CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-03 Medicare National Coverage Determinations	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 137	**Date: November 23, 2011**
	Change Request 7636

SUBJECT: Intensive Behavioral Therapy for Cardiovascular Disease

I. SUMMARY OF CHANGES: Effective for claims with dates of service on and after November 8, 2011, CMS covers intensive behavioral therapy for cardiovascular disease, inclusive of one face-to-face risk reduction visit annually.

This revision [to the Medicare National Coverage Determinations Manual] is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries,[contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions], quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: November 8, 2011
IMPLEMENTATION DATE: December 27, 2011 for non-shared system edits, April 2, 2012 for shared system edits, July 2, 2012, for CWF provider screens, HICR changes and MCS MCDST Changes

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-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N	1/210.11/Intensive Behavioral Therapy for Cardiovascular Disease

III. FUNDING:
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.

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: 137	Date: November 23, 2011	Change Request: 7636

SUBJECT: Intensive Behavioral Therapy for Cardiovascular Disease

Effective Date: November 8, 2011

Implementation Date: December 27, 2011 for non-shared system edits
April 2, 2012 for shared system edits
July 2, 2012, for CWF provider screens, HICR changes, and MCS MCSDT changes

I. GENERAL INFORMATION

A. Background: Pursuant to §1861(ddd) of the Social Security Act, the Centers for Medicare and Medicaid Services (CMS) may add coverage of "additional preventive services" through the National Coverage Determination (NCD) process. The preventive services must meet all of the following criteria: (1) reasonable and necessary for the prevention or early detection of illness or disability, (2) recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF), and, (3) appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

The CMS reviewed the USPSTF recommendations and supporting evidence for intensive behavioral therapy for cardiovascular disease and determined that the criteria listed above was met, enabling the CMS to cover this preventive service. Effective November 8, 2011, Medicare will cover intensive behavioral therapy for cardiovascular disease if the service is provided by primary care practitioners in primary care settings such as the beneficiary's family practice physician, internal medicine physician, or nurse practitioner in the doctor's office.

B. Policy: Effective November 8, 2011, CMS covers intensive behavioral therapy for cardiovascular disease (referred to below as a CVD risk reduction visit), which consists of the following three components:

- encouraging aspirin use for the primary prevention of cardiovascular disease when the benefits outweigh the risks for men age 45-79 years and women 55-79 years;
- screening for high blood pressure in adults age 18 years and older; and,
- intensive behavioral counseling to promote a healthy diet for adults with hyperlipidemia, hypertension, advancing age, and other known risk factors for cardiovascular and diet-related chronic disease.

We note that only a small proportion (about 4%) of the Medicare population is under 45 years (men) or 55 years (women), therefore the vast majority of beneficiaries should receive all three components. Intensive behavioral counseling to promote a healthy diet is broadly recommended to cover close to 100% of the population due to the prevalence of known risk factors.

Effective for claims with dates of service on and after November 8, 2011, CMS covers one face-to-face CVD risk reduction per 12-month period for Medicare beneficiaries who are competent and alert at the time that counseling is provided, and whose counseling is furnished by a qualified primary care physician or other primary care practitioner in a primary care setting.

For the purposes of this covered service, a primary care setting is defined as one in which there is provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of

family and community. Emergency departments, inpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities, and hospices are not considered primary care settings under this definition.

The behavioral counseling intervention for aspirin use and healthy diet should be consistent with the Five A's approach that has been adopted by the USPSTF to describe such services:

1. **Assess**: Ask about/assess behavioral health risk(s) and factors affecting choice of behavior change goals/methods.
2. **Advise**: Give clear, specific, and personalized behavior change advice, including information about personal health harms and benefits.
3. **Agree**: Collaboratively select appropriate treatment goals and methods based on the patient's interest in and willingness to change the behavior.
4. **Assist**: Using behavior change techniques (self-help and/or counseling), aid the patient in achieving agreed-upon goals by acquiring the skills, confidence, and social/environmental supports for behavior change, supplemented with adjunctive medical treatments when appropriate.
5. **Arrange**: Schedule follow-up contacts (in person or by telephone) to provide ongoing assistance/support and to adjust the treatment plan as needed, including referral to more intensive or specialized treatment.

NOTE: A new HCPCS code, G0446, *Annual face-to-face intensive behavioral therapy for cardiovascular disease, individual, 15 minutes,* will be effective November 8, 2011, and will be included in the January 2012 updates of the Medicare Physician Fee Schedule Database (MPFSDB) and Integrated Outpatient Code Editor (IOCE).

