

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-02 Medicare Benefit Policy	Centers for Medicare & Medicaid Services (CMS)
Transmittal 10573	Date: March 24, 2021
	Change Request 12115

SUBJECT: Update to Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Program Manual Sections

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to make Medicare Contractors aware of updates to Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Program Manual Sections of the Medicare Claims Processing Manual and Benefit Policy Manual.

EFFECTIVE DATE: January 1, 2010

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

IMPLEMENTATION DATE: April 26, 2021

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	15/231/Pulmonary Rehabilitation (PR) Program Services Furnished On or After January 1, 2010
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: 10573	Date: March 24, 2021	Change Request: 12115
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SUBJECT: Update to Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Program Manual Sections

EFFECTIVE DATE: January 1, 2010

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

IMPLEMENTATION DATE: April 26, 2021

I. GENERAL INFORMATION

A. Background: Section 144(a) of the Medicare Improvements for Patients and Providers Act (MIPPA) of 2008 established coverage provisions for PR, CR and ICR programs. The statute specified certain conditions for coverage of these services and an effective date of January 1, 2010. Conditions of coverage for PR, CR and ICR consistent with the statutory provisions of section 144(a) of the MIPPA were codified in 42 CFR 410.47 and 410.49 respectively through the Calendar Year (CY) 2010 PFS final rule with comment period (74 FR 61872-61886 and 62002-62003 (PR) 62004-62005 (CR/ICR)). In 2014 CMS expanded coverage of CR through the National Coverage Determination (NCD) process (NCD 20.10.1, Cardiac Rehabilitation Programs for Chronic Heart Failure (Pub. 100-03 20.10.1)). In 2018, §51004 of the Bipartisan Budget Act (BBA of 2018) expanded coverage of ICR to include chronic heart failure. Section 410.49 was updated to codify this expansion of coverage through the CY 2020 PFS final rule (84 FR 62897-62899 and 63188).

B. Policy: Under §410.47(b), Medicare part B covers PR program services for beneficiaries with moderate to very severe chronic obstructive pulmonary disease (defined as GOLD classification II, III and IV), when referred by the physician treating the chronic respiratory disease and allows additional medical indications to be established through an NCD. CMS has not expanded coverage of PR further using the NCD process.

Under § 410.49(b), Medicare part B covers CR and 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 (PTCA) or coronary stenting;
- A heart or heart-lung transplant;
- Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent 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, on or after February 18, 2014 for CR and on or after February 9, 2018 for ICR; or
- Other cardiac conditions as specified through an NCD. The NCD process may also be used to specify non-coverage of a cardiac condition for ICR if coverage is not supported by clinical evidence.

These conditions of coverage are reflected in multiple CMS program manuals. It has come to our attention that there is misalignment between the regulatory text in the Code of Federal Regulations (CFR) and some manual language.

To address this misalignment, CMS is updating the affected manual language to accurately reflect the regulatory text in §410.47 and 410.49. The updates are to chapter 15, sections 231 and 232 of the Medicare Benefit Policy Manual (Pub. 100-02) and chapter 32, section 140 including subsections 140.2, 140.3, 140.4 of the Medicare Claims Processing Manual (Pub. 100-04).

NOTE: Please note there are no policy changes.

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	
12115 - 02.1	The Medicare contractors shall be aware of the manual updates in Pub 100-02, chapter 15, section 231 and 232	X	X							

III. PROVIDER EDUCATION TABLE

Number	Requirements	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
	None					

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 and Analysis Group) , Sarah Fulton, 410-786-2749 or Sarah.Fulton@cms.hhs.gov (Coverage and Analysis Group) , Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage and Analysis Group).

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

231 - Pulmonary Rehabilitation (PR) Program Services Furnished On or After January 1, 2010

(Rev. 10573; Issued: 03-24-2021; Effective: 01-01-2010; Implementation: 04-26-2021)

Pulmonary rehabilitation (PR) *means* a physician-supervised *program for chronic obstructive pulmonary disease (COPD) and certain other chronic respiratory diseases* designed to optimize physical and social performance and autonomy. Effective January 1, 2010, Medicare Part B pays for PR programs and related items and services if specific criteria *are* met by the Medicare beneficiary, the PR program itself, the setting in which it is administered, and the physician administering the program, as outlined below.

