

The Office of Vermont Health Access Medical Policy

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

Last Review: 2008

Revision 3:

Revision 2:

Revision 1:

Original Effective: 08/01/08

Technical Revision: 09/08/09

Description of Service or Procedure

The “Trofile Assay” is diagnostic laboratory blood test for patients who are HIV-positive. 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 is only valid if the beneficiary is eligible for the applicable item or service on the date of service.

Medicaid Rule

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

Coverage Position

Coverage of the Trofile lab test is subject to the terms, conditions and limitations of the beneficiary’s Medicaid benefits.

Coverage of the Trofile lab test is considered *medically necessary* per the medical need criteria set forth in the OVHA Clinical Guidelines.

Clinical Guidelines

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, and
- Has evidence of viral replication, and
- Is resistant to or intolerant of multiple (2 or more) anti-viral agents or those agents are contra-indicated, 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.

Medicare Coverage

Medicare covers the Trofile Assay lab test.

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.

When Service or Procedure Is Covered

The Trofile lab test is covered when medically necessary per the medical need criteria set forth in the OVHA Clinical Guidelines.

When Service or Procedure Is Not Covered

Coverage is not available when the OVHA 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: 08/01/08

Until a specific procedure code is assigned, VT Medicaid accepts the use of unlisted laboratory procedure code 87999. Prior authorization from the OVHA 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.

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.

References

- www.aidsinfo.nih.gov/ContentFiles (The National Institutes of Health)
- VT AMAP Guidelines for authorization of Maraviroc
- Monogram Virology, "Trofile"
- www.hivandhepatitis.com
- <http://files.medi-cal.gov>
- Blue Cross and Blue Shield Association

- www.hayesinc.com/subscribers
- Cigna HealthCare Coverage Position # 0012
- Pfizer Inc
- Blue Cross Blue Shield of Massachusetts
- Aetna Clinical Policy Bulletin # 0316
- Jeff Salzman, Corporate Account Manager, Northeast, Monogram Biosciences, Inc.

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The Medicaid Rule only lists coverage availability, it does not guarantee individual determinations of medical necessity. Please check with the appropriate department to determine if the service/item in question is a covered service/item under a particular benefit plan. Use of Medicaid rule is not intended to replace independent medical judgment for treatment of individuals.

This document has been classified as public information.

