SUBJECT: An Omnibus CR Covering: (1) Removal of Two National Coverage Determination (NCDs), (2) Updates to the Medical Nutrition Therapy (MNT) Policy, and (3) Updates to the Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR), and Intensive Cardiac Rehabilitation (ICR) Conditions of Coverage

I. SUMMARY OF CHANGES: The purpose of this Omnibus change request is to make Medicare contractors aware of the updates to remove two National Determination NCDs, updates to the Medical Nutritional Therapy (MNT) policy and updates to the Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR), and Intensive Cardiac Rehabilitation (ICR) resulting from changes specified in the calendar year 2022 Physician Fee Schedule (PFS) final rule published on November 19, 2021.

EFFECTIVE DATE: January 1, 2022 - By Statute
*Unless otherwise specified, the effective date is the date of service.

IMPLEMENTATION DATE: July 5, 2022

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.

<table>
<thead>
<tr>
<th>R/N/D</th>
<th>CHAPTER / SECTION / SUBSECTION / TITLE</th>
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<tr>
<td>R</td>
<td>15/231/Pulmonary Rehabilitation (PR) Program Services Furnished On or After January 1, 2010</td>
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<td>R</td>
<td>15/232/Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Services Furnished On or After January 1, 2010</td>
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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
I. GENERAL INFORMATION

A. Background: Updates to Pulmonary Rehabilitation (PR), Cardiac Rehabilitation (CR) and Intensive Cardiac Rehabilitation (ICR) Conditions of Coverage:

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 MIPPA were codified in 42 Code of Federal Regulations (CFR) sections 410.47 and 410.49, respectively, through the Calendar Year (CY) 2010 Medicare Physician Fee Schedule (MPFS) Final Rule (FR) with comment period (74 FR 61872-61886 and 62002-62003 (PR) 62004-62005 (CR/ICR)).

In 2014, the Centers for Medicare & Medicaid Services (CMS) expanded coverage of CR through the National Coverage Determination (NCD) process (NCD 20.10.1, Cardiac Rehabilitation Programs for Chronic Heart Failure (CHF)).

In 2018, §51004 of the Bipartisan Budget Act (BBA of 2018) expanded coverage of ICR to include CHF. Section 410.49 was updated to codify this expansion of coverage through the CY 2020 MPFS final rule (84 FR 62897-62899 and 63188).

In the CY 2022 MPFS final rule (86 FR 65244 dated November 19, 2021) CMS finalized revisions to §§ 410.47 and 410.49 to improve consistency and accuracy across the PR and CR/ICR conditions of coverage, removed the PR requirement for direct physician-patient contact, and expanded coverage of PR for beneficiaries with confirmed or suspected COVID-19 and experience persistent symptoms that include respiratory dysfunction for at least 4 weeks.

NCD Removal:

CMS is removing two NCDs from Publication (Pub.) 100-03, NCD Manual, as a result of the NCD removal process through rulemaking in the CY 2022 MPFS (86 FR 65244 dated November 19, 2021).

Medical Nutritional Therapy (MNT):

Section 1861(s)(2)(V) of the Social Security Act (the Act) authorizes Medicare Part B coverage of MNT for certain beneficiaries who have diabetes or a renal disease, effective for services furnished on or after January
1, 2002. Regulations for MNT were established at 42 CFR §§410.130 – 410.134. This NCD establishes the duration and frequency limits for the MNT benefit and coordinates MNT and Diabetes Outpatient Self-Management Training (DSMT) as an NCD.

In 2002, the regulation at 42 CFR 410.132(c) required that an MNT referral must be made by the ‘treating’ physician. The treating physician was defined as the primary care physician or specialist coordinating care for the beneficiary with diabetes or renal disease.

B. Policy:
Updates to PR, CR), and ICR Conditions of Coverage:

Under § 410.47(b), Medicare Part B 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;
- Who have had confirmed or suspected COVID-19 and experience persistent symptoms that include respiratory dysfunction for at least 4 weeks (effective January 1, 2022);
- Additional medical indications for coverage for PR program services may 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 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, CHF 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, 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. CMS is updating the affected manual language to accurately reflect the updated regulatory text and policy changes finalized in the CY 2022 PFS final rule 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 of the Medicare Claims Processing Manual (Pub. 100-04).