Beneficiaries *who may be covered*:

As specified in 42 CFR 410.47, Medicare covers PR for *beneficiaries* with moderate to very severe COPD (defined as GOLD classification II, III, and IV), when referred by the physician treating the chronic respiratory disease. Additional medical indications for coverage for PR program services may be established through *a* national coverage determination (*NCD*).

PR *includes all of the following components*:

Physician-prescribed exercise. *Physician-prescribed exercise means physical activity, including aerobic exercise, prescribed and supervised by a physician that improves or maintains an individual's pulmonary functional level.* This physical activity includes techniques such as exercise conditioning, breathing retraining, step, and strengthening exercises. Some aerobic exercise must be included in each PR session.

Education or training. *Education or training* closely and clearly related to the individual's care and treatment *which is* tailored to the individual's needs. *Education* includes information on respiratory problem management and, if appropriate, brief smoking cessation counseling. Any education or training *prescribed* must assist in achievement of individual goals towards independence in activities of daily living, adaptation to limitations and improved quality of life.

Psychosocial assessment. *Psychosocial* assessment means a written evaluation of an individual's mental and emotional functioning as it relates to the individual's rehabilitation or respiratory condition. *The psychosocial assessment* includes: (i) An assessment of those aspects of *an* individual's family and home situation that affects the individual's rehabilitation treatment. (ii) A *psychosocial* evaluation of the individual's response to and rate of progress under the treatment plan.

Outcomes assessment. *Outcomes assessment means a written evaluation of the patient's progress as it relates to the individual's rehabilitation which includes the following*: (i) Beginning and end evaluations, based on patient-centered outcomes, which are conducted by the physician at the start and end of the program. (ii) Objective clinical measures of the effectiveness of the PR program for the individual patient, including exercise performance and self-reported measures of shortness of breath and behavior.

Individualized treatment plan. Individualized treatment plan means a written plan established, reviewed, and signed by a physician every 30 days, that describes all of the following: (i) The individual's diagnosis. (ii) The type, amount, frequency, and duration of the items and services under the plan. (iii) The goals set for the individual under the plan. The *individualized treatment* plan must be established, reviewed, and signed by a physician, *who is involved in the patient's care and has knowledge related to his or her condition*, every 30 days.

As specified at 42 CFR 410.47(f), PR program sessions are limited to a maximum of 2 1-hour sessions per day for up to 36 sessions, with the option for an additional 36 sessions if *approved by the Medicare contractor*.

PR Settings:

PR items and services must be furnished in a physician's office or a hospital outpatient setting. *All settings must have the following available for immediate use and accessible at all times: (i) The necessary cardio-pulmonary, emergency, diagnostic, and therapeutic life-saving equipment accepted by the medical community as medically necessary (for example, oxygen, cardiopulmonary resuscitation equipment, and defibrillator) to treat chronic respiratory disease. (ii) A physician must be immediately available and accessible for medical consultations and emergencies at all times when services are being provided under the program.* This provision is satisfied if the physician meets the requirements for direct supervision for physician office services as specified at 42 CFR 410.26, and for hospital outpatient services as specified at 42 CFR 410.27.

PR Physician Standards:

Medicare Part B pays for PR services for PR programs supervised by a physician who meets the following requirements: (1) *Is responsible and accountable for the PR program, including oversight of the PR staff.* (2) *Is involved substantially, in consultation with staff, in directing the progress of the individual in the program including direct patient contact related to the periodic review of his or her treatment plan.* (3) *Has expertise in the management of individuals with respiratory pathophysiology, and cardiopulmonary training and/or certification including basic life support.* (4) *Is licensed to practice medicine in the state in which the PR program is offered.*

Medical director means the physician who oversees or supervises the PR program.

