05-86000-24

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Reviewed: 01/23/25

Revised: 04/01/25

Subject: Laboratory Tests Post Transplant and for Heart Failure

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CEbRTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

DESCRIPTION:

Clinical assessment and noninvasive imaging of chronic heart failure can be limited in accurately diagnosing patients with heart failure because symptoms and signs can poorly correlate with objective methods of assessing cardiac dysfunction. For management of heart failure, clinical signs and symptoms (eg, shortness of breath) are relatively crude markers of decompensation and occur late in the course of an exacerbation. A number of objective disease biomarkers have been investigated to diagnose and assess heart failure patient prognosis, manage patients diagnosed with chronic heart failure and to guide therapy.

In transplant recipients, despite the progress in immunosuppressant therapy, risk of rejection remains. Diagnosis of allograft rejection continues to rely on clinical monitoring and histologic confirmation by tissue biopsy. However, due to limitations of tissue biopsy, including a high degree of interobserver variability in the grading of results and its potential complications, less invasive alternatives have been investigated. Several laboratory-tested biomarkers of transplant rejection have been evaluated and are commercially available for use.

Summary and Analysis of Evidence: The evidence for patients with a heart transplant who receive dd-cfDNA testing to determine acute rejection includes diagnostic accuracy studies. The evidence for patients with a renal transplant who receive dd-cfDNA testing for surveillance or suspicion of rejection includes diagnostic accuracy studies. The American Society of Transplant Surgeons Statement on Donor-derived Cell-free DNA (dd-cf-DNA) (2023) states: “The accumulated evidence supporting the use of dd-cfDNA argues that its use should no longer be considered investigational. The use of dd-cfDNA is evidence-based and validated, and a prime example of much needed innovation in transplant organ surveillance. Statement recommendations regarding clinical utility include: “We recommend that

clinicians measure dd-cfDNA levels in kidney transplant recipients with acute allograft dysfunction to exclude the presence of rejection, particularly antibody-mediated rejection; "We recommend that dd-cfDNA may be utilized to rule out subclinical rejection in heart transplant recipients". The International Society for Heart and Lung Transplantation (ISHLT) Guidelines for the Care of Heart Transplant Recipients (2022) recommendations include: "Gene Expression Profiling (i.e. Allomap) of peripheral blood can be used in low-risk patients between 2 months and 5 years after heart transplant"; and monitoring for rejection may include "surveillance endomyocardial biopsy and noninvasive rejection monitoring" (i.e. Allomap, donor-derived cell free DNA). The evidence is sufficient to support the use of donor-derived cell free DNA testing for heart and kidney transplant recipients. For dd-cfDNA testing to assess lung allograft rejection, the evidence includes diagnostic studies. The studies were limited by small sample sizes, and no clinical utility studies were identified. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. Patients who receive the sST2 assay for chronic heart failure or to determine prognosis or predict acute cellular rejection after heart transplant, the evidence includes correlational and retrospective studies on Presage ST2 assay. Several studies found the sST2 test results did not provide additional prognostic information and no comparative studies were identified on the use of the sST2 assay to guide the management of patients diagnosed with chronic heart failure. No prospective studies were identified that provide evidence on the ability of sST2 to predict transplant outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome. The evidence for the measurement of volatile organic compounds to assess cardiac allograft rejection includes a diagnostic accuracy study. This single study is not sufficient to determine the clinical validity of the test measuring volatile organic compounds and no studies on clinical utility were identified. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

POSITION STATEMENT:

AlloMap® molecular expression testing **meets the definition of medical necessity** as a non-invasive method of determining the risk of rejection in heart transplant recipients (15 years or older) who are between 2 months and 5 years post-transplant.

AlloMap molecular expression testing is considered **experimental or investigational** for all other indications. The evidence is insufficient to determine the effects of the technology on health outcomes.

