

## Transplant Rejection Testing, Medical 99

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[Effective Date](#) 10/2007  
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[Coverage Policy](#) Medical 99  
[Version](#) 8

**Member-specific benefits take precedence over medical policy and benefits may vary across plans. Refer to the individual's benefit plan for details <sup>\*</sup>.**

### Purpose:

This policy addresses the medical necessity of laboratory testing for transplant rejection.

### Description & Definitions:

AlloMap Molecular Expression Test detects the absence of rejection in a transplanted heart.

AlloSure Heart test detects the probability of rejection in heart transplant recipients.

AlloSure is a targeted, next generation sequencing (NGS) assay measuring single-nucleotide polymorphisms (SNPs) to quantify donor-derived cell-free DNA (dd-cfDNA) without separating genotype of either the recipient or donor. This assay utilizes fractioning to quantify dd-cfDNA in both unrelated and related donor-recipient pairs.

Renal Transplant Rejection testing uses donor-derived cell-free DNA to evaluate renal allograft injury or rejection.

### Criteria:

Transplant Rejection Testing is considered medically necessary for **1 or more** of the following:

- AlloMap Molecular Expression Testing is considered medically necessary with **All** of the following:
  - Individual is at least 55 days post heart transplant
  - Individual needs monitoring for rejection in heart transplant

Transplant Rejection Testing is considered **not medically necessary** for uses other than those listed in the clinical criteria , to include but not limited to:

- AlloSure CareDX for lung transplant
- AlloSure® Donor-Derived Cell-Free DNA Test Renal Transplant Rejection Testing
- AlloSure Heart Testing
- Heartsbreath Testing
- Heart Molecular Microscope Diagnostic System (MMDx-Heart)
- Molecular Microscope® Diagnostic System for Kidney (MMDx® Kidney)
- myTAIHEART
- Prospera™ Renal Transplant Rejection Testing

- QSant (NephroSant)
- TruGraf
- Viracor

## Coding:

### Medically necessary with criteria:

Coding	Description
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 a rejection risk score
81599	Unlisted multianalyte assay with algorithmic analysis

### Considered Not Medically Necessary:

Coding	Description
0055U	Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma
0087U	Cardiology (heart transplant), mRNA gene expression profiling by microarray of 1283 genes, transplant biopsy tissue, allograft rejection and injury algorithm reported as a probability score
0088U	Transplantation medicine (kidney allograft rejection), microarray gene expression profiling of 1494 genes, utilizing transplant biopsy tissue, algorithm reported as a probability score for rejection
0118U	Transplantation medicine, quantification of donor-derived cell-free DNA using whole genome next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA
81479	Unlisted molecular pathology procedure

U.S. Food and Drug Administration (FDA) - approved only products only.

## Document History:

### Revised Dates:

- 2024: January
- 2023: March
- 2022: April
- 2021: August
- 2020: January
- 2016: March, April
- 2015: April

### Reviewed Dates:

- 2024: March
- 2021: April
- 2020: May
- 2018: October
- 2017: December
- 2015: March, November
- 2014: April
- 2013: April
- 2012: January
- 2011: July
- 2010: July
- 2009: July
- 2008: July

Effective Date:

- October 2007

## References:

Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

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## Special Notes: \*

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or

medical care. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving, and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

Services mean both medical and behavioral health (mental health) services and supplies unless We specifically tell You otherwise. We do not cover any services that are not listed in the Covered Services section unless required to be covered under state or federal laws and regulations. We do not cover any services that are not Medically Necessary. We sometimes give examples of specific services that are not covered but that does not mean that other similar services are covered. Some services are covered only if We authorize them. When We say You or Your We mean You and any of Your family members covered under the Plan. Call Member Services if You have questions.

### Keywords:

SHP AlloMap Molecular Expression Testing and AlloSure Testing, SHP Medical 99, Transplant Testing for Organ Rejection, cardiac allograft rejection, immune system, cardiac transplant, heart transplant, AlloMap gene expression profile (GEP), AlloSure CareDX, Renal, MoIDX: Prospera, MoIDX: AlloSure