



PROTOCOL
Selzentry™ Maraviroc

Approval Criteria:

- 1) Maraviroc is a substrate of CYP3A and Pgp and hence its pharmacokinetics is likely to be modulated by inhibitors and inducers of these enzymes/transporters. Therefore, a dose adjustment may be required when Selzentry™ is co-administered with those drugs.

When given with strong CYP3A inhibitors (with or without CYP3A inducers) including PIs (except tipranavir/ritonavir), delavirdine.	150mg twice daily
With NRTIs, tipranavir/ritonavir, nevirapine, and other drugs that are not strong CYP3A inhibitors or CYP3A inducers.	300mg twice daily
With CYP3A inducers including efavirenz (without a strong CYP3A inhibitor).	600mg twice daily

- 2) **If no, deny.** Testing must be completed.

If yes, verify tropism assay report. The FDA approved Selzentry™ in combination with other antiretroviral agents for treatment experienced adult patients infected with only CCR5-tropic HIV-1 detectables who have evidence of viral replication and HIV-1 strains resistant to multiple antiretroviral agents, August 2007.

As of November 2009 the FDA approved the expanded use of Selzentry™ tablets in combination with other antiretroviral agents for the treatment naïve adult patients infected with only CCR5-tropic HIV-1.

Use of Selzentry™ is not recommended in patients with dual mixed or CXCR4-tropic HIV-1 as efficacy was not demonstrated in a phase 2 study of this patient group.

- 3) **If no, deny.** The safety and efficacy of Selzentry™ has not been established in pediatric patients.
- 4) Review claims profile or medical records for medication history and proceed to #5.
- 5) Patient must have current results for ALL three lab tests, unless patient is treatment naïve. In which case, resistance testing may not show mutations, therefore only CD4 and viral load test results are required.

**** This Prior Authorization request may be approved for up to 1 year. ****