Clinical Edit Criteria Proposal

Drug/Drug Class:	**Selzentry® (Maraviroc) Clinical Edit**
Date:	**June 30, 2011**
Prepared for:	
Prepared by:	**MO HealthNet**

☐ **New Criteria** ☒ **Revision of Existing Criteria**

Executive Summary

Purpose:	To review and establish the appropriate approval criteria needed for coverage of Selzentry®.
Why was this Issue Selected:	Selzentry® (Maraviroc) is currently the only FDA-approved cellular chemokine receptor (CCR5) antagonist on the market. It works by selectively binding to the human chemokine receptor CCR5 present on the cell membrane and preventing the interaction of HIV-1 gp 120 and CCR5. This interaction is needed for CCR5-tropic HIV-1 to enter cells. However, if a patient has chemokine-related receptor CXCR4 or dual/mixed receptors, Maraviroc is ineffective in blocking entrance into the cell. In fact, the efficacy of Maraviroc has not been established in patients with dual/mixed CXCR4 tropic HIV-1. The Trofile™ test is used to determine if a patient's virus is suitable for a CCR5 co-receptor antagonist therapy. Pending the results of the Trofile™ test the prescribing physician will then know if Maraviroc would be an appropriate treatment choice for the patient.
Setting & Population:	Patients 16 years of age and older
Type of Criteria:	☐ **Increased risk of ADE** ☐ **Non-Preferred Agent** ☒ **Appropriate Indications** ☐ **Other:**
Data Sources:	☐ **Only administrative databases** ☒ **Databases + Prescriber-supplied**

Setting & Population

- Age range: Patients 16 years of age and older
- Gender: males and females

Approval Criteria

- Patient is HIV infected
- Patient is 16 years of age or older
- **For patients with a viral load > 1000 copies/ml (87999/22) there is positive viral *RNA* tropism for CCR5-tropic HIV and not for CCR4 or Dual/Mixed (contains both CCR5 and CCR4)**
- **For patients with a viral load < 1000 copies/ml there is positive viral *DNA* tropism for CCR5-tropic HIV and not for CCR4 or Dual/Mixed (contains both CCR5 and CCR4)**
- Patient is considered to be treatment experienced (defined as treatment with 3 different antiretroviral medications in the past 12 months).
- Patient is currently on additional antiretroviral medication besides maraviroc (defined as ≥ antiretroviral medications besides maraviroc).

Denial Criteria

- Lack of approval criteria
- Treatment naïve – more subjects treated with Selzentry experienced virologic failure and developed lamivudine resistance compared to efavirenz.

Required Documentation

Laboratory results:	☒	Progress notes:	☐
MedWatch form:	☐		☐

Disposition of Edit

- **Denial:** Edit 682 "Clinical Edit"

References

1. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2010.
2. Facts and Comparisons; 2010.
3. USPDI, Micromedex, 2010.
4. Pfizer, Inc., "Selzentry Package Insert", New York City, NY, 10017; 2010