

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11429	Date: May 23, 2022
	Change Request 12607

Transmittal 11263, dated February 10, 2022, are being rescinded and replaced by Transmittal 11429, dated, May 23, 2022 to extend the implementation date to January 3, 2023. All other information remains the same.

SUBJECT: Revisions to National Coverage Determination (NCD) 240.2 (Home Use of Oxygen) and 240.2.2 (Home Oxygen Use for Cluster Headache)

I. SUMMARY OF CHANGES: The purpose of the Change Request is to revise Section 240.2 and Section 240.2.2 of the National Coverage Determination (NCD) Manual (Pub. 100-03), Chapter 1, Part 4, and to inform the Medicare Administrative Contractors (MAC)s of the changes associated with these NCDs effective September 27, 2021. The Centers for Medicare & Medicaid Services finalized revisions to two separate, but medically related, NCDs for oxygen therapy and oxygen equipment in the home.

Effective for claims with dates of service on or after September 27, 2021, CMS is revising NCD 240.2, Home Use of Oxygen, to nationally expand patient access to oxygen and oxygen equipment in the home. Oxygen therapy and oxygen equipment is nationally covered in the home for acute or chronic conditions, short or long term, when the patient exhibits hypoxemia, as defined in Subsection B of the revised NCD. Initial claims for oxygen therapy for patients exhibiting hypoxemia must be based on the results of a clinical test that has been ordered and evaluated by the treating practitioner. Secondly, the revised NCD identifies circumstances of non-coverage of home oxygen and oxygen equipment. Thirdly, MACs may determine that coverage of home oxygen and oxygen equipment is reasonable and necessary for patients with a medical need who are not exhibiting hypoxemia (as defined in Subsection B of the NCD) and who are not otherwise precluded by nationally non-covered indications described in Subsection C of the NCD.

In addition, CMS is removing NCD 240.2.2, ending coverage with evidence development for home use of oxygen to treat cluster headache, and allowing the MACs to make coverage determinations regarding the use of home oxygen and oxygen equipment for patients with cluster headaches (as allowed under Section D of the revised NCD 240.2).

The Federal government creates NCDs that are binding on the MACs who review and/or adjudicate claims, make coverage determinations, and/or payment decisions, and also binds quality improvement organizations, qualified independent contractors, the Medicare appeals council, and Administrative Law Judges (ALJs) (see 42 Code of Federal Regulations (CFR) section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: September 27, 2021

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

IMPLEMENTATION DATE: January 3, 2023 - Extended in Correction CR from original implementation date of June 14, 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	20/30.6/Oxygen and Oxygen Equipment
D	20/100.2.3/ Evidence of Medical Necessity for Oxygen

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: 11429	Date: May 23, 2022	Change Request: 12607
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SUBJECT: Revisions to National Coverage Determination (NCD) 240.2 (Home Use of Oxygen) and 240.2.2 (Home Oxygen Use for Cluster Headache)

EFFECTIVE DATE: September 27, 2021

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I. GENERAL INFORMATION

A. Background: Medicare previously issued a NCD providing coverage of home oxygen and oxygen equipment only for patients with significant chronic hypoxemia who met the specified medical documentation, laboratory evidence, and health conditions of Section 240.2, Home Use of Oxygen, of the NCD Manual (Pub 100-03), Chapter 1, Part 4. Also, The Centers for Medicare & Medicaid Services (CMS) reconsidered NCD 240.2 in 2011, and specified in Section 240.2.2, Home Oxygen Use to Treat Cluster Headache, that Medicare provided coverage for the home use of oxygen for cluster headaches through Coverage with Evidence Development (CED).

In August 2020, CMS opened NCD 240.2.2 based on a formal request to reconsider Medicare's coverage of the home use of oxygen for cluster headaches. In addition to the formal request, lessons learned from the COVID Public Health Emergency (PHE) compelled CMS to reconsider the current coverage policy at NCD 240.2 to ensure that Medicare beneficiaries have access to home oxygen.

B. Policy: Effective for claims with dates of service on or after September 27, 2021, CMS is removing NCD 240.2.2 in the Medicare NCD Manual, ending CED, and allowing the Medicare Administrative Contractors (MACs) to make coverage determinations regarding the use of home oxygen and oxygen equipment for cluster headaches (as allowed under subsection D of the revised NCD 240.2).

In addition, CMS is revising NCD 240.2, Home Use of Oxygen, in the Medicare NCD Manual to nationally expand patient access to oxygen therapy and oxygen equipment in the home. Oxygen therapy and oxygen equipment is covered in the home for acute or chronic conditions, short or long-term, when the patient exhibits hypoxemia as defined in Subsection B of the revised NCD 240.2. Initial claims for oxygen therapy for hypoxemic patients must be based on the results of a clinical test that has been ordered and evaluated by the treating practitioner. Secondly, the revised NCD 240.2, Home Use of Oxygen identifies circumstances of non-coverage of home oxygen and oxygen equipment. Thirdly, the MAC may determine that coverage of home oxygen and oxygen equipment is reasonable and necessary for patients with a medical need who are not exhibiting hypoxemia (as defined Subsection B of the NCD) and who are not otherwise precluded by nationally non-covered indications described in Subsection C of the NCD.