For members post **single-kidney transplant**, the use of donor-derived cell-free DNA testing to assess the probability of allograft rejection **meets the definition of medical necessity** when **all** of the following are met:

- The member is 18 years of age or older; **and**
- At least 14 days post-transplant; **and**
- Testing frequency is once per month for members 1-6 months post-transplant: **or**
- Testing every 3 months for members who are greater than 6 months post-transplant.

The use of donor-derived cell-free DNA tests for all other indications post **kidney** transplant is considered **experimental or investigational**. The evidence is insufficient to determine the effects of the technology on health outcomes.

For members post **heart** transplant, the use of donor-derived cell-free DNA testing to assess the probability of allograft rejection **meets the definition of medical necessity** when all of the following are met:

- The member is 18 years of age or older; **and**
- At least 29 days post transplant; **and**
- Testing frequency is once per month for members 1- 12 months post transplant; **or**
- Testing every 3 months for members who are greater than 12 months post-transplant.

The use of donor-derived cell-free DNA tests for all other indications post **heart** transplant is considered **experimental or investigational**. The evidence is insufficient to determine the effects of the technology on health outcomes.

The use of donor-derived cell-free DNA tests for members post **lung** transplant is considered **experimental or investigational** for all indications. The evidence is insufficient to determine the effects of the technology on health outcomes.

The use of all other molecular expression and biomarker blood tests in the management of members after transplantation is considered **experimental or investigational**. The evidence is insufficient to determine the effects of the technology on health outcomes.

The measurement of volatile organic compounds (e.g. Heartsbreath® test) to assist in the detection of moderate grade 2R (formerly grade 3) heart transplant rejection is considered **experimental or investigational**. The evidence is insufficient to determine the effects of the technology on health outcomes.

The use of the Presage® ST2 assay is considered **experimental or investigational** for all indications including, but not limited to:

- predicting prognosis and predicting acute cellular rejection in the post cardiac transplantation period
- evaluating the prognosis of members diagnosed with chronic heart failure
- guiding management (eg, pharmacologic, device-based, exercise) of members diagnosed with chronic heart failure.

The evidence is insufficient to determine the effects of the technology on health outcomes.

The use of the myTAIHEART® assay in the post cardiac transplantation period, including but not limited to predicting prognosis and predicting acute cellular rejection, is considered **experimental or investigational**. The evidence is insufficient to determine the effects of the technology on health outcomes.

BILLING/CODING INFORMATION:

CPT Coding:

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 [AlloMap]
83006	Growth stimulation expressed gene 2 (ST2, Interleukin 1 receptor like-1) (**Investigational**)
0018M	Transplantation medicine (allograft rejection, renal), measurement of donor and third-party-induced CD154+T-cytotoxic memory cells, utilizing whole peripheral blood, algorithm reported as a rejection risk score (**Investigational**) [Pleximark™]
0055U	Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma (**Investigational**) [myTAIHEART]
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 (**Investigational**) [Molecular Microscope® MMDx-Heart]
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 (**Investigational**) [Molecular Microscope® MMDx-Kidney]
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 [Viracor TRAC™ dd-cfDNA]
0221U	Red cell antigen (ABO blood group) genotyping (ABO), gene analysis, next-generation sequencing, ABO (ABO, alpha 1-3-N-acetylgalactosaminyltransferase and alpha 1-3-galactosyltransferase) gene (**Investigational**)
0319U	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using pretransplant peripheral blood, algorithm reported as a risk score for early acute rejection (**Investigational**) [Clarava]
0320U	Nephrology (renal transplant), RNA expression by select transcriptome sequencing, using posttransplant peripheral blood, algorithm reported as a risk score for acute cellular rejection **(Investigational)** [Tuteva]
0493U	Transplantation medicine, quantification of donor-derived cell-free DNA (cfDNA) using nextgeneration sequencing, plasma, reported as percentage of donor derived cell-free DNA [Prospera]
0540U	Transplantation medicine, quantification of donor derived cell-free DNA using next-generation sequencing analysis of plasma, reported as percentage of donor derived cell-free DNA to determine probability of rejection [AlloSure]

