

**Criteria for Use: Maraviroc (Selzentry)**  
**VHA Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel**

*The following recommendations are based on current medical evidence. The content of the document is dynamic and will be revised as new clinical data become available. The purpose of this document is to assist practitioners in clinical decision making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. The clinician, however, must make the ultimate judgment regarding the propriety of any course of treatment in light on individual patient situations*

Refer to the Maraviroc Monograph at [www.pbm.va.gov](http://www.pbm.va.gov) or <http://vaww.pbm.va.gov>.

**FDA APPROVED INDICATION FOR USE**

Maraviroc, in combination with other antiretroviral agents, is indicated for treatment-experienced adult patients infected with only CCR5-tropic HIV-1 detectable, who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents.

**EXCLUSION CRITERIA (If one is selected, patient is NOT eligible)**

- Baseline tropism assay indicates the presence of CXCR4 or dual/mixed tropic virus
- HIV-2

**INCLUSION CRITERIA (All must be selected for patient to be eligible)**

- Highly treatment-experienced patient (defined as at least 6 months of antiretroviral treatment and 3 class experience with at least one protease inhibitor failure)
- Evidence of virologic failure (documented by a viral load >1,000 copies/mL)
- Able to construct a multi-drug regimen that includes, preferably, at least one additional active antiretroviral drug (if available) in addition to maraviroc
- Confirmed infection with CCR5 tropic virus (as determined by tropism assay result at screening) prior to maraviroc initiation.
- Under the care of an experienced HIV practitioner

**DOSAGE AND ADMINISTRATION (Refer to PI for dosage recommendations in organ dysfunction)**

Due to drug-drug interactions, the recommended dose of maraviroc is guided by the presence of concomitantly administered medications. Maraviroc may be taken with or without food.

Concomitant Medications	Maraviroc dosage regimen
CYP3A inhibitors (with or without CYP3A inducers) including protease inhibitors (except tipranavir/ritonavir), delavirdine, ketoconazole, itraconazole, clarithromycin, telithromycin and other strong CYP3A inhibitors (e.g., nefazadone)	150mg orally twice daily
Other concomitant medications including tipranavir/ritonavir, NRTIs, nevirapine, enfuvirtide and drugs that are not strong CYP3A inhibitors or inducers	300mg orally twice daily
CYP3A inducers including (without a strong CYP3A inhibitor) including efavirenz, rifampin, carbamazepine, phenobarbital, phenytoin	600mg orally twice daily

**RECOMMENDED MONITORING**

- In addition to standard monitoring in a patient receiving ART,
- 1) Baseline and frequent monitoring of LFTs particularly in patients with pre-existing liver dysfunction or co-infected with viral hepatitis B or C.
  - 2) Baseline lipid panels should be obtained and monitored every 6 months.
  - 3) Patients with signs and symptoms of hepatitis or allergic reaction following use of maraviroc should be evaluated immediately. Hepatotoxicity has been reported with maraviroc use. Evidence of a systemic allergic reaction (e.g., pruritic rash, eosinophilia, or elevated IgE) prior to the development of hepatotoxicity may occur.

- Caution should be used in patients with increased risk of cardiovascular events.
- Caution should be used in patients with a history of postural hypotension, concomitant medication known to lower blood pressure, or when administered with CYP3A4 inhibitors.
- Patients should be monitored closely for evidence of infections.
- Potential risk for malignancy

**ISSUES FOR CONSIDERATION**

- A tropism assay at baseline is required prior to initiation of maraviroc; the results of the tropism assay will take approximately 3 weeks and a prescription for maraviroc should not be written until the results indicate CCR5 tropism.
- 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, maraviroc should generally be discontinued. In failing patients who have CCR5 virus, a maraviroc resistance assay may also be necessary.
- Metabolized by CYP3A4 and is a P-gp substrate, therefore potential for drug interactions exist