

Oxazolidinone Antibiotics Prior Authorization Worksheet

Fax Number: 1-800-268-2990

Processing may be delayed if information submitted is illegible or incomplete. If your fax includes the standardized fax form, only the **Member Name, DOB, ID, and Clinical Criteria** need to be completed and faxed as an attachment to process your request.

ENROLLEE INFORMATION

Enrollee's Last Name: _____

Enrollee's First Name: _____

Date of Birth: _____

Enrollee's Medicaid ID (2 letters, 5 numbers, 1 letter): _____

PRESCRIBER INFORMATION

Prescriber's Last Name: _____

Prescriber's First Name: _____

National Provider Identifier (NPI) Number: _____

Board Certified Specialty: _____

Prescriber's Phone Number: _____

Prescriber's Fax Number: _____

DRUG INFORMATION

Drug Name: _____ Drug Strength: _____

Quantity¹: _____ Refills²: _____

Directions: _____

New Prescription: Yes No If **NO**, date therapy was initiated: _____Expected length of therapy³: _____

¹ Prescriptions for tedizolid (Sivextro[®]) are limited to a 6-day supply. Continuation of therapy will require a new prescription and PA number.

² Refills for linezolid (Zyvox[®]) are only allowed for diagnoses of extensively drug-resistant TB (XDR-TB) or treatment intolerant/non-responsive multidrug-resistant TB (MDR-TB).

³ Diagnosis and length of therapy will be reviewed by a Clinical Pharmacist and/or Medical Director. Please submit progress notes for documentation of diagnosis with treatment plan.

Enrollee's Last Name:

Enrollee's First Name:

CLINICAL CRITERIA

1. What is the diagnosis³ documented in the patient's chart that requires treatment with an oxazolidinone antibiotic?

Diagnosis: _____

Date of last evaluation for this diagnosis³: _____

2. If the diagnosis is extensively drug-resistant TB (XDR-TB) or treatment -intolerant/non-responsive multidrug-resistant TB (MDR-TB), is linezolid being used in combination with pretomanid and bedaquiline?

Yes No

If **NO**, please provide clinical rationale for not using the three drug regimen for this diagnosis:

3. Were cultures and sensitivities performed confirming the diagnosis?

Yes No

If **NO**, please provide the clinical rationale for prescribing this oxazolidinone antibiotic without performing culture and sensitivities?

4. Has treatment with this oxazolidinone antibiotic already been established?

Yes No

5. Were other antibiotics used to treat this diagnosis?

Yes No

MEDICATION HISTORY

6. What is the patient's medication history for at least the last three months?

| Medication Trial/ Previous Therapies | Therapy Start Date | Therapy End Date | Strength | Frequency | Reason for Discontinuation |
|---|-----------------------|---------------------|----------|-----------|----------------------------|
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According to Sivextro[®] prescribing information, in an animal model of infection, the antibacterial activity of Sivextro[®] was reduced in the absence of granulocytes. Alternative therapies should be considered when treating patients with neutropenia (neutrophil counts < 1,000 cells/mm³) and acute bacterial skin and skin structure infection.

Enrollee's Last Name:

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7. For tedizolid (Sivextro®), is the patient neutropenic?

Yes No Neutrophil count: _____ cells/mm³

If **YES**, please provide the rationale for using tedizolid (Sivextro®) in a neutropenic patient?

8. Has the total duration of oxazolidinone therapy, including treatment in an inpatient setting, exceeded 14 days with linezolid (Zyvox®) or 6 days with tedizolid (Sivextro®)?

Yes No

If **YES**, please provide the rationale for exceeding 14 days of treatment with linezolid or 6 days with tedizolid:

9. For renewal requests, have you confirmed that the patient does not have myelosuppression?

Yes No Please provide the date of laboratory testing: _____

According to Zyvox® prescribing information, myelosuppression (including anemia, leukopenia, pancytopenia, and thrombocytopenia) has been reported in patients receiving Zyvox®. Complete Blood Counts (CBCs) should be monitored weekly, particularly in patients receiving Zyvox® for longer than two weeks.

According to Sivextro® prescribing information, in Phase 3 trials, clinically significant changes in myelosuppression parameters were generally similar for both tedizolid and linezolid treatment arms, and Phase 1 studies in healthy adults exposed to tedizolid (Sivextro®) showed a possible dose and duration effect on hematologic parameters beyond 6 days of treatment.

Please be aware that the US Food and Drug Administration (FDA) has received reports of serious central nervous system (CNS) reactions when Zyvox® is given to patients taking serotonergic psychiatric medications. Some cases have been fatal. According to Zyvox® prescribing information under Serotonin Syndrome, "patients taking serotonergic antidepressants should receive Zyvox® only if no other therapies are available." In addition to complete FDA approved prescribing information, for more information and a list of the serotonergic psychiatric medications that can interact with Zyvox®, please also visit <http://www.fda.gov/Drugs/DrugSafety/ucm265305.htm>.

Also note that although both Zyvox® and Sivextro® are reversible monoamine oxidase inhibitors (MAOI), comparable information for Sivextro is limited as subjects taking MAOIs or serotonergic psychiatric medications were excluded from trials.

Prescriber Signature (Required)

Date

I attest that this oxazolidinone antibiotic is medically necessary for this patient and that all the information on this form is accurate to the best of my knowledge. I attest that documentation of the above diagnosis and medical necessity is available for review if requested by New York Medicaid.

Fax Number: 1-800-268-2990

Prior Authorization Call Line: 1-877-309-9493

Billing Questions: 1-800-343-9000

For clinical questions or Clinical Drug Program Review questions, please visit <http://newyork.fhsc.com> or call 1-877-309-9493.