

05-86000-24

Original Effective Date: 03/15/05

Reviewed: 01/25/24

Revised: 10/01/24

Subject: Laboratory Tests Post Transplant and for Heart Failure

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, 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.

[Position Statement](#)

[Billing/Coding](#)

[Reimbursement](#)

[Program Exceptions](#)

[Definitions](#)

[Related Guidelines](#)

[Other](#)

[References](#)

[Updates](#)

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 4 diagnostic studies. All 4 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]

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: MoIDX: Molecular Testing for Solid Organ Allograft Rejection (A58019)
- Local Coverage Determination (LCD): MoIDX: Molecular Testing for Solid Organ Allograft Rejection (L38568).

DEFINITIONS:

None.

RELATED GUIDELINES:

None.

OTHER:

Donor-derived cell-free DNA Tests:

Note: The use of specific test names is illustrative only. It is not intended to be a recommendation of one test over another and is not intended to represent a complete listing of all tests available.

AlloSure®

Prospera™

Viracor TRAC™

REFERENCES:

1. Agbor-Enoh S, Shah P, et al. Cell-Free DNA to Detect Heart Allograft Acute Rejection. *Circulation*. 2021 Mar 23;143(12):1184-1197. PMID:33435695.
2. Agbor-Enoh S, Wang Y, et al. Donor-derived cell-free DNA predicts allograft failure and mortality after lung transplantation. *EBioMedicine*. 2019 Feb;40:541-553.
3. American Society of Transplant Surgeons (ASTS). ASTS Statement on donor-derived cell-free DNA (dd-cf-DNA), March 2023; accessed at [asts.org](https://www.astsonline.org).
4. Anglicheau D, Malone A, et al. Kidney transplantation in adults: Investigational methods in the diagnosis of acute kidney allograft rejection. In: UpToDate, Brennan DC, Legendre C, Lam AO (Eds), UpToDate, Waltham, MA; accessed at [uptodate.com](https://www.uptodate.com).
5. Bloom RD, Bromberg JS, et al. Cell-Free DNA and Active Rejection in Kidney Allografts. *J Am Soc Nephrol*. 2017 Jul;28(7):2221-2232.
6. Blue Cross Blue Shield Association Evidence Positioning System®. 2.01.68 Laboratory Tests Post Transplant and for Heart Failure, 11/23.
7. Blue Cross Blue Shield Association Technology Evaluation Center (TEC). Gene expression profiling as a noninvasive method to monitor for cardiac allograft rejection. TEC Assessments 2011; volume 26, tab 8.
8. BuL, Gupta G, et al. Clinical outcomes from the Assessing Donor-derived cell-free DNA Monitoring Insights of kidney Allografts with Longitudinal surveillance (ADMIRAL) study. *Kidney Int*. 2022 Apr;101(4):793-803. doi: 10.1016/j.kint.2021.11.034.
9. Bu L, Gupta G, et al. Validation and clinical outcome in assessing donor-derived cell-free DNA monitoring insights of kidney allografts with longitudinal surveillance (ADMIRAL) study. *Kidney Int*. 2021 Dec 22;S0085-2538(21)01168-6.
10. CareDx Inc. AlloSure® Heart, Advanced Non-Invasive DNA Testing for Heart Transplant Injury and Rejection Dossier, December 2020.
11. CareDx Inc. AlloSure® Kidney, Donor-Derived cell-free DNA Testing for Transplant Kidney Injury and Rejection Dossier; V3.0 January 2022.
12. CareDx Inc. AlloSure® Kidney Executive Summary 2022.
13. Centers for Medicare & Medicaid Services (CMS), National Coverage Determination (NCD) for Heartsbreath Test for Heart Transplant Rejection (260.10); accessed at [cms.org](https://www.cms.gov).
14. Costanzo MR, Dipchand A, Starling R et al. The International Society of Heart and Lung Transplantation Guidelines for the care of heart transplant recipients. *J Heart Lung Transplant* 2010; 29(8):914-56 accessed at [ishlt.org](https://www.isHLT.org).
15. Crespo-Leiro MG, Stypmann J, Schulz U, et al. Clinical usefulness of gene-expression profile to rule out acute rejection after heart transplantation: CARGO II. *Eur Heart J*. Jan 7 2016.
16. Dengu F. Next-generation sequencing methods to detect donor-derived cell-free DNA after transplantation. *Transplant Rev (Orlando)*. 2020 Jul;34(3):100542. PMID:32265093.
17. Deng MC, Eisen HJ, Mehra MR, et al., Noninvasive Discrimination of Rejection in Cardiac Allograft Recipients Using Gene Expression Profiling, *American Journal of Transplantation*, Vol 6, Issue 1, page 150-160, January 2006.
18. Deng MC, Elashoff B, Pham MX et al. Utility of Gene Expression Profiling Score Variability to Predict Clinical Events in Heart Transplant Recipients. *Transplantation* 2014 Mar 27; 97(6): 708–714.
19. Eisen HJ. Heart transplantation in adults: Diagnosis of acute allograft rejection. In: UpToDate, Hunt SA, Dardas TF (Eds), UpToDate, Waltham, MA; accessed at [uptodate.com](https://www.uptodate.com).

