**The Department of Vermont Health Access Clinical Criteria**

**Subject:** Cardiology (heart transplant), Gene Expression Testing (AlloMap)

**Last Review:** February 18, 2020

**Past Revisions:** June 15, 2017; 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 beneficiaries, 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. An algorithm generating a 0–40 score range is applied to the results to predict the likelihood of rejection. A lower score indicates a lower risk of graft rejection.

**AlloMap Test Results:**

Low risk threshold score
- **Month 2-6:** 30  Score < threshold: No biopsy
- **Month 6-12:** 34  Score ≥ threshold: Biopsy within 5 days of result (>34)
- **Month 12+:** 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 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**


Medicaid Rules
- 7102.2  Prior Authorization Determination
- 7103  Medical Necessity
Coverage Position

Cardiology (heart transplant), Gene Expression Testing (AlloMap) may be covered for beneficiaries:

- When the test is prescribed by a licensed medical provider, enrolled in the Vermont Medicaid program, operating within their scope of practice as described in their Vermont State Practice Act, who is knowledgeable regarding Cardiology (heart transplant), Gene Expression Testing (AlloMap) and who provides medical care to the beneficiary AND
- When the clinical criteria below are met.

Coverage Criteria

Cardiology (heart transplant), Gene Expression Testing (AlloMap) may be covered for beneficiaries who:

- Are age 15 years or older
- Are not pregnant
- Are between 6 months and 5 years from the time of the heart transplant.
- Do not show signs or symptoms of cardiac allograft dysfunction
  o absence of signs or symptoms of congestive heart failure
  o left ventricular ejection fraction (LVEF) ≥40%
- Have a low probability of moderate or severe acute cellular rejection as demonstrated by BOTH of the following:
  o International Society for Heart and Lung Transplantation rejection status Grade 0R or 1R on all previous endomyocardial biopsies
  o No history or evidence of antibody medicated rejection
- Have no history of elevated genetic expression profile that prompted subsequent endomyocardial biopsy to clarify rejection status

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

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 ± edema, ± hemorrhage ± Vasculitis

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

Early and Periodic Screening, Diagnostic and Treatment (EPSDT) exception: 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.

Clinical criteria for repeat service or procedure

The use of this test is limited to:

- monthly from 3-6 months, 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. (E.g., 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 Testing (AlloMap) is not medically necessary in heart transplant recipients:

- who are acutely symptomatic; OR
- with recurrent rejection; OR
- who are < six months post-transplant; OR
- who have had myeloablative therapy in the past 21 days; OR
- who have received blood products or hematopoietic growth factors in the past 30 days; OR
- who are pregnant; OR
- who are <15 years old; OR
- following rejection therapy; OR
- following transfusion within the past 30 days; OR
- receiving ≥ 20 mg of daily oral prednisone doses or received high-dose intravenous (IV) corticosteroids (CSs); OR
- receiving dialysis (hemodialysis or peritoneal dialysis).

**References**


*This document has been classified as public information.*