

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

*FHK- Florida Healthy Kids

Sivextro (tedizolid)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	30 days

Medications	Quantity Limit
Sivextro (tedizolid) 200mg tablet	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 a minimum total lesion surface area of approximately 75 cm² (FDA, 2013); **AND**
- III. Individual has at least 1 regional or 1 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
- IV. Infection is caused by methicillin-resistant *Staphylococcus aureus* [MRSA]; **AND**
- V. Individual has had a trial of or has contraindications* to an alternative antibiotic that the organism is susceptible to (depending on manifestation, severity of infection and culture or local sensitivity patterns, examples of alternative antibiotics may include, but are not limited to: TMP/SMX, doxycycline, vancomycin, daptomycin, televancin, clindamycin) (IDSA 2014); **OR**
- VI. Individual started treatment with intravenous antibiotic(s) in the hospital and requires continued outpatient therapy for an organism susceptible to Sivextro (tedizolid).

*Contraindications may include but are not limited to: adverse events, allergic reaction, lack of venous access or complications from venous access devices (for IV antibiotics).

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.

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

- I. Treatment of gram-negative infections.

Note: To reduce the development of bacterial resistance and maintain effectiveness of Sivextro (tedizolid), Sivextro should only be used to treat ABSSSI 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 culture and susceptibility information, local epidemiology and susceptibility patterns may contribute to empiric selection of therapy.

State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed January 30, 2017.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.

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