Easy Choice Health Plan

Missouri Care

'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona

OneCare (Care1st Health Plan Arizona, Inc.)

Staywell of Florida

WellCare (Arizona, Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)

WellCare Prescription Insurance

WellCare Texan Plus (Medicare – Dallas & Houston markets)

Heart Transplant Rejection Tests (Heartsbreath and Allomap™ Molecular Expression Test

Policy Number: HS-060

Original Effective Date: 11/20/2008

Revised Date(s): 11/24/2009; 11/12/2010; 10/6/2011; 11/1/2012; 11/7/2013; 11/6/2014; 11/5/2015; 11/3/2016; 9/7/2017; 9/6/2018

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on www.wellcare.com. Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

BACKGROUND

Heart transplantation is a widely accepted therapy for the treatment of end-stage cardiac disease. Approximately 20,000 people in the United States and more than 30,000 people throughout the world live with a transplanted heart. Even with modern drug therapy, cardiac allograft rejection (i.e., rejection of a transplanted heart) remains a constant hazard for heart transplantation patients. Allograft rejection is most frequent within the first month following cardiac transplantation and declines progressively thereafter. Patient survival depends on accurate and timely monitoring for allograft rejection and graft dysfunction. Transplant recipients must be tested repeatedly for signs of rejection, typically with an endomyocardial biopsy. Alternative noninvasive techniques to detect and monitor allograft rejection are under investigation.

HEART TRANSPLANT REJECTION TESTS (HEARTSBREATH AND ALLOMAP™ MOLECULAR EXPRESSION TEST) HS-060

The AlloMap™ Molecular Expression Test is a noninvasive, 20-gene expression assay that measures the activity of the immune system with respect to the risk of cardiac allograft rejection. In essence, the test detects the absence of rejection in a transplanted heart. The patient's peripheral blood is drawn according to particular specifications, the sample is sent to the XDx Laboratory, and the messenger RNA (mRNA) in the sample is quantified using real-time polymerase chain reaction. Each gene is tested in triplicate. An algorithm that combines the gene expression values of genes that are linked to cardiac allograft rejection is applied to generate a clinically useful "AlloMap score." This score, which ranges from 0 to 40, indicates the immune system's response to the transplanted heart – the higher the score, the greater the risk of rejection. Additional clinical experience and independent replication of study data is necessary, if proven effective in well-designed trials, this test may allow some patients to safely reduce the number of endomyocardial biopsies required after heart transplantation. The impact of the results of this test on clinical decision making requires further evaluation.[1]

The Heartsbreath test works on the principle that rejection of the transplanted heart is accompanied by oxidative stress that degrades membrane polyunsaturated fatty acids, evolving alkanes and methylalkanes that are excreted in the breath as volatile organic compounds (VOCs). The patient breathes for two minutes through a disposable mouthpiece attached to a breath collecting device, which then analyses the VOCs in alveolar and room air and interprets the values, using a proprietary algorithm to predict the probability of Grade 3 heart transplant rejection.

Based on a review of the published peer-reviewed scientific literature, there is insufficient evidence to conclude that the breath test for detection of heart transplant rejection results in improved management of heart transplant recipients. There is insufficient evidence that use of this test will result in earlier or more efficient detection of heart transplant rejection or that this test is equal to or superior than the standard test, endomyocardial biopsy. Well-designed clinical trials are needed to further evaluate the potential utility of this test and define the role of the test in management of heart transplantation.

The diagnosis of rejection may be graded based upon the consensus classification for cardiac allograft rejection published by the International Society for Heart and Lung Transplantation (ISHLT). The grades were initially published in 1990 and have been subsequently updated. The current standard cardiac biopsy grading is:

Grade 0	No rejection
Grade 1 R, mild	Interstitial and/or perivascular infiltrate with up to 1 focus of myocyte damage
Grade 2 R, moderate	Two or more foci of infiltrate with associated myocyte damage
Grade 3 R, severe	Diffuse infiltrate with multifocal myocyte damage ± edema ± hemorrhage ± vasculitis

POSITION STATEMENT

Applicable To:

- ☑ Medicaid – All Markets
- ☑ Medicare – All Markets

The Heartsbreath Breath Test (Menssana Research, Inc) **is considered experimental and investigational and NOT a covered benefit.** The Allomap™ Molecular Expression Test (XDX, Inc) **is considered experimental and investigational and NOT a covered benefit.**

Effective for services performed on or after December 8, 2008, the Centers for Medicare & Medicaid Services has determined that the evidence does not adequately define the technical characteristics of the test nor demonstrate that Heartsbreath testing to predict heart transplant rejection improves health outcomes in Medicare beneficiaries. Thus, we conclude that the Heartsbreath test is not reasonable and necessary under section 1862(a)(1)(A) of the Social Security Act and is non-covered.[2,3]

CODING

Non-Covered CPT®* Codes

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 [when specified as AlloMap test]

Original Effective Date: 11/20/2008 - Revised: 11/24/2009, 11/12/2010, 10/6/2011, 11/1/2012, 11/7/2013, 11/6/2014, 11/5/2015, 11/3/2016, 9/7/2017, 9/6/2018

86849 Unlisted immunology procedure [when specified as AlloMap test]

Non-Covered CPT®* Category III Code
0085T Breath test for heart transplant rejection (Sunset January 2016)

Non-Covered ICD-10-CM Diagnosis Code
T86.20 - T86.298 Complications of transplanted organ, Heart
T86.30 - T86.39 Complications of transplanted organ, Heart
Z94.1 Heart transplant status
Z48.21 Encounter for aftercare following heart transplant
Z48.280 Encounter for aftercare following heart-lung transplant
Z94.3 Heart and lungs transplant status

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

REFERENCES

1. AlloMap® Molecular Expression (XDx Inc.) for detection of heart transplant rejection. Hayes Directory Web site. http://www.hayesinc.com. Published August 10, 2016 (Archived November 28, 2016). Accessed August 23, 2018.
2. National coverage determination for HeartsBreath test for heart transplant rejection (260.10). Centers for Medicare and Medicaid Services Web site. http://www.cms.hhs.gov/mcd/search.asp. Published 2009. Accessed August 8, 2017.
3. Proposed decision memo for Heartsbreath test for heart transplant rejection (CAG-00394N). Centers for Medicare and Medicaid Services Web site. http://www.cms.hhs.gov/mcd/search.asp. Published 2008. Accessed August 8, 2017.

MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
9/6/2018, 9/7/2017, 11/3/2016	• Approved by MPC. No changes.
11/5/2015	• Approved by MPC. Coding update only.
11/6/2014	• Approved by MPC. Changes to coding only.
11/7/2013	• Approved by MPC. No changes.
11/1/2012	• Approved by MPC. Added CMS NCD statement of non-coverage.
12/1/2011	• New template design approved by MPC.
10/6/2011	• Approved by MPC. Reformatted references; no major changes.

Original Effective Date: 11/20/2008 - Revised: 11/24/2009, 11/12/2010, 10/6/2011, 11/1/2012, 11/7/2013, 11/6/2014, 11/5/2015, 11/3/2016, 9/7/2017, 9/6/2018