

CMS Manual System	Department of Health & Human Services
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services
Transmittal 1697	Date: MARCH 12, 2009
	Change Request 6366

Transmittal 1683, Change Request 6366, dated February 13, 2009, has been rescinded and replaced. MCS is removed as a responsible party in business requirement 6366.4, and the A/B MAC and Carrier are added as responsible parties. All other information remains the same.

SUBJECT: Heartsbreath Test for Heart Transplant Rejection

I. SUMMARY OF CHANGES: On December 8, 2008, the Centers for Medicare and Medicaid Services (CMS) issued a decision memorandum in response to a formal request for Menssana Research, Inc., to consider national coverage of the Heartsbreath Test as an adjunct to a 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. CMS determines 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.

NEW / REVISED MATERIAL

EFFECTIVE DATE: DECEMBER 8, 2008

IMPLEMENTATION DATE: APRIL 6, 2009

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N/A	

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

SECTION B: For Medicare Administrative Contractors (MACs):

The Medicare administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions

regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-04	Transmittal: 1697	Date: March 12, 2009	Change Request: 6366
-------------	-------------------	----------------------	----------------------

Transmittal 1683, Change Request 6366, dated February 13, 2009, has been rescinded and replaced. MCS is removed as a responsible party in business requirement 6366.4, and the A/B MAC and Carrier are added as responsible parties. All other information remains the same.

SUBJECT: Heartsbreath Test for Heart Transplant Rejection

Effective Date: December 8, 2008

Implementation Date: April 6, 2009

I. GENERAL INFORMATION

A. Background: On December 8, 2008, the Centers for Medicare & Medicaid Services (CMS) issued a decision memorandum in response to a formal request for Menssana Research, Inc., 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.

B. Policy: CMS determines 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.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6366.1	Effective for claims with dates of service on and after December 8, 2008, contractors shall be aware that the Heartsbreath Test used to predict heart transplant rejection, is nationally non-covered. This coverage change to 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.	X		X	X						MPFSDB April 2009
6366.2	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.	X		X							IOCE April 2009
6366.3	Contractors shall be aware that providers shall issue the appropriate liability notice to a beneficiary for the Heartsbreath Test.	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6366.4	Standard system maintainers shall assign liability for the denied charges to the provider unless documentation of the ABN is present on the claim.	X			X		X				
6366.5	When denying claims for CPT code 0085T, contractors shall use: MSN 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 M51: 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 . If you do not have web access, you may contact the contractor to request a copy of the NCD.	X			X						
6366.5.1	Contractors shall be aware that providers shall issue an Advanced Beneficiary Notice (ABN) to beneficiaries who choose to have this procedure. The ABN shall indicate that Medicare issued a national coverage determination (NCD) section 260.10 of the Medicare NCD Manual) stating that the Heartsbreath test are not reasonable and necessary for Medicare beneficiaries. Therefore, Medicare never pays for this service and the beneficiary would be held financially responsible if they decide to have this procedure. NOTE: Beginning March 1, 2009, the ABN-G will no longer be valid and providers must issue the revised ABN (CMS-R-131).	X		X	X						
6366.5.2	Contractors shall include the Group Code, CO (Contractor Obligation) or PR (Provider Responsibility) depending on liability.	X		X	X						
6366.6	For claims with dates of service between December 8, 2008, and April 1, 2009, contractors shall not search their files, but may go back and adjust claims that are brought to their attention.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)
--------	-------------	---

		A / B M A C	D M E M A C	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
6366.7	<p>A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv.</p> <p>Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.</p>	X		X	X						

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below:

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
	N/A

Section B: For all other recommendations and supporting information, use this space:

V. CONTACTS

Pre-Implementation Contact(s): Sandy Jones, coverage, 410-786-2273, Sandra-d.jones@cms.hhs.gov, Patricia Brocato-Simons, coverage, 410-786-0261, patricia.brocatosimons@cms.hhs.gov, Yvette Cousar, practitioner claims processing, 410-786-2160, Yvette.cousar@cms.hhs.gov, Wendy Tucker, institutional claims processing, 410-786-3004, wendy.tucker@cms.hhs.gov.

Post-Implementation Contact(s):

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs)*, *Regional Home Health Intermediaries (RHHIs)*, and/or *Carriers*:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs):*

The Medicare administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.