X	X

Sivextro (tedizolid) may **not** be approved for the following:

- I. Treatment of gram-negative infections.

**Key References:**

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: March 13, 2020.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
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. *Clin Infect Dis*. 2014 Jul 15;59(2):e10-52. doi: 10.1093/cid/ciu296.
5. US Food and Drug Administration (FDA). Guidance for Industry. Acute bacterial skin and skin structure infections: developing drugs for treatment. October 2013. Accessed: March 14, 2020.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.