20. Fang, K, Clinical Utilities of Peripheral blood Gene Expression Profiling in the Management of Cardiac Transplant Patients, *Journal of Immunotoxicology*, Vol 4, July 2007, pages 209-217.
21. Fujita B, Proashovikj F, et al. Predictive value of gene expression profiling for long-term survival after heart transplantation. *Transpl Immunol*. 2017 Mar;41:27-31. Doi: 10.1016/j.trim.2017.02.001. Epub 2017 Feb 4. PMID: 28167272.
22. Gondi KT, Kao A, et al. Single-center utilization of donor-derived cell-free DNA testing in the management of heart transplant patients. *ClinTransplant*. 2021 May;35(5):e14258.
23. Halloran PF, Reeve J, et al. Combining Donor-derived Cell-free DNA Fraction and Quantity to Detect Kidney Transplant Rejection Using Molecular Diagnoses and Histology as Confirmation. *Transplantation*. 2022 Dec 1;106(12):2435-2442.
24. Henricksen E, Moayedi Y, et al. Combining donor derived cell free DNA and gene expression profiling for non-invasive surveillance after heart transplantation. *Clin Transplant*. 2023 Mar;37(3):e14699. doi: 10.1111/ctr.14699.
25. JA T. Gene Expression Profiling for the Diagnosis of Heart Transplant Rejection. *California Technology Assessment Forum*. 2010, accessed at ctaf.org 07/18/12.
26. Jordan SC, Bunnapradist S, et al. Donor-derived Cell-free DNA Identifies Antibody-mediated Rejection in Donor Specific Antibody Positive Kidney Transplant Recipients. *Transplant Direct*. 2018 Aug 20;4(9):e379.
27. Keller M, Mutebi C, et al. Biological Variation of Donor-Derived Cell-Free DNA in Stable Lung Transplant Recipients. *J Appl Lab Med*. 2022 Jun 30;7(4):901-909. doi: 10.1093/jalm/jfab171. PMID: 35024828.
28. Keller M, Sun J, et al. Donor-derived cell-free DNA as a composite marker of acute lung allograft dysfunction in clinical care. *J Heart Lung Transplant*. 2022 Apr;41(4):458-466. doi: 10.1016/j.healun.2021.12.009. Epub 2021 Dec 26. PMID: 35063338.
29. Khush KK, De Vlaminc I, et al. Donor-derived, cell-free DNA levels by next-generation targeted sequencing are elevated in allograft rejection after lung transplantation. *ERJ Open Res*. Jan 2021; 7(1). PMID: 33532456.
30. Kim PJ, Olymbios M, et al. A novel donor-derived cell-free DNA assay for the detection of acute rejection in heart transplantation. *J Heart Lung Transplant*. 2022 Jul;41(7):919-927.
31. Levine DJ, Ross, DJ, et al. Single Center "Snapshot" Experience With Donor-Derived Cell-Free DNA After Lung Transplantation. *BiomarkInsights*. 2020 Sep 16;15:1177271920958704.
32. Loupy A, Woodward RN, et al. Distinct Patterns of Gene Expression Identified Longitudinally and within AlloMap Score Ranges are Associated with Clinical Outcomes. *Journal of Heart and Lung Transplantation*, Vol. 38, Issue 4, Supplement, April 2019 Page S51.
33. Mayer KA, Doberer K, et al. Diagnostic value of donor-derived cell-free DNA to predict antibody mediated rejection in donor-specific antibody-positive renal allograft recipients. *Transpl Int*. Sep 2021; 34(9): 1689-1702. PMID: 34448270.
34. Mehra MR, Uber PA, Genomic Biomarkers and Heart Transplantation, *Heart Fail Clin*. 2007 Jan; 3(1): 83-6.
35. Moayedi Y, Fouroutan F, et al. Risk evaluation using gene expression screening to monitor for acute cellular rejection in heart transplant recipients. *J Heart Lung Transplant*. 2019 Jan;38(1):51-58. Doi: 10.1016/j.healun.2018.09.004. Epub 2018 Sep 12. PMID: 30352779.
36. Nah EH, Cho S, et al. Reference interval and the role of soluble suppression of tumorigenicity 2 (sST2) in subclinical cardiac dysfunction at health checkups. *J Clin Lab Anal*. 2020 Jul 7;e23461. PMID: 32638437.

