CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11426	**Date: May 20, 2022**
	Change Request 12613

Transmittal 11272, dated February 18, 2022, is being rescinded and replaced by Transmittal 11426, dated, May 20, 2022 to revise chapter 32 of the IOM for Pub. 100-04. This correction does not make any revisions to the companion Pub. 100-02 or Pub. 100-03; all revisions are associated with Pub. 100-04. All other information remains the same.

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.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/180/1/ Medical Nutrition Therapy
R	1/180/2/Enteral and Parenteral Nutritional Therapy
R	1/ 220/6/ Positron Emission Tomography (PET) Scans

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. 100-03	Transmittal: 11426	Date: May 20, 2022	Change Request: 12613

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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

EFFECTIVE DATE: January 1, 2022 - By Statute
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IMPLEMENTATION DATE: July 5, 2022

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 three (3(hours. Basic coverage in subsequent years for renal disease or diabetes is two (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.

Number	Requirement	Responsibility								
		A/B MAC			DME	Shared-System Maintainers				Other
		A	B	HHH	MAC	FISS	MCS	VMS	CWF	
12613 - 03.1	Contractors shall determine coverage for the following two (2) NCDs effective for claims with dates of service on and after January 1, 2022: NCD 180.2 Enteral/Parenteral Nutritional Therapy NCD 220.6 Positron Emission Tomography (PET) Scans (NOTE: This change does not	X	X		X					

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	impact any PET-related NCDs currently covered or non-covered under NCD 220.6.) NOTE: Also, refer to Pub 100-04, Claims Processing Manual (CPM), chapter 4, section 300, Pub 100-04, CPM, chapter 32, section 140, Pub 100-02, Benefit Policy Manual, chapter 15, sections 231, 232, and Pub 100-03, NCD Manual, sections 180.2 and 220.6.									
12613 - 03.2	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 - 03.3	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 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.	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): Sarah Fulton, Sarah.Fulton@cms.hhs.gov (Coverage and Analysis) , Wanda Belle, 14107867491 or wanda.belle@cms.hhs.gov (Coverage and Analysis) , Patricia Brocato-Simons, 14107860261 or Patricia.BrocatoSimons@cms.hhs.gov (Coverage and Analysis) , Rachel Katonak, Rachel.Katonak@cms.hhs.gov (Coverage and Analysis) , Heather Hostetler, Heather.Hostetler@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

180.1 - Medical Nutrition Therapy *(MNT)*

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

A. General

Section 1861(s)(2)(V) of the *Social Security* Act authorizes Medicare part B coverage of medical nutrition therapy services (MNT) for certain beneficiaries who have diabetes or a renal disease. Regulations for MNT were established on January 2, 2002, at 42 CFR 410.130 - 410.134. This national coverage determination *(NCD)* establishes the duration and frequency limits for the MNT benefit and coordinates MNT and diabetes outpatient self-management training (DSMT) as *an NCD*.

B. Nationally Covered

Effective January 1, 2022, 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 three hours of administration. Basic coverage in subsequent years for renal disease or diabetes is two hours. The dietitian/nutritionist may choose how many units are administered per day as long as all of the other requirements in this NCD and 42 CFR 410.130-410.134 are met. Pursuant to the exception at 42 4CFR 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 is 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.

C. Nationally Non-Covered

N/A

D. Other

N/A

(This NCD last reviewed December 2021.)

180.2 - Enteral and Parenteral Nutritional Therapy

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

Effective January 1, 2022, the Centers for Medicare & Medicaid Services determined that no national coverage determination (NCD) is appropriate at this time for Enteral and Parenteral Nutritional Therapy. In the absence of an NCD, coverage determinations will be made by the Medicare Administrative Contractors under 1862(a)(1)(A) of the Social Security Act.

220.6 - Positron Emission Tomography (PET) Scans

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

Effective January 1, 2022, the Centers for Medicare & Medicaid Services removed the umbrella national coverage determination (NCD) for Positron Emission Tomography (PET) Scans. In the absence of an NCD, coverage determinations for all oncologic and non-oncologic uses of PET that are not included in another NCD under section 220.6 will be made by the Medicare Administrative Contractors under section 1862(a)(1)(A) of the Social Security Act. All PET indications currently covered or non-covered under NCDs under section 220.6 remain unchanged and MACs shall not alter coverage for indications covered under NCDs.