Supervising physician means a physician that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished under the PR program.

(See Publication 100-04, Claims Processing Manual, chapter 32, section 140.4, for specific claims processing, coding, and billing requirements for PR program services.)

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

(Rev. 10573; Issued: 03-24-2021; Effective: 01-01-2010; Implementation; 04-26-2021)

Cardiac rehabilitation (CR) means a physician-supervised program that furnishes physician prescribed exercise; cardiac risk factor modification, including education, counseling, and behavioral intervention; psychosocial assessment; and outcomes assessment. Intensive cardiac rehabilitation (ICR) program means a physician-supervised program that furnishes CR and has 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 are met by the Medicare beneficiary, the CR/ICR program itself, the setting in which it is administered, and the physician administering the program, as outlined below.

Covered beneficiary cardiac and intensive cardiac rehabilitation services:

Medicare *part B* covers CR *and* 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.*
- *Stable, chronic heart failure defined as patients with left ventricular ejection fraction of 35 percent or less and New York Heart Association (NYHA) class II to IV symptoms despite being on optimal medical therapy for at least 6 weeks, on or after February 18, 2014 for CR and on or after February 9, 2018 for ICR; or*
- *Other cardiac conditions as specified through a national coverage determination (NCD). The NCD process may also be used to specify non-coverage of a cardiac condition for ICR if coverage is not supported by clinical evidence.*

CR *and* ICR programs must include all of the following:

Physician-prescribed exercise. *Physician-prescribed exercise means* aerobic exercise combined with other types of exercise (*that is*, strengthening, stretching) as determined to be appropriate for individual patients by a physician each day CR/ICR items *and* services are furnished.

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

Psychosocial assessment. *Psychosocial* assessment means an evaluation of an individual's mental and emotional functioning as it relates to the individual's rehabilitation *which* includes an assessment of those aspects of *an* individual's family and home situation that affects the individual's rehabilitation treatment, and, psychosocial evaluation of the individual's response to and rate of progress under the treatment plan.

Outcomes assessment. *Outcomes assessment means an evaluation of progress as it relates to the individual's rehabilitation which includes all of the following:* (i) *Minimally*, assessments from the commencement and conclusion of CR *and* ICR, based on patient-centered outcomes which must be measured by the physician immediately at the beginning *of the program* and *at the* end of the program. (ii) *Objective clinical measures of exercise performance and self-reported measures of exertion and behavior.*

Individualized treatment plan. *Individualized treatment plan means a written plan tailored to each individual patient that includes all of the following:* (i) *A* description of the individual's diagnosis. (ii) *The* type, amount, frequency, and duration of the items *and* services furnished *under the plan*. (iii) *The* goals set for the individual under the plan. The individualized treatment plan *detailing how components are utilized for each patient*, must be established, reviewed, and signed by a physician every 30 days.

As specified at 42 CFR 410.49(f)(1), CR *program* 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 *Medicare* contractor under section 1862(a)(1)(A) of the Act. *As specified at 42 CFR 410.49(f)(2)*, ICR *program* 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 *and* ICR Settings:

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

Standards for an ICR Program:

To be approved as an ICR program, a program 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.* (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 *5* 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.* (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.

All prospective ICR sites *must apply to* enroll *as an ICR program site* 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 and ICR Physician Standards:

A physician responsible for a CR or ICR program is identified as *the* medical director. *Medical director means a physician that* oversees or supervises the CR or ICR program at a particular site. The medical director, in consultation with staff, is involved in directing the progress of individuals in the program, *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.* (3) *Be* licensed to practice medicine in the state in which the CR or ICR program is offered.

Supervising physician means a physician that is immediately available and accessible for medical consultations and medical emergencies at all times items and services are being furnished to individuals under CR and ICR programs. 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. (3) Be licensed to practice medicine in the state in which the CR or ICR program is offered.

(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 10, section 10.2.2.H, for specific claims processing, coding, and billing requirements for CR/ICR program services.)