

The Department of Vermont Health Access Medical Policy

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

Last Review: October 3, 2016*

Revision 4: September 9, 2015

Revision 3: December 11, 2013

Revision 2: September 14, 2011

Revision 1: December 4, 2009

Original Effective: August 1, 2008

***Please note: Most current content changes will be highlighted in yellow.**

Description of Service or Procedure

The “Trofile Assay” is diagnostic laboratory blood test performed to determine the (tropism) pathway the virus uses to enter a certain type of cell. The trofile test identifies HIV-positive members who would most likely benefit from treatment with Maraviroc. The Food and Drug Administration (FDA) requires a tropism test before consideration or initiation of treatment with Maraviroc

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 Vermont Medicaid program, operating within their scope of practice in accordance with Vermont



State Practice Act, who is knowledgeable in the use of the Trofile Assay lab test and who provides medical care to the members AND

- When the clinical guidelines below are met.

Coverage Criteria

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

- The member is 18 years old or older, who is HIV-infected with HIV-1 strains that are resistant to multiple antiretroviral agents, **AND**
- The member must have a viral load greater than 1,000 copies/ml 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 Vermont 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 (less than 18) patients.

When should this procedure be performed:

- For maximum accuracy, the viral load should be drawn within 2-4 weeks of the Trofile assay draw.
- Prior to initiating a combination antiretroviral drug regime with a coreceptor antagonist (CCR5 inhibitor, that is maraviroc); or
- In an individual who has experienced virologic failure while receiving therapy that contains a CCR5 inhibitor.

Clinical guidelines for repeat service or procedure

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

Type of service or procedure covered

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)

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 18 years of age.

Not recommended for:

- HIV tropism testing without immediate plans to prescribe HIV co-receptor antagonists such as Maraviroc.

- Repeat HIV tropism testing during co-receptor antagonist treatment or after failure with co-receptor antagonists
- HIV tropism testing to predict disease progression (irrespective of co-receptor antagonist treatment)

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

Until a specific procedure code is assigned, Vermont 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. *Trofile HIV Tropism Assay. Annual Review: September 2, 2015*. Landsdale, PA: Hayes, Inc.; Retrieved on July 18, 2016.

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