

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 99	Date: February 13, 2009
	Change Request 6366

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. NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs)

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:

R=REVISED, N=NEW, D=DELETED-Only One Per Row.

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
N	1/260.10/Heartsbreath Test for Heart Transplant Rejection

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
Manual Instruction**

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

Attachment - Business Requirements

Pub. 100-03	Transmittal: 99	Date: February 13, 2009	Change Request: 6366
-------------	-----------------	-------------------------	----------------------

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 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.

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 M A C	D M 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	
6366.1	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. See Pub. 100-04, accompanying this CR package for detailed business requirements and Pub. 100-03, for detailed coverage policy.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M 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	
6366.2	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMMattersArticles/ shortly	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 H I	Shared-System Maintainers				OTHER
							F I S S	M C S	V M S	C W F	
	<p>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>										

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.brocato-simons@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): Appropriate CMS ROs.

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs)*, *Regional Home Health Intermediaries (RHHIs)*, and/or *Carriers*, use only one of the following statements:

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)*, include the following statement:

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.

**Medicare National Coverage
Determinations Manual**
Chapter 1, Part 4 (Sections 200 – 310.1)
Coverage Determinations

Table of Contents
(Rev. 99, 02-13-09)

260.10 – Heartsbreath Test for Heart Transplant Rejection (Effective December 8, 2008)

260.10 - Heartsbreath Test for Heart Transplant Rejection (Effective December 8, 2008)

(Rev.99, Issued: 02-13-09, Effective: 12-08-08, Implementation: 04-06-09)

A. General

The Heartsbreath test is a Food and Drug Administration-approved Humanitarian Use Device for use only as an adjunct to the endomyocardial biopsy to detect grade 3 heart transplant rejection in patients who have had a heart transplant within the last year and an endomyocardial biopsy within the prior month. The test involves collecting breath samples from the patient and analysis of the samples performed in a laboratory. These test results are then compared to endomyocardial biopsy findings and the results are provided to the clinician shortly thereafter.

B. Nationally Covered Indications

N/A

C. Nationally Non-Covered Indications

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.

D. Other

N/A

(This NCD last reviewed December 2008.)