Transplant Rejection Testing, Medical 99

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Effective Date	10/2007
Next Review Date	3/2025
Coverage Policy	Medical 99
Version	8

All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*.

Purpose:

This policy addresses the medical necessity of organ transplant rejection testing.

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
81479	Unlisted molecular pathology procedure
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

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

Document History:

Revised Dates:

- 2024: January
- 2023: April
- 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:

Including but not limited to: 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: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

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.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan. Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*

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, MolDX: Prospera, MolDX: AlloSure