**Note**: 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:**

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**Date of Birth: Enrollee’s Medicaid ID (2 letters, 5 numbers, 1 letter):**

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# PRESCRIBER INFORMATION

**Prescriber’s Last Name: Prescriber’s First Name:**

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**Contact Person:**

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**National Provider Identifier (NPI) Number:**

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**Office Phone Number: Office Fax Number:**

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**Enrollee’s Last Name: Enrollee’s First Name:**

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# Drug Information

**Drug being requested:**

linezolid (Zyvox®)  tedizolid (Sivextro®)

**Strength:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Directions:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Quantity[[1]](#footnote-1):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Refills[[2]](#footnote-2):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**New prescription:**  Yes  No

If **No**, please provide the date that therapy was initiated:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Expected length of therapy****[[3]](#footnote-3):** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Enrollee’s Last Name: Enrollee’s First Name:**

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# CLINICAL CRITERIA

1. What is the diagnosis2 documented in the patient’s chart that requires treatment with an oxazolidinone antibiotic?

Diagnosis: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date of last evaluation for this diagnosis2: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. 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

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1. 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?

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

Yes  No

1. Were other antibiotics used to treat this diagnosis?

Yes  No

*(Form continued on next page.)*

**Enrollee’s Last Name: Enrollee’s First Name:**

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# Medication History

1. What is the patient’s medication history for at least the last three months?

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| --- | --- | --- | --- | --- | --- |
| **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.**

1. 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?

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1. 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:

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

Yes  No

Please provide the date of laboratory testing: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*(Form continued on next page.)*

**Enrollee’s Last Name: Enrollee’s First Name:**

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# Medication History (*continued*)

**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)  *I attest that this oxazolidinone antibiotic is medically necessary for this patient and that all of 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.* |  | Date |

**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.

1. Prescriptions for tedizolid (Sivextro®) are limited to a 6-day supply. Continuation of therapy will require a new prescription and PA number. [↑](#footnote-ref-1)
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) [↑](#footnote-ref-2)
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. [↑](#footnote-ref-3)