

Arkansas Medicaid Medication Prescription Drug Program

Selzentry® (maraviroc) Statement of Medical Necessity

After completion of this form, **fax** to Empower Healthcare Solutions.

Fax this form to 1-866-546-0484

For questions call 1-844-865-7829.

If the following information is not complete, correct, or legible, the prior authorization (PA) process can be delayed. Please use one form per beneficiary. Information contained in this form is Protected Health Information under HIPAA.

BENEFICIARY INFORMATION

Beneficiary Last Name: _____

Beneficiary First Name: _____

Medicaid ID Number: _____ Date of Birth: _____

PRESCRIBER INFORMATION

Prescriber Last Name: _____

Prescriber First Name: _____

Prescriber NPI: _____ DEA Number: _____

Prescriber Phone: _____ Prescriber Fax: _____

DRUG INFORMATION

Drug Name: **Selzentry**

Drug Strength: 150 mg 300 mg

SELZENTRY is indicated in combination with other antiretroviral agents for the treatment of only CCR5-tropic human immunodeficiency virus type 1 (HIV-1) infection in adult and pediatric patients weighing at least 2 kg. **Limitations of Use:** SELZENTRY is not recommended in patients with dual/mixed- or CXCR4-tropic HIV-1.

Note: Medicaid Preapproval for Trofile® Assay testing requires meeting requirements in Part 1; prior approval for the drug maraviroc requires meeting requirements in Part 1 and Part 3.

PART 1: INITIAL APPROVAL CRITERIA

Use of maraviroc for treatment-experienced or treatment-naïve patient (Please check all that apply; all must be true for patient to be eligible):

1. Under the care of an experienced HIV practitioner; **and**
2. Evidence of virologic failure (documented by viral load > 1,000 copies/mL not related to non-adherence to prescribed ARV); **and**
3. Unable to construct a multi-drug regimen from preferred^o, alternative*, or acceptable[^] regimens as defined by the Department of Health and Human Services Guidelines for Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents² that includes at least two additional active antiretroviral drug in addition to maraviroc.

^oPreferred Regimens (Regimens with optimal and durable efficacy, favorable tolerability and toxicity profile, and ease of use.)

^{*}Alternative Regimens (Regimens that are effective and tolerable but have potential disadvantages compared with preferred regimens. An alternative regimen may be the preferred regimen for some patients.)

Beneficiary's Name: _____

PART 1: INITIAL APPROVAL CRITERIA (CONTINUED)

^**Acceptable Regimens (CI)** (Regimens that may be selected for some patients but are less satisfactory than preferred or alternative regimens.)

PART 2: MEDICAID APPROVAL REQUIREMENTS FOR TROFILE® ASSAY TEST

This section to be completed by AR Medicaid only.

Does the Patient meet criteria stated in Part 1 above?

Yes No

If patient meets Part 1 criteria, Medicaid Utilization Review will be notified that patient meets Medicaid criteria for proceeding with Trofile® Assay Test.

- A highly sensitive tropism assay at baseline is required prior to initiation of maraviroc; the results of the tropism assay may take approximately 3 weeks and **a prescription for maraviroc should not be written until the results indicate only CCR5 tropism.**
- Prior approval from Medicaid is required for a repeat tropism assay. A repeat tropism assay should only be performed if the provider is considering a change of treatment due to increasing VL and/or decreasing CD4 count. If CXCR4 or DM virus is detected during therapy, the PA for maraviroc will be discontinued. In failing patients who have CCR5 virus, a maraviroc resistance assay may also be necessary.

PART 3: APPROVAL OR DENIAL FOR SELZENTRY® (MARAVIROC)

1. Does the patient have confirmed infection with only CCR5 tropic virus as determined by Trofile® Assay Test result screening prior to maraviroc initiation? (Copy of lab test results required as part of the manual review process.)

Yes No

2. The prior approval is NDC and dose specific. AR Medicaid will allow up to a maximum of 1200 mg/day in the following dosing regimens.

Please indicate intended dose*:

- 150 mg tablet, 1 tablet twice daily
- 300 mg tablet, 1 tablet twice daily
- 300 mg tablet, 2 tablets twice daily

*Caution and/or dosing adjustments may be warranted in patients with renal or hepatic impairment. Please refer to prescribing information in manufacturer's package insert for dosing and contraindications.

Attachments

Prescriber Signature: _____ **Date:** _____

Prescriber's original signature required; copied, stamped, or e-signature are not allowed.

By signature, the prescriber confirms the above information is accurate and verifiable by patient records.

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