

## The Department of Vermont Health Access Medical Policy

**Subject:** TROFILE ASSAY (a co-receptor tropism blood test)

**Last Review:** September 14, 2011

**Revision 3:**

**Revision 2:**

**Revision 1:** December 4, 2009

**Original Effective:** August 1, 2008

### Description of Service or Procedure

The “Trofile Assay” is diagnostic laboratory blood test for patients who are HIV-positive and exhibit resistance to multiple anti-retroviral agents in multiple drug classes. It is used to determine which co-receptor a person’s HIV strain uses to enter their T-cells. This knowledge assists in determining which antiretroviral medication to provide for treatment.

### Disclaimer

Coverage is limited to that outlined in Medicaid Rule that pertains to the beneficiary’s aid category. Prior Authorization (PA) is only valid if the beneficiary is eligible for the applicable item or service on the date of service.

### Medicaid Rule

[7102.2](#) Prior Authorization Determination

[7103](#) Medical Necessity

[7405](#) Covered laboratory and radiology services.

Medicaid Rules can be found at <http://humanservices.vermont.gov/on-line-rules>

### Coverage Position

A Trofile Assay lab test may be covered for beneficiaries:

- When the Trofile Assay lab test is prescribed by a licensed medical provider enrolled in the VT Medicaid program who is knowledgeable in the use of the Trofile Assay lab test and who provides medical care to the beneficiary AND
- Who meet the clinical guidelines below.



## **Coverage Guidelines**

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Coverage of the Trofile lab test is considered medically necessary if **all** of the following criteria are met:

- The beneficiary is 16 years old or older, **AND**
- Is HIV-infected with HIV-1 strains that are resistant to multiple antiretroviral agents, and
- Has evidence of viral replication, **AND**
- Is being considered for treatment with a chemokine co-receptor antagonist (such as Maraviroc, Selzentry), **AND**
- The Trofile test is being prescribed by a participating Medicaid provider with expertise in the treatment and management of HIV-1, **AND**
- The Trofile test is (to be) performed by a qualified laboratory enrolled with VT Medicaid.

According to the Manufacturer:

1. Tropism testing and the patient's treatment history shall guide the use of Selzentry (Maraviroc).
2. Use of Selzentry (Maraviroc) is not recommended in patients with dual/mixed- or CXCR4-tropic HIV-1. Studies have not demonstrated efficacy.
3. The safety and efficacy of Selzentry (Maraviroc) has not been established in pediatric patients.

### **Contraindications/Precautions**

- The Trofile Assay takes about 2 weeks to perform and requires a plasma viral load equal to or greater than 1,000 copies/mL.
- Processing must be conducted within certified laboratories.
- Interpretation of the test results must be performed by an expert in the treatment and management of HIV-infected patients.

### **Clinical guidelines for repeat service or procedure**

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No coverage for repeat testing. This test is limited to once per lifetime.

### **Type of service or procedure covered**

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This is a diagnostic laboratory blood test for select patients who are HIV-positive.

### **Type of service or procedure not covered (this list may not be all inclusive)**

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Coverage is not available when the DVHA criteria are not met and/or when authorization is not obtained in advance of ordering or performing the procedure and when the beneficiary is under 16 years of age.

### **Coding/Billing Information current as of: 8/01/08**

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Until a specific procedure code is assigned, VT Medicaid accepts the use of unlisted laboratory procedure code 87999. Prior authorization from the DVHA Clinical Operations Unit is required in advance of ordering or performing the Trofile Assay lab test.

**Modifiers** - None

**Additional Information** - Only one billed unit of service is valid. One unit equals the complete laboratory testing necessary to determine which co-receptor(s) a person's HIV strain uses to enter the T-cells.

## References

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Hayes, Inc. Hayes Medical Technology Outlook. *Updated Guidelines for HIV Treatment*. Lansdale, PA: Hays, Inc.; August 2008.

Hayes, Inc. Hayes Medical Technology Outlook. *Selzentry<sup>TM</sup> (maraviroc) for the treatment of human immunodeficiency virus (HIV) infection*. Lansdale, PA: Hays, Inc.; December 2007.

Office of AIDS Research Advisory Council. (2009). *Guidelines for the use of antiviral agents in HIV-1-Infected Adults and adolescents* (DHHS Publication). Retrieved April 29, 2011, from: [www.aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf](http://www.aidsinfo.nih.gov/contentfiles/AdultandAdolescentGL.pdf)

U.S. Food and Drug Administration. (2009). Expanded indication for Selzentry (maraviroc). U.S. Department of Health and Human Services. Retrieved April 29, 2011, from: <http://www.fda.gov/ForConsumers/ByAudience/ForPatientAdvocates/HIVandAIDSActivities/ucm191962.htm>

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