IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured’s benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member.

The Medicare Advantage Medical Policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and the Centers of Medicare and Medicaid Services (CMS) policies, when available. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of CMS guidance for a requested service or procedure, the health plan may apply their Medical Policy Manual or MCG™ criteria, both of which are developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Medicare and EOCs exclude from coverage, among other things, services or procedures considered to be investigational, cosmetic, or not medically necessary, and in some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services.

DESCRIPTION

Noninvasive laboratory tests may be used as an alternative to biopsy in order to detect cellular rejection following heart transplantation.

MEDICARE ADVANTAGE POLICY CRITERIA

<table>
<thead>
<tr>
<th>CMS Coverage Manuals*</th>
<th>None</th>
</tr>
</thead>
</table>
| National Coverage Determinations (NCDs)* | For the **Heartsbreath test (Category III Code 0085T)**:  
- [x] Heartsbreath Test for Heart Transplant Rejection (260.10) |
| Noridian Healthcare Solutions (Noridian) Jurisdiction F (J-F) Local | N/A – see next row for testing performed in California |
### Coverage Determinations (LCDs) and Articles (LCAs)*

#### Non-Noridian J-F LCDs and LCAs*

For the **AlloMap® test (CareDx):**

**Note:** This test is performed by CareDx, Inc. (Brisbane, CA). Medicare guidelines state jurisdiction for coverage determinations for diagnostic laboratory services is by the contractor assigned jurisdiction over the service area in which the tests are performed.\[^{1,2}\] Therefore, the Medicare contractor for California (Noridian, Jurisdiction E, or J-E) is responsible for establishing coverage determinations.

- MolDX: AlloMap Billing and Coding Guidelines ([A54364](#))

For the **myTAIHEART test (0055U):**

**Note:** This test is performed by TAI Diagnostics, Inc. (Wauwatosa, WI). As previously stated, jurisdiction for coverage for diagnostic laboratory services is by the contractor assigned jurisdiction over the service area where the tests are performed.\[^{1,2}\] Therefore, the Medicare contractor for Wisconsin (National Government Services, Jurisdiction 6, or J-06) is responsible for establishing coverage determinations.

- Molecular Pathology Procedures ([L35000](#)) (*This LCD states, “Testing assay(s) are Food and Drug Administration (FDA) approved/cleared or if LDT (lab developed test) or LDT protocol or FDA modified test(s) the laboratory documentation should support assay(s) of analytical validity and clinical utility.” While this LCD states the AlloMap test may be considered medically necessary, the myTAIHEART is not noted to have established analytical validity or clinical utility in this LCD. Therefore, this test is not medically reasonable or necessary.*)

**Scroll to the “Public Version(s)” section at the bottom of the LCD or LCA for links to prior versions if necessary.

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### POLICY GUIDELINES

### REQUIRED DOCUMENTATION
The information below must be submitted for review to determine whether policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome:

- Medical records and any related clinical documentation, with the specific diagnosis, as well as documentation of how the testing will be used to guide patient treatment;
- Name of test that will be performed.

**REGULATORY STATUS**

- The Heartsbreath test is a Food and Drug Administration-approved Humanitarian Use Device thought to predict heart transplant rejection. The test involves collecting breath samples from the patient, analyzing the samples, and then comparing the results to endomyocardial biopsy findings. *(NCD 260.10)*

- AlloMap is an In Vitro Diagnostic Multivariate Index assay (IVDMIA) test which is FDA approved to aid in the identification of heart transplant recipients with stable allograft function who have a low probability of moderate/severe acute cellular rejection (ACR) at the time of testing in conjunction with standard clinical assessment. *(Noridian LCA A54366)*

- The myTAIHEART test examines the cell-free DNA (cfDNA) in a patient blood sample as a marker for transplanted organ injury. This test is intended to aid in the identification of heart transplant recipients who have a low probability of moderate/severe acute cellular rejection (Grade 2R or higher) at the time of testing in conjunction with standard clinical assessment.

**CROSS REFERENCES**

None

**REFERENCES**

1. Medicare Claims Processing Manual, Chapter 1 - General Billing Requirements, §10.1.5.4 - Independent Laboratories
2. Medicare Managed Care Manual, Chapter 4 - Benefits and Beneficiary Protections, §90.4.1 - MAC with Exclusive Jurisdiction over a Medicare Item or Service
3. MolDX: AlloMap Coding and Billing Guidelines (M00016)

**CODING**

<table>
<thead>
<tr>
<th>Codes</th>
<th>Number</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>0085T</td>
<td>Breath test for heart transplant rejection</td>
</tr>
<tr>
<td>Codes</td>
<td>Number</td>
<td>Description</td>
</tr>
<tr>
<td>-------</td>
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<tr>
<td>0055U</td>
<td>Cardiology (heart transplant), cell-free DNA, PCR assay of 96 DNA target sequences (94 single nucleotide polymorphism targets and two control targets), plasma</td>
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<tr>
<td>81479</td>
<td>Unlisted molecular pathology procedure</td>
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<tr>
<td>81595</td>
<td>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</td>
<td></td>
</tr>
<tr>
<td>86849</td>
<td>Unlisted Immunology procedure</td>
<td></td>
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</tbody>
</table>

**IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.