PreferredOne®

Department of Origin: Integrated Healthcare Services	**Effective Date:** 03/05/24
Approved by: Medical Policy Quality Management Subcommittee	**Date Approved:** 03/05/24
Clinical Policy Document: Laboratory Testing for Detection of Heart Transplant Rejection	**Replaces Effective Clinical Policy Dated:** 03/07/23
Reference #: MC/L014	**Page:** 1 of 4

PURPOSE:
The intent of this clinical policy document is to ensure services are medically necessary.

Please refer to the member's benefit document for specific information. To the extent there is any inconsistency between this policy and the terms of the member's benefit plan or certificate of coverage, the terms of the member's benefit plan document will govern.

POLICY:
Benefits must be available for health care services. Health care services must be ordered by a provider. Health care services must be medically necessary, applicable conservative treatments must have been tried, and the most cost effective alternative must be requested for coverage consideration.

GUIDELINES:
Medical Necessity Criteria - Requesting AlloMap® or AlloSure® molecular testing for heart allografts - Must satisfy the following: I - II

I. Test is ordered by a transplantation center; and

II. Member is more than two months post heart-transplantation.

EXCLUSIONS (not limited to):
Refer to member's Certificate of Coverage or Summary Plan Description

The following is considered investigative (see Investigative List)

- MyTAIHEART® for detection of heart transplant rejection

BACKGROUND:
AlloMap® is intended to aid in the identification of heart transplant recipients with stable allograft function who have a low probability of moderate to severe acute cellular rejection at the time of testing in conjunction with standard clinical assessment. It is a panel test of 20 gene assays, 11 informative and 9 used for normalization and/or quality control, which produces gene expression data used on the calculation of a test score – an integer ranging from 0-40.

Compared with patients in the same post-transplant period, the lower the score, the lower the probability of acute cellular rejection at the time of testing. The test is performed at XDx Reference Laboratory.

The premise for AlloSure® is that rejection entails injury, including increased cell death in the allograft, leading to increased donor-derived cell-free DNA (dd-cfDNA) released into the bloodstream. The AlloSure® test for dd-cfDNA detected in the blood of transplant recipients has been developed as a noninvasive marker for diagnosis of graft rejection. The AlloSure® assay is a targeted next-generation sequencing assay that uses 266 single-nucleotide polymorphisms (SNPs) to accurately quantify dd-cfDNA in transplant recipients without separate genotyping of donor or recipient. The assay quantifies the fraction of dd-cfDNA in both unrelated and related donor-recipient pairs and can be completed within 3

days of peripheral blood collection, a practical turnaround time for management of transplant recipients. AlloSure® assay results are reported as the percentage of dd-cfDNA in total cfDNA.

Prior Authorization: Yes, per network provider agreement

CODING:
CPT® or HCPCS
81595 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 rejection risk score

REFERENCES:
1. Integrated Healthcare Services Process Manual: UR015 Use of Medical Policy and Criteria
2. Clinical Policy: Coverage Determination Guidelines MP/C009
3. Clinical Policy: Laboratory Tests MP/L001
4. Eisen HJ. Heart transplantation in adults: Diagnosis of allograft rejection (Topic 3519, Version 21.0; ~~20.0;~~ last updated: 01-10-23). In: Hunt SA, ed. *UpToDate*. Waltham, Mass.: UpToDate; 2020. www.uptodate.com. Accessed 12-12-23.
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Provides free aids and services to people with disabilities to communicate effectively with us, such as:

- Qualified sign language interpreters
- Written information in other formats (large print, audio, accessible electronic formats, other formats)

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

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If you believe that PCHP has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:

Grievance Specialist
PreferredOne Community Health Plan
PO Box 59052
Minneapolis, MN 55459-0052
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, a Grievance Specialist is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

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ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

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U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
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