



MEDICAL COVERAGE POLICY

SERVICE: Heart Transplant Rejection Monitoring (AlloMap®)

Policy Number:	231
Effective Date:	05/01/2018
Last Review:	02/06/2018
Next Review Date:	02/06/2019

Important note

Even though this policy may indicate that a particular service or supply may be considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Senior Care members, this policy will apply unless Medicare policies extend coverage beyond this Medical Policy & Criteria Statement. Senior Care policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website.

SERVICE: Heart Transplant Rejection Monitoring (AlloMap®)

PRIOR AUTHORIZATION: Required.

POLICY: Molecular expression testing (AlloMap®) may be medically necessary to monitor for cardiac transplant rejection when ALL of the following criteria are met:

1. Member is 15 years old or older.
2. Member is clinically stable with no clinical evidence of graft dysfunction or rejection
3. Testing is requested at least 6 months post-transplant and less than 5 years post-transplant.
4. Member is not receiving more than 20 mg per day of prednisone
5. Member has not had a transfusion less than 30 days prior to the test.
6. An endomyocardial biopsy has not been obtained at the time of, or during two weeks preceding, the AlloMap® test.

Note:The testing window is based on a Task Force report from the ISHLT (International Society of Heart and Lung Transplantation) guidelines for gene expression profiling: "Gene Expression Profiling (Allomap®) can be used to ruleout the presence of ACR of grade 2R or greater in appropriate low-risk patients, between 6 months and 5 years after HT. Level of Evidence: B." (See reference 1)

Permissible scheduling of AlloMap® beginning no earlier than 6 months post-transplant:

Time Post-Transplant	Testing Sequence	Threshold Score
10 weeks to off-prednisone for 8 weeks	Every 2 weeks	≤ 30
Off prednisone for 8 weeks until 10 months	Every month	≤ 32
Between 12 and 24 months	Every 3 months	≤ 34

OVERVIEW:

AlloMap®, in conjunction with standard clinical assessment, is intended for use in heart transplant recipients with stable allograft function to aid in the identification of those who have a low probability of moderate to severe acute cellular rejection (ACR) at the time of testing. Endomyocardial biopsy (EMB) is currently the established method for detecting cellular and antibody-mediated allograft rejection after heart transplantation. Although EMB is the reference standard for rejection surveillance, it is associated with a small, but not inconsequential, complication risk of approximately 1.0%. In addition, EMB negative rejection occurs in up to 20% of patients



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Although the technology seems promising, there are currently no published studies on analytic validity, clinical validity studies, and very limited clinical utility studies to provide evidence for the AlloMap® test. Thus additional studies are needed to support the analytic validity, clinical validity, and clinical utility of this test.

MANDATES: None

SUPPORTING DATA:

CODES:

Important note:

CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	81595
CPT Not Covered:	
ICD10 codes:	Z48.21 Encounter for aftercare following heart transplant Z94.1 Heart transplant status
ICD10 Not covered:	

CMS: Currently no NCD or LCD

POLICY HISTORY:

Status	Date	Action
New	03/07/2017	New policy
Reviewed	02/06/2018	No changes

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. The international society of heart and lung transplantation guidelines for the care of heart transplant recipients. Chair: David Taylor MD; Co-Chairs: Bruno Meiser MD; Steven Webber MD. Journal of Heart and Lung Transplantation, 2010-08-01, Volume 29, Issue 8, Pages 914-956.
2. Mehra MR, Kobashigawa JA, Deng MC, et al.; CARGO Investigators. Clinical implications and longitudinal alteration of peripheral blood transcriptional signals indicative of future cardiac allograft rejection. J Heart Lung Transplant. 2008;27(3):297-301.
3. Pham MX, Teuteberg JJ, Kfoury AG, et al.; IMAGE Study Group. Gene-expression profiling for rejection surveillance after cardiac transplantation. N Engl J Med. 2010;362(20):1890-1900.
4. Yamani MH, Taylor DO, Haire C, Smedira N, Starling RC. Post-transplant ischemic injury is associated with up-regulated AlloMap gene expression. Clin Transplant. 2007a;21(4):523-525.