Arkansas Medicaid Prescription Drug Program

Selzentry® (maraviroc) Statement of Medical Necessity

After completing the information below please fax to Empower Healthcare Solutions. Fax: 1-866-546-0484 For questions call: 1-844-865-7829.

If the following information is not complete, correct, or legible, the PA process can be delayed. Use one form per beneficiary please.

Beneficiary Information

LAST NAME: | **FIRST NAME:**

MEDICAID ID NUMBER: | **DATE OF BIRTH:** – –

Prescriber Information

LAST NAME: | **FIRST NAME:**

NPI NUMBER: | **DEA NUMBER:**

PHONE NUMBER: – – | **FAX NUMBER:** – –

Selzentry® (maraviroc) FDA APPROVED INDICATION FOR USE[1]:

"Maraviroc, in combination with other antiretroviral agents, is indicated for treatment of adults infected with only CCR5-tropic HIV-1."

- "In treatment-naïve subjects, more subjects treated with maraviroc experienced virologic failure compared to efavirenz.
- Tropism testing with a highly sensitive tropism assay is required for the appropriate use of maraviroc."

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°, 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 Adolescents[2] that includes at least two additional active antiretroviral drug in addition to maraviroc.

°Preferred 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.)

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

[1] Pfizer Package Insert. Highlights of Prescribing Information. Revised 5/10.

[2] Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. January 10, 2011; 1–166. Available at http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Accessed January 25, 2011; 43-44.

Part 2: Medicaid Approval Requirements for Trofile® Assay Test:

This section to be completed by AR Medicaid only. Patient meets 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 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.

_____ _____

Prescriber Signature (Required) ***Date***

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

(By signature, the Physician confirms the above information is accurate and verifiable by patient records.)