

Clinical Pharmacy Program Guidelines for Sivextro

Program	Prior Authorization
Medication	Sivextro (tedizolid)
Issue Date	9/2014
Pharmacy and Therapeutics Approval Date	11/2017
Effective Date	1/2018

1. Background:

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.

2. Coverage Criteria:

<p>A. <u>Authorization</u></p> <p>1. Sivextro will be approved based on the following:</p> <p style="padding-left: 40px;">a. One of the following:</p> <p style="padding-left: 80px;">(1) As continuation of therapy when transitioning from one of the following:</p> <ul style="list-style-type: none"> • Intravenous daptomycin • Intravenous vancomycin • Intravenous tigecycline • Intravenous telavancin • Intravenous linezolid therapy • Intravenous Sivextro therapy <p style="text-align: center;">OR</p> <p style="padding-left: 80px;">(2) For continuation of therapy upon hospital discharge</p>

OR

(3) Both of the following:

(a) One of the following diagnoses:

i. All of the following:

- Acute bacterial skin and skin structure infection

AND

- Patient does not have osteomyelitis or diabetic foot infection

AND

- Infection caused by methicillin-resistant *Staphylococcus aureus* (MRSA) documented by culture and sensitivity report

OR

ii. All of the following:

- Empirical treatment of patients with acute bacterial skin and skin structure infection

AND

- Patient does not have osteomyelitis or diabetic foot infection

AND

- Presence of MRSA infection is likely

AND

(b) One of the following:

i. History of failure, contraindication, or intolerance to one of the following antibiotics:

- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A tetracycline
- Clindamycin

OR

ii. History of resistance to all of the following antibiotics:

- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A tetracycline
- Clindamycin

OR

(4) All of the following:

(a) Diagnosis of acute bacterial skin and skin structure infection

AND

(b) Patient does not have osteomyelitis or diabetic foot infection

AND

(c) Infection caused by one of the following:

- Methicillin-susceptible *Staphylococcus aureus* (MSSA) documented by culture and sensitivity report
- *Streptococcus pyogenes* documented by culture and sensitivity report
- *Streptococcus agalactiae* documented by culture and sensitivity report
- *Streptococcus anginosus* Group (including *Streptococcus anginosus*, *Streptococcus intermedius*, and *Streptococcus constellatus*) documented by culture and sensitivity report
- *Enterococcus faecalis* documented by culture and sensitivity report

AND

(d) One of the following:

i. History of failure, contraindication, or intolerance to two of the following antibiotics:

- Dicloxacillin
- A cephalosporin
- A tetracycline
- Amoxicillin/clavulanate
- Clindamycin
- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A fluoroquinolone

OR

ii. History of resistance to all of the following antibiotics:

- Dicloxacillin
- A cephalosporin
- A tetracycline
- Amoxicillin/clavulanate
- Clindamycin
- Sulfamethoxazole-trimethoprim (SMX-TMP)
- A fluoroquinolone

Authorization will be issued for up to 6 days.

3. References:

1. Sivextro [package insert], Lexington, MA: Cubist Pharmaceuticals; 2016.
2. Eron L, Lipsky B, Low D, Nathwani D, Tice A, Volturo G. Managing skin and soft tissue infections: expert panel recommendations on key decision points. *J Antimicrob Chemother.* 2003;52:S-i3-i17.
3. 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;59(2):e10-52
4. CDC. Strategies for clinical management of MRSA in the community: summary of an experts' meeting convened by the Centers for Disease Control and Prevention. March 2006. Available at: <http://www.cdc.gov/mrsa/pdf/MRSA-Strategies-ExpMtgSummary-2006.pdf>. Accessed July 25, 2014.
5. Micromedex[®] Healthcare Series [Internet database]. Greenwood Village, Colo: Thomson Reuters (Healthcare) Inc. Updated periodically. Accessed July 17, 2017.
6. Gilbert DN, Chambers HF, Eliopoulos GM, Saag MS, eds. *The Sanford Guide to Antimicrobial Therapy 2014*, 44th ed. Sperryville, VA: Antimicrobial Therapy; 2014.
7. Mospan G, Hulisz D. Treating skin and soft tissue infections. *JA APA.* 2017;30(1):51-54.

Program	Prior Authorization –Sivextro (tedizolid)
Change Control	
Date	Change
9/2014	New policy
12/2015	Annual review, no change
11/2016	Annual review, updated policy template
9/2017	Updated authorization duration to "up to" 6 days. Updated references.
11/2017	Updated trial/failure/contraindication and resistance step therapy language to be consistent with the Zyvox policy.