



## Heartsbreath Test for Heart Transplant Rejection – JA6366

**Note:** MLN Matters article MM6366 was revised to reflect a revised transmittal related to Change Request (CR) 6366. The CR release date, transmittal number, and the Web address for accessing the transmittal were changed.

Related CR Release Date: March 12, 2009 **Revised**

Date Job Aid Revised: March 23, 2009

Effective Date: December 8, 2008

Implementation Date: April 6, 2009

**Key Words** MM6366, CR6366, R1697CP, R99NCD, Heartsbreath, Transplant, Rejection, Heart, NCD

**Contractors Affected**

- Part A/B Medicare Administrative Contractors (A/B MACs)
- Medicare Carriers
- Fiscal Intermediaries (FIs)

**Provider Types Affected** Providers submitting claims to Medicare Carriers, FIs, and/or A/B MACs for Heartsbreath testing services provided to Medicare beneficiaries



CR6366 announces that the Centers for Medicare & Medicaid Services (CMS) determined that the Heartsbreath Test is not reasonable and necessary under Section 1862(a)(1)(A) of the Social Security Act, and is non-covered for dates of service on or after December 8, 2008.

### Coverage Change

**Provider Needs to Know...**

- Effective for claims with dates of service on and after December 8, 2008, the Heartsbreath Test used to predict heart transplant rejection is nationally non-covered.
- This coverage change to Current Procedural Terminology (CPT) Code 0085T, breath test for heart transplant rejection, will be effective with the April 1, 2009, quarterly update of the Medicare Physician Fee Schedule Database.
- Effective with the April 1, 2009, quarterly update of the Integrated Outpatient Code Editor, CPT code 0085T, breath test for heart transplant rejection, is no longer payable by Medicare.

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### Denial of Claims for CPT Code 0085T

- When denying claims for CPT code 0085T, Medicare contractors will use:
  - Medicare Summary Notice message 16.10: "Medicare does not pay for this item or service",
  - Claim Adjustment Reason Code 50: "These are non-covered services because this is not deemed a medical necessity by the payer";
  - Claim Adjustment Remark Code MA 51: "Missing/Incomplete/Invalid Procedure Code(s)"; and
  - N386: "This decision was based on an NCD. An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at <http://www.cms.hhs.gov/mcd/search.asp> on the CMS website."
- Providers who do not have Web access may contact their Medicare contractor to request a copy of the NCD.

### Beneficiaries Who Choose to Have the Heartsbreath Test

- Providers will issue an Advance Beneficiary Notice (ABN) indicating that Medicare issued an NCD at Section 260.10 of the *National Coverage Determinations Manual* stating that the Heartsbreath Test is not reasonable and necessary for Medicare beneficiaries.
- Beginning March 1, 2009, the ABN-G will no longer be valid and providers must issue the revised ABN (CMS-R-131.)
- Medicare contractors will include the Group Code CO (contractor obligation) or PR (provider responsibility) depending on liability.

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### Background

- Menssana Research, Inc., made a formal request for CMS to consider national coverage of the Heartsbreath Test as an adjunct to the heart biopsy to detect grade 3 heart transplant rejection in patients who have had a heart transplant within the last year and an endomyocardial biopsy in the prior month.
  - On December 8, 2008, CMS issued a decision memorandum in response to this request.
  - CMS 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.
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**Operational  
Impact**

For claims already processed with dates of service between December 8, 2008, and April 1, 2009, contractors will not search their files, but may go back and adjust claims that are brought to their attention.

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**Reference  
Materials**

The related MLN Matters article can be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM6366.pdf> on the CMS website.

The official instruction (CR6366) issued regarding this change was issued to via two transmittals:

- The first conveys the revised claims processing instructions and may be found at <http://www.cms.hhs.gov/Transmittals/downloads/R1697CP.pdf> on the CMS website; and
  - The second transmittal conveys the change to the *National Coverage Determinations Manual* and may be found at <http://www.cms.hhs.gov/Transmittals/downloads/R99NCD.pdf> on the CMS website.
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