

## The Department of Vermont Health Access Medical Policy

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

**Last Review:** December 29, 2015

**Revision 3:**

**Revision 2:**

**Revision 1:**

**Original Effective:** December 29, 2015

### Description of Service or Procedure

The definition of the code is: Cardiology (heart transplant), mRNA, gene expression profiling by real-time quantitative PCR of 20 genes (11 content and 9 housekeeping), utilizing subfraction of peripheral blood, algorithm reported as a rejection risk score is the description of the code.

AlloMap is a blood test designed to evaluate changes in the expression of 11 genes. The test aids in the identification of heart transplant recipients who have a low probability of moderate/severe cellular risk of rejection at the time of testing.

An algorithm generating a 0–40 score range is applied to the results to predict the likelihood of rejection. The predictive value of the score varies by post-heart transplant time intervals.

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 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**

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### **7102.2** Prior Authorization Determination

### **7103** Medical Necessity

Medicaid Rules can be found at <http://humanservices.vermont.gov/on-line-rules>

## **Coverage Position**

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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 in accordance with Vermont State Practice Act, who is knowledgeable in the use of Cardiology (heart transplant), Gene Expression Testing (AlloMap) results and who provides medical care to the beneficiary AND
- When the clinical guidelines below are met.

## **Coverage Guidelines**

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

- Age 15 years or older
- At least two months ( $\geq 55$  days) since transplantation
- heart allograft function is stable as demonstrated by ALL of the following:
  - absence of signs or symptoms of congestive heart failure
  - current echocardiogram with left ventricular ejection fraction (LVEF)  $\geq 45\%$
  - absence of severe cardiac allograft vasculopathy
- 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 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  $\pm$  edema,  $\pm$  hemorrhage  $\pm$  vasculitis

## **Clinical guidelines for repeat service or procedure**

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The use of this test is limited to monthly from 3-6 months, every 2-3 months until one year, 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 that are:

- acutely symptomatic; OR
- those with recurrent rejection; OR
- those < 55 days post-transplant; OR
- have had myeloablative therapy in the past 21 days; OR
- received blood products or hematopoietic growth factors in the past 30 days; OR
- pregnant; OR
- <15 years old; OR
- Following rejection therapy; OR
- Following transfusion within the past 30 days; OR
- Members receiving  $\geq 20$  mg of daily oral prednisone doses or received high-dose intravenous (IV) corticosteroids (CSs); OR
- Receiving dialysis (hemodialysis or peritoneal dialysis).

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