CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 193	**Date: August 29, 2014**
	Change Request 8758

Transmittal 191, dated July 18, 2014, is being rescinded and replaced by Transmittal 193, dated AUGUST 29, 2014 to clarify in section 232 that chronic heart failure is an added indication to NCD 20.10.1, cardiac rehabilitation only. All other information remains the same.

SUBJECT: Cardiac Rehabilitation Programs for Chronic Heart Failure

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is effective for dates of service on and after February 18, 2014, Medicare covers cardiac rehabilitation services to beneficiaries with stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35% or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks.

EFFECTIVE DATE: February 18, 2014
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: August 18, 2014

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
R	15/232/Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Services Furnished On or After January 1, 2010

III. FUNDING:
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 obliged 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

Attachment - Business Requirements

Pub. 100-02	Transmittal: 193	Date: August 29, 2014	Change Request: 8758

Transmittal 191, dated July 18, 2014, is being rescinded and replaced by Transmittal 193, dated August 29, 2014 to clarify in section 232 that chronic heart failure is an added indication to NCD 20.10.1, cardiac rehabilitation only. All other information remains the same.

SUBJECT: Cardiac Rehabilitation Programs for Chronic Heart Failure

EFFECTIVE DATE: February 18, 2014
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IMPLEMENTATION DATE: August 18, 2014

I. GENERAL INFORMATION

A. Background: On June 4, 2013, the Centers for Medicare & Medicaid Services (CMS) initiated a national coverage analysis (NCA) to expand Medicare coverage of cardiac rehabilitation to beneficiaries diagnosed with chronic heart failure.

As per Sections 1861(s)(2)(CC) and 1861(eee)(1) of the Social Security Act, items and services furnished under a Cardiac Rehabilitation (CR) program may be covered under Medicare Part B. Among other things, Medicare regulations at 42CFR410.49 define key terms, address the components of a CR program, establish the standards for physician supervision, and limit the maximum number of program sessions that may be furnished. The regulations also describe the cardiac conditions that would enable a beneficiary to obtain CR services.

Specifically, coverage is permitted for beneficiaries who have experienced one or more of the following:

- Acute myocardial infarction within the preceding 12 months
- Coronary artery bypass surgery
- Current stable angina pectoris
- Heart valve repair or replacement
- Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting or
- Heart or heart-lung transplant

This change request adds chronic heart failure to the list of cardiac conditions, see above, that would enable a beneficiary to obtain CR services.

CMS may add “other cardiac conditions as specified through a national coverage determination” (42 CFR §410.4(b)(vii).

B. Policy: Effective for dates of service on and after February 18, 2014, Medicare has determined that the evidence is sufficient to expand coverage for cardiac rehabilitation services under 42 CFR §410.49(b)(1)(vii) to beneficiaries with stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35% or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks. Stable patients are defined as patients who have not had recent (≤6 weeks) or

planned (≤6 months) major cardiovascular hospitalizations or procedures. (See section A above for indications covered42 CFR §410.49(b)(1)(vii).

NOTE: Refer to Pub. 100-03, Medicare National Coverage Determinations Manual, chapter 1, part 1, section 20.10.1, Pub. 100-04, Medicare Claims Processing Manual, chapter 32, section 140, Pub. 100-08, Medicare Program Integrity Manual, chapter 15, section 4.2.8, and Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, section 232 for detailed information regarding chronic heart failure policy and claims processing instructions. Note as referenced above that chronic heart failure is an added indication for purposes of coverage for cardiac rehabilitation programs. Change Request 6850 implemented this policy previously, so no actual editing changes will be necessary.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
8758 - 02.1	Effective for dates of service on and after February 18, 2014, Medicare contractors shall cover cardiac rehabilitation services under 42 CFR §410.49(b)(1)(vii) to beneficiaries with stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35% or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks. Refer to Pub. 100-03, Medicare National Coverage Determinations Manual, chapter 1, part 1, section 20.10.1, Pub. 100-04, Medicare Claims Processing Manual, chapter 32, section 140, Pub. 100-08, Medicare Program Integrity Manual, chapter 15, section 4.2.8, and Pub. 100-02, Medicare Benefit Policy Manual, chapter 15, section 232 for detailed information regarding chronic heart failure policy and claims processing instructions.	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
8758 - 02.2	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/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 sites 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 the contractor's 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			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Patricia Brocato-Simons, 410-786-0261 or Patricia.Brocatosimons@cms.hhs.gov (Coverage), William Ruiz, 410-786-9283 or William.Ruiz@cms.hhs.gov (Intermediary Part A), April Billingsley, 410-786-0140 or April.Billingsley@cms.hhs.gov (Practitioner Part B Claims), Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage), Michelle Issa, 410-786-6656 or Michelle.Issa@cms.hhs.gov (Coverage)

Post-Implementation Contact(s): Contact your Contracting Officer's Representative (COR).

VI. FUNDING

Section A: 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.

