POLICY AND PROCEDURE

POLICY TITLE: **Selzentry (Maraviroc)**
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***October 2007 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Selzentry (maraviroc)

Selzentry (maraviroc) is a novel antiretroviral agent known as CCR5 co-receptor antagonist. Selzentry (maraviroc) is indicated for combination antiretroviral treatment of adults infected with only CCR-5 tropic HIV-1. In treatment-naïve patients, more subjects treated with maraviroc (Selzentry) experienced virologic failure and developed lamivudine resistance compared to efavirenz. Tropism testing with highly sensitive tropism assay is required for appropriate use of Selzentry (maraviroc) according to prescribing information.

There is a black box warning regarding hepatotoxicity with Selzentry (maraviroc) use. Selzentry (maraviroc) should be used with caution in patients with pre-existing liver dysfunction or who are co-infected with viral hepatitis B or C.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the

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criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, Selzentry (maraviroc), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

For All Diagnoses:

- Must be 16 years of age and older
- Must be prescribed by or in consultation with a physician who specializes in the treatment of HIV/AIDS
- Must submit documentation showing that the member has had a diagnostic tropism test to determine the presence of only CCR-5 tropic HIV-1 detectable virus [Maraviroc (Selzentry) is not indicated for dual/mixed or CXCR 4 trophic virus.]

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to duration of member's membership with plan
Reauthorization	N/A
Quantity Limits	
Selzentry (maraviroc)	• 150mg tablet: 60 tablets per 30 days • 300mg tablet: 120 tablets per 30 days

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Selzentry [package literature]. New York, NY: Pfizer Inc; November 2009.
2. Department of Health and Human Services: Guidelines for the Use of Antiretroviral Agents in HIV-1-Infected Adults and Adolescents. Department of Health and Human Services. Washington, DC. 2011. Available from URL: http://aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf. As accessed 2011-06-03.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/17, 02/18*

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