

<b>CMS Manual System</b>	<b>Department of Health &amp; Human Services (DHHS)</b>
<b>Pub 100-04 Medicare Claims Processing</b>	<b>Centers for Medicare &amp; Medicaid Services (CMS)</b>
<b>Transmittal 10573</b>	<b>Date: March 24, 2021</b>
	<b>Change Request 12115</b>

**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.*

<b>R/N/D</b>	<b>CHAPTER / SECTION / SUBSECTION / TITLE</b>
R	32/140/Cardiac Rehabilitation Programs, Intensive Cardiac Rehabilitation Programs, and Pulmonary Rehabilitation Programs
R	32/140/140.2/Cardiac Rehabilitation Program Services Furnished On or After January 1, 2010
R	32/140/140.3/Intensive Cardiac Rehabilitation Program Services Furnished On or After January 1, 2010
R	32 /140/140.4/Pulmonary Rehabilitation Program 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. 100-04	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**

**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 - 04.1	The Medicare contractors shall be aware of the manual updates in Pub 100-04, chapter 32, section 140 including subsections 140.2, 140.3, 140.4	X	X							

## III. PROVIDER EDUCATION TABLE

Number	Requirement	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.*

<b>X-Ref Requirement Number</b>	<b>Recommendations or other supporting information:</b>
---------------------------------	---

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

## V. CONTACTS

**Pre-Implementation Contact(s):** Sarah Fulton, 410-786-2749 or Sarah.Fulton@cms.hhs.gov (Coverage and Analysis), Wanda Belle, 410-786-7491 or Wanda.Belle@cms.hhs.gov (Coverage and Analysis), Patricia Brocato-Simons, 410-786-0261 or Patricia.BrocatoSimons@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: 0**

## **140 - Cardiac Rehabilitation Programs, Intensive Cardiac Rehabilitation Programs, and Pulmonary Rehabilitation Programs**

*(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.

### **140.2 – Cardiac Rehabilitation Program Services Furnished On or After January 1, 2010**

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

As specified at 42 CFR 410.49, Medicare covers cardiac rehabilitation *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; *or*
- *Other cardiac conditions as specified through a national coverage determination (NCD).*

Cardiac rehabilitation programs must include *all of* the following:

- Physician-prescribed exercise each day cardiac rehabilitation items and services are furnished.
- Cardiac risk factor modification, including education, counseling, and behavioral intervention, tailored to patients' individual needs.
- Psychosocial assessment.
- Outcomes assessment.
- An individualized treatment plan detailing how components are utilized for each patient. *The individualized treatment plan must be established, reviewed, and signed by a physician every 30 days.*

Cardiac rehabilitation items and services 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 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.

As specified at 42 CFR 410.49(f)(1), cardiac rehabilitation 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.

### **140.3 – Intensive Cardiac Rehabilitation Program Services Furnished On or After January 1, 2010**

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

As specified at 42 CFR 410.49, Medicare covers intensive cardiac rehabilitation *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 9, 2018; 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.*

Intensive cardiac rehabilitation programs must include *all of* the following:

- Physician-prescribed exercise each day cardiac rehabilitation items and services are furnished.
- Cardiac risk factor modification, including education, counseling, and behavioral intervention, tailored to patients' individual needs.
- Psychosocial assessment.
- Outcomes assessment.
- An individualized treatment plan detailing how components are utilized for each patient. *The individualized treatment plan must be established, reviewed, and signed by a physician every 30 days.*

*A list of approved intensive cardiac rehabilitation programs, identified through the national coverage determination process, will be posted to the CMS Web site and listed in the Federal Register.* In order to be approved, a program must demonstrate through peer-reviewed, published research that it has accomplished one or more of the following for its patients:

- Positively affected the progression of coronary heart disease.
- Reduced the need for coronary bypass surgery.
- Reduced the need for percutaneous coronary interventions.

An intensive cardiac rehabilitation 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 cardiac rehabilitation services to after cardiac rehabilitation services:

- Low density lipoprotein.
- Triglycerides.
- Body mass index.

- Systolic blood pressure.
- Diastolic blood pressure.
- The need for cholesterol, blood pressure, and diabetes medications.

Intensive cardiac rehabilitation items and services 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 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.

As specified at 42 CFR 410.49(f)(2), *intensive cardiac rehabilitation* program sessions are limited to 72 1-hour sessions, up to 6 sessions per day, over a period of up to 18 weeks.

#### **140.4 – Pulmonary Rehabilitation Program Services Furnished On or After January 1, 2010**

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

As specified in 42 CFR 410.47, Medicare covers pulmonary rehabilitation 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.

Pulmonary rehabilitation includes *all of* the following components:

- Physician-prescribed exercise. Some aerobic exercise must be included in each pulmonary rehabilitation session.
- Education or training closely and clearly related to the individual's care and treatment which is tailored to the individual's needs, including information on respiratory problem management and, if appropriate, brief smoking cessation counseling.
- Psychosocial assessment.
- Outcomes assessment.
- An individualized treatment plan detailing how components are utilized for each patient. *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.*

Pulmonary rehabilitation items and services must be furnished in a physician's office or a hospital outpatient setting. *All settings must have the necessary cardio-pulmonary, emergency, diagnostic, and therapeutic life-saving equipment accepted by the medical community as medically necessary to treat chronic respiratory disease.* All settings must have a physician immediately available and accessible for medical consultations and emergencies at all time *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.

As specified at 42 CFR 410.47(f), pulmonary rehabilitation 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, based on medical necessity.*