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7636-03.1	Effective for claims with date of service on and after November 8, 2011, contractors shall pay claims for intensive behavioral therapy for cardiovascular disease for Medicare beneficiaries one time per 12-month period subject to criteria in Pub. 100-03, NCD Manual, section 210.11. Refer to Pub 100-04, Claims Processing Manual, Chapter 18, section 160, for claims processing instructions, as well as the corresponding Pub. 100-04 Transmittal accompanying this CR.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7636-03.2	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. 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.	X		X	X						

IV. SUPPORTING INFORMATION

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

X-Ref Requirement Number	Recommendations or other supporting information:

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

V. CONTACTS

Pre-Implementation Contact(s):

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Post-Implementation Contact(s): Contact your Contracting Officer's Technical Representative (COTR) or Contractor Manager, as applicable.

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.

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

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(Rev.137, 11-23-11)

210.11 – Intensive Behavioral Therapy for Cardiovascular Disease (CVD) (Effective November 8, 2011)

(Rev. 137, Issued: 11-23-11, Effective: 11-08-11, Implementation: 12-27-11 non-shared system edits, 04-02-12 shared system edits, 07-02-12 CWF/HICR/MCS MCDST)

A. General

Cardiovascular disease (CVD) is the leading cause of mortality in the United States. CVD, which is comprised of hypertension, coronary heart disease (such as myocardial infarction and angina pectoris), heart failure and stroke, is also the leading cause of hospitalizations. Although the overall adjusted mortality rate from heart disease has declined over the past decade, opportunities for improvement still exist. Risk factors for CVD include being overweight, obesity, physical inactivity, diabetes, cigarette smoking, high blood pressure, high blood cholesterol, family history of myocardial infarction, and older age.

Under §1861(ddd) of the Social Security Act (the Act), the Centers for Medicare & Medicaid Services (CMS) has the authority to add coverage of additional preventive services through the National Coverage Determination (NCD) process if certain statutory requirements are met. Following its review, CMS has determined that the evidence is adequate to conclude that intensive behavioral therapy for CVD is reasonable and necessary for the prevention or early detection of illness or disability, is appropriate for individuals entitled to benefits under Part A or enrolled under Part B, and is comprised of components that are recommended with a grade of A or B by the U.S. Preventive Services Task Force (USPSTF).

B. Nationally Covered Indications

Effective for claims with dates of service on or after November 8, 2011, CMS covers intensive behavioral therapy for CVD (referred to below as a CVD risk reduction visit), which consists of the following three components:

- *encouraging aspirin use for the primary prevention of CVD when the benefits outweigh the risks for men age 45-79 years and women 55-79 years;*
- *screening for high blood pressure in adults age 18 years and older; and*
- *intensive behavioral counseling to promote a healthy diet for adults with hyperlipidemia, hypertension, advancing age, and other known risk factors for cardiovascular- and diet-related chronic disease.*

We note that only a small proportion (about 4%) of the Medicare population is under 45 years (men) or 55 years (women), therefore the vast majority of beneficiaries should receive all three components. Intensive behavioral counseling to promote a healthy diet is broadly recommended to cover close to 100% of the population due to the prevalence of known risk factors.

Therefore, CMS covers one, face-to-face CVD risk reduction visit per year for Medicare beneficiaries who are competent and alert at the time that counseling is provided, and whose counseling is furnished by a qualified primary care physician or other primary care practitioner in a primary care setting.

The behavioral counseling intervention for aspirin use and healthy diet should be consistent with the Five As approach that has been adopted by the USPSTF to describe such services:

- ***Assess**: Ask about/assess behavioral health risk(s) and factors affecting choice of behavior change goals/methods.*
- ***Advise**: Give clear, specific, and personalized behavior change advice, including information about personal health harms and benefits.*
- ***Agree**: Collaboratively select appropriate treatment goals and methods based on the patient's interest in and willingness to change the behavior.*
- ***Assist**: Using behavior change techniques (self-help and/or counseling), aid the patient in achieving agreed-upon goals by acquiring the skills, confidence, and social/environmental supports for behavior change, supplemented with adjunctive medical treatments when appropriate.*
- ***Arrange**: Schedule follow-up contacts (in person or by telephone) to provide ongoing assistance/support and to adjust the treatment plan as needed, including referral to more intensive or specialized treatment.*

For the purpose of this NCD, a primary care setting is defined as the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Emergency departments, inpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities, and hospices are not considered primary care settings under this definition.

For the purpose of this NCD, a "primary care physician" and "primary care practitioner" are defined consistent with existing sections of the Act (§1833(u)(6), §1833(x)(2)(A)(i)(I) and §1833(x)(2)(A)(i)(II)).

§1833(u)
(6) Physician Defined.—For purposes of this paragraph, the term "physician" means a physician described in section 1861(r)(1) and the term "primary care physician" means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

§1833(x)(2)
(A) Primary care practitioner.—The term "primary care practitioner" means an individual—
(i) who—
(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or
(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5)).

C. Nationally Non-Covered Indications

Unless specifically covered in this NCD, any other NCD, or in statute, preventive services are non-covered by Medicare.

D. Other

Medicare coinsurance and Part B deductible are waived for this preventive service.

(This NCD last reviewed November 2011.)