37. Nikolaidis LA, Borzognia B, Bove AA, Limitations of Molecular Expression Profiling (Allomap Score) in Predicting Endomyocardial biopsy Findings in Cardiac Allograft Recipients: Two Year Follow-Up Surveillance Study, *Circulation*. October 2007; 116:II_505.
38. North PE, Ziegler E, et al. Cell-free DNA donor fraction analysis in pediatric and adult heart transplant patients by multiplexed allele-specific quantitative PCR: Validation of a rapid and highly sensitive clinical test for stratification of rejection probability. *PLoS One*. 2020 Jan 13;15(1):e0227385.
39. Pai A, Swan JT, et al. Clinical Rationale for a Routine Testing Schedule Using Donor-Derived Cell-Free DNA After Kidney Transplantation. *Ann Transplant*. Jul 02 2021; 26: e932249. PMID: 34210952.
40. Palmetto GBA, Local Coverage Article: Billing and Coding: MoIDX: Molecular Testing for Solid Organ Allograft Rejection (A58019); accessed at palmettogba.com.
41. Palmetto GBA, Local Coverage Determination (LCD):MoIDX: Molecular Testing for Solid Organ Allograft Rejection (L38568); accessed at palmettogba.com.
42. Pham MX, Deng MC, Kfoury AG, et al, Molecular Testing for Long-Term Rejection surveillance in Heart Transplant Recipients: Design of the Invasive Monitoring Attenuation Through Gene Expression (IMAGE) trial, *J Heart Lung Transplant*. 2007 Aug; 26(8): 808-14.
43. Plawecki M, Morena M, et al. sST2 as a New Biomarker of Chronic Kidney Disease-Induced Cardiac Remodeling: Impact on Risk Prediction. *Mediators Inflamm*. 2018 Oct 8;2018:3952526. PMID:30402040.
44. Puliyananda DP, Swinford R, et al. Donor-derived cell-free DNA (dd-cfDNA) for detection of allograft rejection in pediatric kidney transplants. *Pediatr Transplant*. Mar 2021; 25(2): e13850. PMID: 33217125.
45. Richmond ME, Zangwill SD, et al. Donor fraction cell-free DNA and rejection in adult and pediatric heart transplantation. *J Heart Lung Transplant*.2020 May;39(5):454-463.PMID:31983667.
46. Rodgers N, Gerding B, et al. Comparison of two donor-derived cell-free DNA tests and a blood gene-expression profile test in heart transplantation. *Clin Transplant*. 2023 Apr 10;e14984. doi: 10.1111/ctr.14984.
47. Sawinski DL, Mehta S, et al. Association between dd-cfDNA levels, de novo donor specific antibodies, and eGFR decline: An analysis of the DART cohort. *Clin Transplant*. Sep 2021; 35(9): e14402. PMID: 34184326.
48. Sayah D, Weigt SS, et al. Plasma Donor-derived Cell-free DNA Levels Are Increased During Acute Cellular Rejection After Lung Transplant: Pilot Data. *Transplant Direct*. 2020 Sep 24;6(10):e608. doi: 10.1097/TXD.0000000000001063.
49. Seeto RK, Fleming JN, et al. Understanding and using AlloSure donor derived cell-free DNA. *Biophys Rev*. 2020 Aug;12(4):917-924.
50. Sigdel TK, Archila FA, et al. Optimizing Detection of Kidney Transplant Injury by Assessment of Donor-Derived Cell-Free DNA via Massively Multiplex PCR. *J Clin Med*. 2018 Dec 23;8(1):19.
51. Stewart S, Winters GL, Fishbein MC, et al. Revision of the 1990 working formulation for the standardization of nomenclature in the diagnosis of heart rejection. *J Heart Lung Transplant*. Nov 2005;24(11):1710-1720; accessed at ishlt.org.
52. Stites E, Kumar D, et al. High levels of dd-cfDNA identify patients with TCMR 1A and borderline allograft rejection at elevated risk of graft injury. *Am J Transplant*. 2020 Sep;20(9):2491-2498.PMID:32056331.
53. TAI Diagnostics- myTAI_{HEART} Test Dossier, February 2020.
54. Trindade AJ, Chapin KC, et al. Assessment of dd-cfDNA Levels in Clinically Stable Lung Allograft Recipients Beyond the Initial 2 y Posttransplant. *Transplant Direct*. 2022 Nov 17;8(12):e1411. doi: 10.1097/TXD.0000000000001411.

55. U.S. Food and Drug Administration (FDA), accessed at fda.gov.
56. Velleca A, Shullo MA, et al. The International Society for Heart and Lung Transplantation (ISHLT) guidelines for the care of heart transplant recipients. J Heart Lung Transplant. 2023 May;42(5):e1-e141. doi: 10.1016/j.healun.2022.10.015. Epub 2022 Dec 20.
57. Yamani MH, Taylor DO, Rodriguez ER, et al, Transplant Vasculopathy is Associated with Increased AlloMap Gene Expression Score, J Heart Lung Transplant. 2007 Apr; 26(4):403-6.
58. Yancy CW, Jessup M, et al. 2017 ACC/AHA/HFSA Focused Update of the 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology/American Heart Association Task Force on Clinical Practice Guidelines and the Heart Failure Society of America. Aug 2017; 23(8):628-651.
59. Zangwill SD, Kindel SJ, et al. Early changes in cell-free DNA levels in newly transplanted heart transplant patients. PediatrTransplant. 2020 Feb;24(1):e13622.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy and Coverage Committee on 01/25/24.

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.