ATTACHMENTS: 0

232 - Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Services Furnished On or After January 1, 2010

(Rev.193, Issued: 08-29-14, Effective: 02-18-14, Implementation: 08- 18-14)

Cardiac rehabilitation (CR) services mean a physician-supervised program that furnishes physician prescribed exercise, cardiac risk factor modification, including education, counseling, and behavioral intervention; psychosocial assessment, outcomes assessment, and other items/services as determined by the Secretary under certain conditions. Intensive cardiac rehabilitation (ICR) services mean a physician-supervised program that furnishes the same items/services under the same conditions as a CR program but must also demonstrate, as shown in peer-reviewed published research, that it improves patients' cardiovascular disease through specific outcome measurements described in 42 CFR 410.49(c). Effective January 1, 2010, Medicare Part B pays for CR/ICR programs and related items/services if specific criteria is met by the Medicare beneficiary, the CR/ICR program itself, the setting in which is it administered, and the physician administering the program, as outlined below:

CR/ICR Program Beneficiary Requirements:

Medicare covers CR/ICR program services for beneficiaries who have experienced one or more of the following:

- Acute myocardial infarction within the preceding 12 months;
- Coronary artery bypass surgery;
- Current stable angina pectoris;
- Heart valve repair or replacement;
- Percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting;
- Heart or heart-lung transplant.

For cardiac rehabilitation only: Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35% or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal heart failure therapy for at least 6 weeks. (Effective February 18, 2014.)

CR/ICR Program Component Requirements:

Physician-prescribed exercise. This physical activity includes aerobic exercise combined with other types of exercise (i.e., strengthening, stretching) as determined to be appropriate for individual patients by a physician each day CR/ICR items/services are furnished.

Cardiac risk factor modification. This includes education, counseling, and behavioral intervention, tailored to the patients' individual needs.

Psychosocial assessment. This assessment means an evaluation of an individual's mental and emotional functioning as it relates to the individual's rehabilitation. It should include: (1) an assessment of those aspects of the individual's family and home situation that affects the individual's rehabilitation treatment, and, (2) a psychosocial evaluation of the individual's response to, and rate of progress under, the treatment plan.

Outcomes assessment. These should include: (i) minimally, assessments from the commencement and conclusion of CR/ICR, based on patient-centered outcomes which must be measured by the physician immediately at the beginning and end of the program, and, (ii) objective clinical measures of the effectiveness of the CR/ICR program for the individual patient, including exercise performance and self-reported measures of exertion and behavior.

Individualized treatment plan. This plan should be written and tailored to each individual patient and include (i) a description of the individual's diagnosis; (ii) the type, amount, frequency, and duration of the CR/ICR items/services furnished; and (iii) the goals set for the individual under the plan. The individualized treatment plan must be established, reviewed, and signed by a physician every 30 days.

As specified at 42 CFR 410.49(f)(1), CR sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions over up to 36 weeks with the option for an additional 36 sessions over an extended period of time if approved by the contractor under section 1862(a)(1)(A) of the Act. ICR sessions are limited to 72 1-hour sessions (as defined in section 1848(b)(5) of the Act), up to 6 sessions per day, over a period of up to 18 weeks.

CR/ICR Program Setting Requirements:

CR/ICR services must be furnished in a physician's office or a hospital outpatient setting (for ICR, the hospital outpatient setting must provide ICR using an approved ICR program). All settings must have a physician immediately available and accessible for medical consultations and emergencies at all times when items/services are being furnished under the program. This provision is satisfied if the physician meets the requirements for direct supervision of physician office services as specified at 42 CFR 410.26, and for hospital outpatient services as specified at 42 CFR 410.27.

ICR Program Approval Requirements:

All prospective ICR programs must be approved through the national coverage determination (NCD) process. To be approved as an ICR program, it must demonstrate through peer-reviewed, published research that it has accomplished one or more of the following for its patients: (i) positively affected the progression of coronary heart disease, (ii) reduced the need for coronary bypass surgery, or, (iii) reduced the need for percutaneous coronary interventions.

An ICR program must also demonstrate through peer-reviewed, published research that it accomplished a statistically significant reduction in five or more of the following measures for patients from their levels before CR services to after CR services: (i) low density lipoprotein, (ii) triglycerides, (iii) body mass index, (iv) systolic blood pressure, (v) diastolic blood pressure, and (vi) the need for cholesterol, blood pressure, and diabetes medications.

A list of approved ICR programs, identified through the NCD process, will be posted to the CMS Web site and listed in the Federal Register.

Once an ICR program is approved through the NCD process, all prospective ICR sites wishing to furnish ICR items/services via an approved ICR program may enroll with their local contractor to become an ICR program supplier using the designated forms as specified at 42 CFR 424.510, and report specialty code 31 to be identified as an enrolled ICR supplier. For purposes of appealing an adverse determination concerning site approval, an ICR site is considered a supplier (or prospective supplier) as defined in 42 CFR 498.2.

CR/ICR Program Physician Requirements:

Physicians responsible for CR/ICR programs are identified as medical directors who oversee or supervise the CR/ICR program at a particular site. The medical director, in consultation with staff, is involved in directing

the progress of individuals in the program. The medical director, as well as physicians acting as the supervising physician, must possess all of the following: (1) expertise in the management of individuals with cardiac pathophysiology, (2) cardiopulmonary training in basic life support or advanced cardiac life support, and (3) licensed to practice medicine in the state in which the CR/ICR program is offered. Direct physician supervision may be provided by a supervising physician or the medical director.

(See *Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Part 1, section 20.10.1*, Pub. 100-04, Medicare Claims Processing Manual, Chapter 32, section 140, *Pub. 100-08, Medicare Program Integrity Manual, Chapter 15, section 15.4.2.8*, for specific claims processing, coding, and billing requirements for CR/ICR program services.)