Medical documentation requirements are not contained within the revised NCDs. The absence of medical documentation in these revised NCDs does not otherwise remove or modify Medicare requirements of the CMN form 484 itself or other medical documentation requirements under other existing authorities.

This Change Request (CR) will implement revisions to Section 30.6 Oxygen and Oxygen Equipment and remove Section 100.2.3 Evidence of Medical Necessity for Oxygen of Chapter 20, Durable Medical Equipment, Prosthetics, Orthotics, & Supplies (DMEPOS) in the Claims Processing Manual to correspond

to the revised NCDs described above.

CMS notes that the changes to NCD 240.2 do not affect either Section 240.2.1, Home Use of Oxygen in Approved Clinical Trials, or Section 20.29, Hyperbaric Oxygen Therapy, of the NCD Manual.

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	
12607 - 04.1	<p>Effective for claims with dates of service on or after September 27, 2021, contractors shall remove any and all NCD editing related to home oxygen use to treat cluster headaches (including those related to the Healthcare Common Procedure Coding System (HPCPS) Codes, International Classification of Diseases (ICD-10) Codes, G-Codes, Modifiers, and Clinical Trial Numbers described or referenced in CMS Transmittal 2465/ CR 7820).</p> <p>***NOTE*** Refer to NCD 100-03, Chapter 1, Part 4, Section 240.2.2 of the NCD Manual.</p>				X					
12607 - 04.1.1	<p>Contractors shall not search their files, but contractors shall adjust claims brought to their attention.</p>				X					
12607 - 04.2	<p>Effective for claims with dates of service on or after September 27, 2021, contractors shall remove any and all NCD editing that would be non-congruent with the revised NCD related to Home Use of Oxygen. Contractors shall not search their files, but contractors will adjust claims brought to their attention.</p> <p>***NOTE*** Refer to NCD 100-03, Chapter 1, Part 4, Section 240.2 of the NCD</p>				X					

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	Manual.									
12607 - 04.2.1	Contractors shall not search their files, but contractors shall adjust claims brought to their attention.				X					
12607 - 04.3	In addition to the IOM revisions included in this transmittal, contractors shall be aware of the revised NCD instructions/policies described in 100-03, Chapter 1, Part 4, Section 240.2 and 240.2.2 of the NCD Manual.				X					

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12607 - 04.4	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	

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:
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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 , Heather Hostetler, 410-786-7515 or heather.hostetler@cms.hhs.gov , Daniel Feller, 410-786-6913 or Daniel.Feller@cms.hhs.gov , Patricia Brocato-Simons, 410-786-0261 or patricia.brocato-simons@cms.hhs.gov

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

30.6 - Oxygen and Oxygen Equipment

(Rev. 11429; Issued: 05-23-22; Effective: 09-27-21; Implementation: 01-03-23)

For oxygen and oxygen equipment, A/B MACs (A) and (HHH), and DME MACs pay a monthly fee schedule amount per beneficiary. Unless otherwise noted below, the fee covers equipment, contents and supplies. Payment is not made for purchases of this type of equipment.

When an inpatient is not entitled to Part A, payment may not be made under Part B for DME or oxygen provided in a hospital or SNF. (See the Medicare Benefit Policy Manual, Chapter 15) Also, for outpatients using equipment or receiving oxygen in the hospital or SNF and not taking the equipment or oxygen system home, the fee schedule does not apply.

There are a number of billing considerations for oxygen claims. The chart in [§130.6](#) indicates what amounts are payable under which situations.

Home Use of Oxygen

Effective for claims with dates of service on or after September 27, 2021, contractors shall be aware that the Centers for Medicare & Medicaid Services has reconsidered and revised National Coverage Determination (NCD) for Home Use of Oxygen (240.2). Claims for home use of oxygen and oxygen equipment must meet the coverage requirements described under Chapter 1, Section 240.2, Publication 100-03 of the NCD Manual.

Home Oxygen Use to Treat Cluster Headache

Effective for claims *between* February 14, 2011 *and September 26, 2021*, payment for the home use of oxygen and oxygen equipment when related to the treatment of cluster headaches is covered under a National Coverage Determination (NCD). For more information, refer to chapter 1, section 240.2.2, Publication 100-03, of the National Coverage Determinations Manual.

Effective for claims with dates of service on or after September 27, 2021, contractors shall be aware that the Centers for Medicare & Medicaid Services removed the Coverage with Evidence Development (CED) NCD for Home Oxygen Use to Treat Cluster Headache (240.2.2) in Chapter 1, Section 240.2.2, Publication 100-03 of the NCD Manual. In the absence of an NCD, coverage determinations will be made by the Medicare Administrative Contractors under section 1862(a)(1)(A) of the Social Security Act, as allowed and described in Chapter 1, Section 240.2 (Home Use of Oxygen), Subsection D, of Publication 100-03 of the NCD Manual.