Department of Origin: Integrated Healthcare Services	**Effective Date:** 06/07/22
Approved by: Medical Policy Quality Management Subcommittee	**Date Approved:** 06/07/22
Clinical Policy Document: Laboratory Testing for Detection of Heart Transplant Rejection	**Replaces Effective Clinical Policy Dated:** 03/08/22
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 ~~expression~~ 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 (PLA 0055U)

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.15 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.15 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.7 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.

MyTAIHEART® is a noninvasive lab test that examines cell-free DNA in patient blood intended to aid identification of "…heart transplant recipients who have a low probability of moderate/severe acute cellular rejection (Grade 2R or higher) at the time of testing in conjunction with standard clinical assessment." Currently, there is insufficient published evidence supporting its effectiveness compared to other established lab tests for heart transplant rejection and the current studies' limited sample sizes. This test is considered investigative and is therefore not covered by the Plan.

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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

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2. Clinical Policy: MP/C009 Coverage Determination Guidelines
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Nondiscrimination & Language Access Policy

Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. *We* do not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

We will:

- Provide 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)
- Provide free language services to people whose primary language is not English, such as:
    - Qualified interpreters
    - Information written in other languages

If *you* need these services, contact *us* at the phone number shown on the inside cover of this *COC*, *your* id card, or aspirushealthplan.com.

If *you* believe that *we* have 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:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1062
Minneapolis, MN 55440
Phone: 1. 866.631.5404 (TTY: 1.866.631.8597)
Fax: 763.847.4010
Email: customerservice@aspirushealthplan.com

You can file a grievance in person or by mail, fax, or email. If *you* need help filing a grievance, the Nondiscrimination Grievance Coordinator 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.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1.866.631.5404 (TTY: 1.866.631.8597).

تنبيه :إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية 1.866.631.5404(رقم هاتف الصم والبك : 1.866.631.8597) متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف **Arabic**

French: ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.866.631.5404 (ATS : 1.866.631.8597).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1.866.631.5404 (TTY: 1.866.631.8597).

Hindi: _यान द_: य_द आप ि◌हंदी बोलते ह_ तो आपके ि◌लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_।1-800-332-650 (TTY: 1.866.631.8597) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.866.631.5404 (TTY: 1.866.631.8597).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1.866.631.5404 (TTY: 1.866.631.8597)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 1.866.631.5404 (TTY: 1.866.631.8597).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1.866.631.5404 (телетайп: 1.866.631.8597).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.866.631.5404 (TTY: 1.866.631.8597).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1.866.631.5404 (TTY: 1.866.631.8597).

Traditional Chinese: 注意：如果您使用繁體中文， 您可以免費獲得語言援助服務。請 致電 1.866.631.5404 (TTY：1.866.631.8597)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.866.631.5404 (TTY: 1.866.631.8597).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1.866.631.5404 (TTY: 1.866.631.8597).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.866.631.5404 (TTY: 1.866.631.8597).