

Policy #: 008

Original policy date: 2/08  
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Page: 1 of 3

**Title**

**Laboratory Testing for HIV Tropism**

**Description**

Acquired immunodeficiency syndrome (AIDS) is caused by the human immunodeficiency virus HIV-1. Viruses, which consist of genetic material coated with proteins, cause illness by penetrating the walls (membranes) of human cells. They penetrate the cell membranes by attaching to proteins on the cell surfaces known as receptors. Once inside the cells, the virus takes over the manufacturing apparatus of the cells and reproduces copies of itself. The copies leave the cells either by passing through the cell membranes again, or by destroying the cells and being released into the bloodstream.

HIV-1 infects a particular type of white blood cell known as the CD4+ lymphocyte. This type of white blood cell helps the body fight infections. When the CD4+ white cells become infected, they are no longer able to fight other types of infections. In addition, the HIV-infected white cells serve as a factory for producing more HIV-1 viruses, which then infect additional CD4+ cells. If untreated, patients will die from overwhelming infection.

A number of drug treatment strategies are being effectively used to slow down the progression of AIDS. Most of these drugs interfere with the ability of the HIV-1 virus to produce copies of itself within the cells. Recently, a new drug, known as maraviroc, has been found to inhibit the progression of AIDS by interfering with the HIV-1 virus' ability to penetrate into uninfected white cells after they are released from infected white cells. It does this by binding to the more common of the two receptors in the white cell walls for the HIV-1 virus, known as CCR-5. Maraviroc is only effective in patients with this type of receptor.

Maraviroc can have toxic side effects, and therefore should only be used in patients who have the CCR-5 receptor and who have failed multiple (2 or more) antiretroviral treatment regimens. Assays for HIV tropism determine what type of receptor a patient has, enabling a provider to prescribe the drug only for those who will benefit from it, and avoid its potential toxicity in patients who will not benefit from it.

**When services are covered for all Products (including Medicare HMO Blue, Medicare PPO Blue and Blue Medicare PFFS PlusRx)**

We cover **HIV tropism testing with the phenotypic assay** for selecting patients for treatment with HIV co-receptor antagonist such as maraviroc. Patients indicated for testing:<sup>1</sup>

- Have failed multiple (2 or more) antiretroviral treatment regimens, **and**
- Have evidence of viral replication.

**When services are not covered for all Products (including Medicare HMO Blue, Medicare PPO Blue and Blue Medicare PFFS PlusRx)**

We do not cover **HIV tropism testing using any other than the phenotypic assay technique<sup>1</sup>**, because it is considered investigational as it does not meet our Medical Technology Assessment Guidelines, #350.

We do not cover **HIV tropism testing in advance of multiple antiretroviral treatment failures (i.e., in advance of plans to prescribe HIV co-receptor antagonists such as maraviroc).**<sup>1</sup>

We do not cover **repeat HIV tropism testing during co-receptor antagonist treatment or after failure with co-receptor antagonists**<sup>1</sup>, because it is considered investigational as it does not meet our Medical Technology Assessment Guidelines, #350.

We do not cover **HIV tropism testing to predict disease progression (irrespective of co-receptor antagonist treatment)**<sup>1</sup>, because it is considered investigational as it does not meet our Medical Technology Assessment Guidelines, #350.

### Individual consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual's unique clinical circumstances may be considered in light of current scientific literature. For consideration of an individual patient, physicians may send relevant clinical information to:

#### For services already billed

Blue Cross Blue Shield of Massachusetts  
Provider Appeals  
PO Box 986065  
Boston, MA 02298

#### Prior to performance of service

Blue Cross Blue Shield of Massachusetts  
Case Creation/Medical Policy  
One Enterprise Drive  
Quincy, MA 02171  
Tel: 1-800-327-6716  
Fax: 1-888-641-5330

### Managed care guidelines

- Referrals are not required.
- Authorizations are not required.