NCD Removal:

The final rule contains a summary of the NCD removal process and explicitly removes the following two NCDs from the NCD Manual:

- NCD 180.2 Enteral/Parenteral Nutritional Therapy
- NCD 220.6 Positron Emission Tomography (PET) Scans
In the absence of an NCD, Medicare Administrative Contractors (MACs) have the authority and discretion to determine whether any Medicare claims for these items/services are reasonable and necessary under §1862(a)(1)(A) of the Act consistent with the existing guidance for making such decisions. Therefore, coverage of the above two NCDs revert to MAC discretion effective for claims with dates of service on and after January 1, 2022.

MNT:

Effective January 1, 2022, the regulations at 42 CFR §§ 410.130 and 410.132 will be consistent with the language of the statute and Medicare will cover MNT services with a referral by a physician (as defined in section 1861(r)(1) of the Act). Basic coverage of MNT for the first year a beneficiary receives MNT with either a diagnosis of renal disease or diabetes as defined at 42 CFR §410.130 is 3 hours. Basic coverage in subsequent years for renal disease or diabetes is 2 hours. The dietitian/nutritionist may choose how many units are performed per day as long as all of the other requirements in the NCD and 42 CFR §§ 410.130-410.134 are met. Pursuant to the exception at 42 CFR §410.132(b)(5), additional hours are considered to be medically necessary and covered if the physician determines that there is a change in medical condition, diagnosis, or treatment regimen that requires a change in MNT and orders additional hours during that episode of care.

If the physician determines that receipt of both MNT and DSMT are medically necessary in the same episode of care, Medicare will cover both DSMT and MNT initial and subsequent years without decreasing either benefit as long as DSMT and MNT are not provided on the same date of service. The dietitian/nutritionist may choose how many units are performed per day as long as all of the other requirements in the NCD and 42 CFR §§ 410.130-410.134 are met. Pursuant to the exception at 42 CFR §410.132(b)(5), additional hours are considered to be medically necessary and covered if the physician determines that there is a change in medical condition, diagnosis, or treatment regimen that requires a change in MNT and orders additional hours during that episode of care.

NOTE: Effective January 1, 2022, the regulations at 42 CFR §§ 410.130 and 410.132 are consistent with the language of the statute. Medicare will cover MNT services with a referral by a physician (as defined in section 1861(r)(1) of the Social Security Act). To align with the conforming changes of this regulation, the Claims Processing Manual, chapter 4, section 300, has been updated to remove the requirement that the medical nutrition therapy referral be made by the “treating” physician.

II. BUSINESS REQUIREMENTS TABLE

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

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<thead>
<tr>
<th>Number</th>
<th>Requirement</th>
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<td>12613</td>
<td>Contractors shall determine coverage for the following two (2) NCDs effective</td>
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<td>for claims with dates of service on and after January 1, 2022:</td>
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<td>NCD 180.2 Enteral/Parenteral Nutritional Therapy</td>
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### Number | Requirement | Responsibility
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 | | A/B MAC | DME MAC | Shared-System Maintainers | Other
 | | A | B | HHH | FISS | MCS | VMS | CWF

**NCD 220.6 Positron Emission Tomography (PET) Scans**

( NOTE: This change does not impact any PET-related NCDs currently covered or non-covered under NCD 220.6.)


| 12613-02.2 | Contractors shall consult Pub.100-04 for associated business requirements and responsibilities regarding policy changes to NCD 180.2 Medical Nutrition Therapy, NCD 220.6 PET Scans, Pulmonary Rehabilitation, Cardiac Rehabilitation, and Intensive Cardiac Rehabilitation. | X | X | X |

### III. PROVIDER EDUCATION TABLE

| Number | Requirement | Responsibility
--- | --- | ---
 | | A/B MAC | DME MAC | CEDI
 | | A | B | HHH

**12613-02.3**

Medicare Learning Network® (MLN): CMS will market provider education content through the MLN Connects® newsletter shortly after CMS releases the CR. MACs shall follow IOM Pub. No. 100-09 Chapter 6, Section 50.2.4.1 instructions for distributing the MLN Connects newsletter information to providers and link to relevant information on your website. You may supplement MLN content with your
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local information after we release the MLN Connects newsletter. Subscribe to the “MLN Connects” listserv to get MLN content notifications. You don’t need to separately track and report MLN content releases when you distribute MLN Connects newsletter content per the manual section referenced above.

IV. SUPPORTING INFORMATION

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

"Should" denotes a recommendation.

