

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 256	Date: February 1, 2019
	Change Request 11117

SUBJECT: Update to Intensive Cardiac Rehabilitation (ICR) Programs

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors of the changes to section 51004 of the Bipartisan Budget Act (BBA) of 2018, Pub. L. No. 115-123 (2018), amended section 1861(eee)(4)(B) of the Act to add to expand coverage in an ICR to additional conditions that became effective February 9, 2018.

EFFECTIVE DATE: February 9, 2018

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

IMPLEMENTATION DATE: March 19, 2019

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
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 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**

Attachment - Business Requirements

Pub. 100-02	Transmittal: 256	Date: February 1, 2019	Change Request: 11117
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SUBJECT: Update to Intensive Cardiac Rehabilitation (ICR) Programs

EFFECTIVE DATE: February 9, 2018

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IMPLEMENTATION DATE: March 19, 2019

I. GENERAL INFORMATION

A. Background: The Medicare Improvements for Patients and Providers Act (MIPPA) of 2008, Pub. L. No. 110-275, § 144 (2008) established coverage for cardiac rehabilitation (CR) programs and intensive cardiac rehabilitation (ICR) programs under Part B. These provisions are primarily codified in section 1861(eee) of the Social Security Act (the Act). CMS implemented the statutory provisions through rulemaking codified at 42 C.F.R. § 410.49. The CR and ICR coverage provisions included in section 42 CFR 410.49 were effective January 1, 2010.

Effective January 1, 2010, Medicare Part B covered ICR program services for beneficiaries who have experienced one or more of the following:

- An acute myocardial infarction within the preceding 12 months;
- A coronary artery bypass surgery;
- Current stable angina pectoris;
- Heart valve repair or replacement;
- Percutaneous transluminal coronary angioplasty or coronary stenting;
- A heart or heart-lung transplant.

B. Policy: Effective February 9, 2018, section 51004 of the Bipartisan Budget Act (BBA) of 2018, Pub. L. No. 115-123 (2018), amended section 1861(eee)(4)(B) of the Act to add to expand coverage in an ICR to additional conditions:

- 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; or,
- Any additional condition for which the Secretary has determined that a cardiac rehabilitation (CR) program shall be covered, unless the Secretary determines, using the same process used to determine that the condition is covered for a CR program, that such coverage is not supported by the clinical evidence.

NOTE: CMS plans to amend our ICR regulations specified at 42 CFR 410.49 to reflect this expanded coverage. CMS anticipates that the changes will be included in the 2020 Medicare Physician Fee Schedule notice of proposed rulemaking. However, because the expanded coverage under the statutory change was effective on enactment, expanded coverage for these conditions will be made effective for services furnished on or after February 9, 2018. See Publication (Pub.) 100-02, Medicare Benefit Policy Manual, Chapter 15, section 232 and Pub 100-04, Chapter 32, section 140.3.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility									
		A/B MAC			D M E M A C	Shared- System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
11117 - 02.1	<p>Effective for claims with dates of service on and after February 9, 2018, contractors shall allow coverage for ICR for beneficiaries with the following additional covered conditions:</p> <ul style="list-style-type: none"> 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; or Any additional condition for which the Secretary has determined that a cardiac rehabilitation (CR) program shall be covered, unless the Secretary determines, using the same process used to determine that the condition is covered for a CR program, that such coverage is not supported by the clinical evidence. <p>See Pub. 100-02, BPM, Chapter 15, section 232 and Pub 100-04, Chapter 32, section 140.3.</p>	X	X								
11117 - 02.2	For claims with dates of service on or after February 9, 2018, but received before the implementation date of this CR, contractors need not search their files. However, contractors shall adjust claims brought to their attention.	X	X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility						
		A/B MAC			D M E M A C	C M E D I C A L	I N F O R M A T I O N	O T H E R
		A	B	H H H				
11117 - 02.3	MLN Article: CMS will make available an MLN Matters provider education article that will be marketed through the MLN Connects weekly newsletter shortly after the CR is released. MACs shall follow IOM Pub. No. 100-09 Chapter 6, section 50.2.4.1, instructions for distributing MLN Connects information to providers, posting the article or a direct link to the article on your	X	X					

Number	Requirement	Responsibility				
		A/B MAC			D M E D I	C M E D I
		A	B	H H H		
	website, and including the article or a direct link to the article in your bulletin or newsletter. You may supplement MLN Matters articles with localized information benefiting your provider community in billing and administering the Medicare program correctly. Subscribe to the “MLN Matters” listserv to get article release notifications, or review them in the MLN Connects weekly newsletter.					

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): Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage and Analysis), Patricia Brocato-Simons, 410-786-0261 or patricia.brocato-simons@cms.hhs.gov (Coverage and Analysis), William Ruiz, 410-786-9283 or William.Ruiz@cms.hhs.gov (Institutional claims), Thomas Dorsey, 410-786-7434 or Thomas.Dorsey@cms.hhs.gov (Professional Claims), Sarah Fulton, 410-786-2749 or sarah.fulton@cms.hhs.gov (Coverage and Analysis)

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: 1

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

(Rev. 256, Issued: 02-01-19, Effective: 02-09-18, Implementation: 03-19-19)

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 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.)

Effective February 9, 2018, section 51004 of the Bipartisan Budget Act (BBA) of 2018, Pub. L. No. 115-123 (2018), amended section 1861(eee)(4)(B) of the Social Security Act to expand coverage in an intensive cardiac rehabilitation program to additional conditions:

- *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; or*
- *Any additional condition for which the Secretary has determined that a cardiac rehabilitation program shall be covered, unless the Secretary determines, using the same process used to determine that the condition is covered for a cardiac rehabilitation program, that such coverage is not supported by the clinical evidence.*

NOTE: CMS plans to amend our intensive cardiac rehabilitation regulations specified at 42 CFR 410.49 to reflect this expanded coverage. CMS anticipates that the changes will be included in the 2020 Medicare Physician Fee Schedule notice of proposed rulemaking. However, because the expanded coverage under the statutory change was effective on enactment, expanded coverage for these conditions will be made effective for services furnished on or after February 9, 2018.

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.)