UnitedHealthcare Community Plan

# Clinical Pharmacy Program Guidelines for Sivextro

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| Program | Prior Authorization |
| Medication | Sivextro (tedizolid) |
| Markets in Scope | Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina |
| Issue Date | 9/2014 |
| Pharmacy and Therapeutics Approval Date | 9/2020 |
| Effective Date | 11/2020 |

## 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*.

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 ABSSSI that are proven or strongly suspected to be caused by susceptible bacteria.

## 2. Coverage Criteria:

**A. <u>Skin and Skin Structure Infections</u>**

1. **Sivextro** will be approved based on the following:

a. **<u>One</u>** of the following:

(1) For continuation of therapy upon hospital discharge

**-OR-**

(2) As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication.

**-OR-**

(3) All of the following:

(a) Diagnosis of acute bacterial skin and skin structure infection (including diabetic foot infections)

**-AND-**

(b) One of the following diagnoses:

i. Both of the following:
- Acute bacterial skin and skin structure infections
- Infection caused by methicillin-resistant *Staphylococcus aureus* (MRSA) documented by culture and sensitivity report

**-OR-**

ii. Both of the following:
- Empirical treatment of patients with acute bacterial skin and skin structure infections
- Presence of MRSA infection is likely

**-AND-**

(c) History of failure, contraindication, or intolerance to linezolid (generic Zyvox)

**-AND-**

(d) History of failure, contraindication, or intolerance to one 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 (including diabetic foot infections)

**-AND-**

(b) Infection caused by an organism that is confirmed to be or likely to be susceptible to treatment with Sivextro

**-AND-**

(c) History of failure, contraindication, or intolerance to linezolid (generic Zyvox)

**-AND-**

(d) 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

**Authorization will be issued for up to 6 days.**

**B. Off-Label Uses**

1. **Sivextro** will be approved based on one of the following:

a. For continuation of therapy upon hospital discharge

**-OR-**

b. As continuation of therapy when transitioning from intravenous antibiotics that are shown to be sensitive to the cultured organism for the requested indication

**-OR-**

c. **Both** of the following:

i. The drug has been recognized for treatment of the indication by the Infectious Diseases Society of America (IDSA).

**-AND-**

ii. History of failure, contraindication, or intolerance to linezolid (generic Zyvox), if culture and susceptibility confirm susceptibility.

**Authorization duration based on provider and IDSA recommended treatment durations, up to 6 months.**

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. References:**

1. Sivextro [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; June 2020.
2. Stevens DL, Bisno AL, Chambers HF, et al. Practice Guidelines for Diagnosis and Management of Skin and Soft Tissue Infections: 2014 Update by the Infectious Disease Society of America. Clin Infect Dis. 2014;59(2);e:10-52.

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| **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. |
| 11/2018 | Annual review. Removed empiric therapy section. Added step through linezolid. Updated references. |
| 7/2019 | Updated MRSA language in section A, removed criteria that the patient cannot have osteomyelitis, and updated references. |
| 9/2020 | Annual review. Updated background and references. |