

The Department of Vermont Health Access Clinical Criteria

Subject: Trofile® Assay Genetic Testing (a co-receptor tropism blood test)

Last Review: July 26, 2023*

Past Revisions: April 5, 2022, August 7, 2020, November 1, 2017, September 9, 2015, December 11, 2013, September 14, 2011, December 4, 2009, and August 1, 2008

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

Description of Service or Procedure

The Trofile® Assay is a diagnostic laboratory blood test that determines the cell type that the human immunodeficiency virus (HIV) targets in an individual. The Trofile® assay is used to determine if the HIV has the capability to infect CD4 cells that have the CCR5 or CXCR4 marker. Trofile® is a viral RNA assay that is valuable in identifying potential CCR5 or CXCR4 antagonists' candidates.

Disclaimer

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

Medicaid Rule

Medicaid and Health Care Administrative Rules can be found at <https://humanservices.vermont.gov/rules-policies/health-care-rules/health-care-administrative-rules-hcar/adopted-rules>

7102.2	Prior Authorization Determination
7405	Laboratory and Radiology Services
4.101	Medical Necessity for Covered Services
4.104	Medicaid Non-Covered Services
4.106	Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services

Coverage Position

A Trofile® Assay lab test may be covered for members:

- When the test is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice as described on the Vermont Office of



Professional Regulation's website*, Statute, or rule who is knowledgeable regarding the Trofile® Assay lab test and who provides medical care to the member AND

- When the clinical criteria below are met.

* Vermont's Office of Professional Regulation's website: <https://sos.vermont.gov/opr/>

Coverage Criteria

The Trofile® Assay lab test may be covered for members who meet all the following criteria:

- The member is 18 years old or older and 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 CCR5 antagonist such as Maraviroc, **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.

Considerations: Providers requesting this test should provide pre- and post-test genetic counseling for the member and family, if applicable.

Early and Periodic Screening, Diagnostic and Treatment (EPSDT): Vermont Medicaid will provide comprehensive services and furnish all Medicaid coverable, appropriate, and medically necessary services needed to correct and ameliorate health conditions for Medicaid members under age 21.

Please note, Vermont Medicaid Clinical Criteria is reviewed based on available literature, evidence-based guidelines/standards, Medicaid rule and policy, and Medicare coverage determinations that may be appropriate to incorporate when applicable.

Clinical criteria for repeat service or procedure

There is 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. Request for testing for individuals under the age of 18 will be reviewed under EPSDT guidelines on a case-by-case basis.

Testing is 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 guidelines

Please see the Medicaid Portal at <http://vtmedicaid.com/#!/feeSchedule> for fee schedules, code coverage, and applicable requirements.

References

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