

The Department of Vermont Health Access Clinical Criteria

Subject: Cardiology (heart transplant) Gene Expression Profiling Test (AlloMap®)

Last Review: July 26, 2023*

Past Revisions: April 5, 2022; February 18, 2020; June 15, 2017; and December 29, 2015

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

Description of Service or Procedure

AlloMap® is a molecular expression test to detect acute heart transplant rejection or the development of graft problems. It can be used to rule out the presence of acute cellular rejection (ACR) in appropriate low-risk members, between 6 months and 5 years after heart transplant. It may also help with the reduction of the number of endomyocardial biopsies (EMB) required during the post-transplant period. **The test works by measuring expression of a group of genes which are involved in transplant rejection.** Based upon measured expression of these genes, an algorithm is used to generate a score of 0–40 to predict the likelihood of rejection of the transplanted heart. A lower score indicates a lower risk of graft rejection. **Test threshold cutoff selection and follow-up protocols are selected by individual transplant centers utilizing guidance from observational randomized studies. Example of threshold and follow-up protocol is seen below:**

AlloMap® test results:

Low risk threshold scores:

- Month 2-6: 30
- Month 6-12: 34
- Month 12+: 34

Follow-up:

Score < threshold: No biopsy

Score ≥ threshold: Biopsy within 5 days of result (>34)

Score ≥ threshold, after 3 prior scores ≥ 34

1. Resume biopsies
2. Defer and screen with echo and clinical assessment, but only after discussion with primary cardiologist.



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

Cardiology (heart transplant) gene expression profiling test (AlloMap®) 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 cardiology (heart transplant) gene expression profiling testing (AlloMap®), 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

Cardiology (heart transplant) gene expression profiling testing (AlloMap®) may be covered for members who:

- Are age 15 years or older
- Are not pregnant
- Are between 6 months and 5 years post-heart transplant.
- Do not show signs or symptoms of cardiac allograft dysfunction including:
 - Absence of signs or symptoms of congestive heart failure
 - Left ventricular ejection fraction (LVEF) $\geq 45\%$ by echocardiography
 - Absence of severe cardiac allograft vasculopathy (CAV)
- Have a low probability of moderate or severe acute cellular rejection as demonstrated by BOTH of the following:
 - International Society for Heart and Lung Transplantation rejection status Grade 0R or 1R on all previous endomyocardial biopsies
 - No history or evidence of antibody mediated rejection
- Have no history of elevated genetic expression profile that prompted subsequent endomyocardial biopsy to clarify rejection status

Note: the result of AlloMap® testing will be used to determine the need for subsequent endomyocardial biopsy to clarify rejection status.

International Society for Heart and Lung Transplantation (ISHLT) ACR grading is as follows:

- Grade 0R- No rejection
- Grade 1R- Mild rejection. Interstitial and/or perivascular infiltrate with up to 1 focus of myocyte damage
- Grade 2R- Moderate rejection. Two or more foci of infiltrate with associated myocyte damage
- Grade 3R- Severe rejection. Diffuse infiltrate with multifocal myocyte damage, with or without edema, hemorrhage, or vasculitis.

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

The use of this test is limited to:

- monthly 6-months post-transplant, then
- every 2-3 months until one year, and then
- once per year up to 5 years post-transplant.

Continuation of AlloMap® testing is not warranted when both of the following are applicable:

- Three AlloMap® scores > 34
- No signs of rejection on any follow-up endomyocardial biopsies.

The use of > 1 “routine” surveillance method is not considered medically necessary. Once AlloMap candidacy is established, it is expected that endomyocardial biopsies will only be performed as a confirmatory procedure for threshold scores >34 or when a clinical rationale can be substantiated.

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

Heartsbreath Test for heart transplant rejection is not a covered service. It is considered investigational.

Cardiology (heart transplant) gene expression profiling (AlloMap) is not medically necessary in heart transplant recipients who:

- are acutely symptomatic, OR
- have recurrent rejection, OR
- are less than six months post-transplant or greater than five years post-transplant, OR
- have received high-dose intravenous corticosteroids (CSs) or myeloablative therapy in the past 21 days, OR

- have received blood products or hematopoietic growth factors in the past 30 days OR
- are pregnant, OR
- are <15 years old; OR
- are post rejection therapy; OR
- have had a transfusion within the past 30 days; OR
- have received ≥ 20 mg of daily oral prednisone doses; OR
- are receiving dialysis (hemodialysis or peritoneal dialysis).

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