### Indemnity and PPO guidelines

- Referrals are not required.
- Authorizations are not required.

### Coding information

*Procedure codes are from current CPT, HCPCS Level II, Revenue Code, and/or ICD-9-CM manuals, as recommended by the American Medical Association, Centers for Medicare and Medicaid Services and American Hospital Associations. Blue Cross Blue Shield Association national codes may be developed when appropriate.*

*The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.*

#### HIV Tropism:

- There is no specific CPT or HCPCS Level II code to report this lab testing, however, the following CPT code has been identified to utilize:
- CPT code 87999, unlisted microbiology procedure, with the narrative of "Trofile test for maraviroc" in the claim comments field section

### Other information

- For our Medical Technology Assessment Guidelines, see document # 350.

## Policy update history

Updated 3/08 after review of BCBSA new medical policy Laboratory Testing for HIV Tropism issued 12/07, to add one coverage statement and four non coverage statements related to HIV tropism testing to Medical Policy #383 HIV Testing, effective 2/08; added rationale and references under footnote 12. New policy, Lab Testing for HIV Tropism, effective 5/08. Updated 3/09 after review of BCBSA national policy issued 12/08: no change in coverage and non coverage statements specific to laboratory testing for HIV Tropism; references 9-12 were added.

## Footnotes

<sup>1</sup> Based upon BCBSA national policy 2.04.49 Laboratory Testing for HIV Tropism issued 12/07, a new BCBSA medical policy.

## References

### References for Footnote 1:

1. Katzenstein DA, Hammer SM, Hughes MD et al. The relation of virologic and immunologic markers to clinical outcomes after nucleoside therapy in HIV-infected adults with 200 to 500 CD4 cells per cubic millimeter. AIDS Clinical Trials Group Study 175 Virology Study Team. N Engl J Med 1996; 335(15):1091-8.
2. Whitcomb JM, Huang W, Fransen S et al. Development and characterization of a novel single-cycle recombinant-virus assay to determine human immunodeficiency virus type 1 coreceptor tropism. Antimicrob Agents Chemother 2007; 51(2):566-75.
3. Panel on Antiretroviral Guidelines for Adult and Adolescents. Guidelines for the use of antiretroviral agents in HIV-infected adults and adolescents. Department of Health and Human Services. October 10, 2006; 1-113. Available at <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf> . Accessed November 14, 2008.
4. Philpott SM. HIV-1 coreceptor usage, transmission, and disease progression. Curr HIV Res 2003; 1(2):217-27.
5. Moyle GJ, Wildfire A, Mandalia S et al. Epidemiology and predictive factors for chemokine receptor use in HIV-1 infection. J Infect Dis 2005; 191(6):866-72.
6. Weber J, Piontkivska H, Quinones-Mateu ME. HIV type 1 tropism and inhibitors of viral entry: clinical implications. AIDS Rev 2006; 8(2):60-77.
7. Pfizer, Inc. Selzentry™ (maraviroc) prescribing information. New York, NY; August 2007. Available online at [http://media.pfizer.com/files/products/uspi\\_maraviroc.pdf](http://media.pfizer.com/files/products/uspi_maraviroc.pdf) . Last accessed November 2008.
8. Daar ES, Kesler KL, Petropoulos CJ et al. Baseline HIV type 1 coreceptor tropism predicts disease progression. Clin Infect Dis 2007; 45(5):643-9.
9. Gulick RM, Lalezari J, Goodrich J et al. Maraviroc for previously treated patients with R5 HIV-1 infection. N Engl J Med 2008; 359(14):1429-41.
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11. Dolin R. A new class of anti-HIV therapy and new challenges. N Engl J Med 2008; 359(14):1509-11.
12. Skrabal K, Low AJ, Dong W et al. Determining human immunodeficiency virus coreceptor use in a clinical setting: degree of correlation between two phenotypic assays and a bioinformatic model. J Clin Microbiol 2007; 45(2):279-84.

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