<table>
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<tr>
<th>X-Ref Requirement Number</th>
<th>Recommendations or other supporting information:</th>
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</thead>
</table>

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

V. CONTACTS

Pre-Implementation Contact(s): Sarah Fulton, Sarah.Fulton@cms.hhs.gov (Coverage and Analysis), Heather Hostetler, Heather.Hostetler@cms.hhs.gov (Coverage and Analysis), Wanda Belle, wanda.belle@cms.hhs.gov (Coverage and Analysis), Patricia Brocato-Simons, Patricia.BrocatoSimons@cms.hhs.gov (Coverage and Analysis), Rachel Katonak, Rachel.Katonak@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
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 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.

**Covered Conditions:**

As specified in 42 CFR 410.47, Medicare Part B 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;
- Who have had confirmed or suspected COVID-19 and experience persistent symptoms that include respiratory dysfunction for at least four weeks (effective January 1, 2022);
- Additional medical indications for coverage for PR program services may be established through a national coverage determination (NCD).

PR must include all of the following components:

**Physician-prescribed exercise.** Physician-prescribed exercise means aerobic exercise combined with other types of exercise (such as conditioning, breathing retraining, step, and strengthening) as determined to be appropriate for individual patients by a physician. Each PR session must include physician-prescribed exercise.

**Education or training.** Education or training that is closely and clearly related to the individual’s care and treatment which is tailored to the individual’s needs and assists in achievement of goals toward independence in activities of daily living, adaptation to limitations and improved quality of life. Education must include information on respiratory problem management and, if appropriate, brief smoking cessation counseling.

**Psychosocial assessment.** Psychosocial assessment means an evaluation of an individual’s mental and emotional functioning as it relates to the individual’s rehabilitation or respiratory condition 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 the following: (i) Evaluations, based on patient-centered outcomes, which must be measured by the physician or program staff at the beginning and end of the program. Evaluations measured by program staff must be considered by the physician in developing and/or reviewing individualized treatment plans. (ii) Objective clinical measures of exercise performance and self-reported measures of shortness of breath 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 410.47(e), the number of PR 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 Administrative Contractor (MAC).

PR Settings:

Medicare Part B pays for PR in a physician’s office or a hospital outpatient setting. All settings must have the following: (i) 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, at 42 CFR 410.26, and for hospital outpatient services at 42 CFR 410.27, and (ii) 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.

PR Physician Standards:

Medical Director. Medical director means the physician who oversees the PR program at a particular site. The medical director is the physician responsible for a PR program and, in consultation with staff, is involved in directing the progress of individuals in the program and must possess all of the following: (1) Expertise in the management of individuals with respiratory 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 PR program is offered.

Supervising Physician. 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 PR programs. Physicians acting as the supervising physician must possess all of the following: (1) Expertise in the management of individuals with respiratory 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 PR program is offered.

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

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

(Rev. 11426; Issued: 05-20-22; Effective: 01-01-22; Implementation: 07-05-22)

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 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 Conditions:

As specified in 42 CFR 410.49, Medicare Part B covers CR and ICR for beneficiaries who have experienced one or more of the following:

- An acute myocardial infarction (MI) within the preceding 12 months;
- A coronary artery bypass surgery;
- Current stable angina pectoris;
CR and ICR must include all of the following **components**:

**Physician-prescribed exercise.** Physician-prescribed exercise means aerobic exercise combined with other types of exercise (such as strengthening and 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 individual’s 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) **Evaluations,** based on patient-centered outcomes, which must be measured by the physician or program staff at the beginning and end of the program. **Evaluations measured by program staff must be considered by the physician in developing and/or reviewing individualized treatment plans.** (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), the number of 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 Medicare Administrative Contractor (MAC).

As specified at 42 CFR 410.49(f)(2), 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 and ICR Settings:**

*Medicare Part B pays for* CR and ICR 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, at 42 CFR 410.26, and for hospital outpatient services at 42 CFR 410.27.

**Standards for an ICR Program:**

- 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% 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 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.
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 listed in the Federal Register and is available on the CMS website at https://www.cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/ICR. 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:

**Medical Director.** Medical director means the physician who oversees the CR or ICR program at a particular site. The medical director is the physician responsible for a CR or ICR program and, in consultation with staff, is involved in directing the progress of individuals in the program and 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.** 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 10.2.2.5, for CR and ICR claims processing, coding, and billing requirements.)