ICD-10 Diagnosis Codes That Support Medical Necessity for AlloMap (81595):

T86.20 – T86.298	Complications of heart transplant
Z48.21	Encounter for aftercare following heart transplant
Z94.1	Heart transplant status

ICD-10 Diagnosis Codes That Support Medical Necessity for donor-derived cell-free DNA test post kidney and post heart transplant:

T86.10 – T86.19	Complications of kidney transplant
T86.20 – T86.298	Complications of heart transplant
Z48.21	Encounter for aftercare following heart transplant
Z48.22	Encounter for aftercare following kidney transplant
Z94.0	Kidney transplant status
Z94.1	Heart transplant status

REIMBURSEMENT INFORMATION:

Refer to section entitled **POSITION STATEMENT**.

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage Products:

The following National Coverage Determination (NCD) was reviewed on the last guideline reviewed date: Heartsbreath Test for Heart Transplant Rejection (260.10) located at cms.gov.

The following were reviewed on the last guideline reviewed date and are located at palmettogba.com:

- Local Coverage Article: Billing and Coding: MolDX: Molecular Testing for Solid Organ Allograft Rejection (A58019)
- Local Coverage Determination (LCD):MolDX: Molecular Testing for Solid Organ Allograft Rejection (L38568).

If this Medical Coverage Guideline contains a step therapy requirement, in compliance with Florida law 627.42393, members or providers may request a step therapy protocol exemption to this requirement if based on medical necessity. The process for requesting a protocol exemption can be found at Coverage Protocol Exemption Request.

DEFINITIONS:

None.

RELATED GUIDELINES:

None.

OTHER:

None.

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COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 01/23/25.

GUIDELINE UPDATE INFORMATION:

03/15/04	New Medical Coverage Guideline.
03/15/06	Annual review; continue investigational status.
03/15/07	Scheduled review; no change in coverage statement; references.
06/15/07	Reformatted guideline.
11/15/07	Revision: title changed, description section updated, position statement updated, Medicare Advantage section updated, references updated.
02/15/08	Annual review: position statements maintained; description section updated; references updated.
02/15/09	Annual review: position statements maintained; description section and references updated.
12/15/09	Annual review: position statements maintained; description section and references updated.
09/15/12	Review; position statements maintained; program exceptions section and references updated.
06/15/13	Annual review; position statements maintained and references updated.
06/15/14	Annual review; position statements maintained, program exception and reference updated.
06/15/15	Annual review; position statements maintained and references updated.
01/01/16	Annual HCPCS/CPT update; code 81595 added.
07/15/16	Annual review; revise the position statement section, coding, program exception, and references.
12/15/17	Annual review; investigational position maintained; description, position statements, and references updated.
12/15/18	Annual review; Investigational position maintained; investigational statement for AlloSure test added; title, description, coding, and references updated.
07/01/19	Quarterly CPT/HCPCS update. Added codes 0087U & 0088U.
01/15/20	Review; position statements, coding, description, and references updated.
12/15/20	Review; position statements and references updated.
01/01/21	Annual CPT/HCPCS update. Code 0085T deleted.
01/15/21	Program Exception section updated.
07/15/21	Review; Position statements and references updated.
10/01/21	Quarterly CPT/HCPCS update. Code 0018M added.
04/01/22	Quarterly CPT/HCPCS update. Code 0320U added.
05/15/22	Review: Position statements and references updated.

12/15/23	Review: Position statements, coding, and references updated.
02/15/24	Review: Position statements, coding, and references updated.
05/15/24	Revision: Description section updated.
10/01/24	Quarterly CPT/HCPCS update. Code 0493U added.
02/15/25	Review: Position statements maintained and references updated.
04/01/25	Quarterly CPT/HCPCS coding update. Code 0540U added.