

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	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Transmittal 11263, dated February 10, 2022, are being rescinded and replaced by Transmittal 11429, dated, May 23, 2022 to extend the implementation date to January 3, 2023.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	1/240.2/Home Use of Oxygen
R	1/240.2.2/Home Oxygen Use to Treat Cluster Headache (CH)

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: 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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IMPLEMENTATION DATE: January 3, 2023 - Extended in Correction CR from original implementation date of June 14, 2022

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 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 Section B, Nationally Covered Indications. 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 modified 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 in the NCD) and that are not otherwise precluded by nationally non-covered indications described in 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 Certificate of Medical Necessity (CMN) form 484 itself or other medical documentation requirements under other existing authorities.

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.

For the corresponding claims processing instructions related to this revised NCD, refer to Chapter 20, Durable Medical Equipment, Prosthetics, Orthotics, & Supplies (DMEPOS) of the Claims Processing Manual. Pub. 100-04.

II. BUSINESS REQUIREMENTS TABLE

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

Number	Requirement	Responsibility										
		A/B MAC			D M E M A C S	Shared- System Maintainers				Other		
		A	B	H H H		F I S S	M C S	V M S	C W F			
12607 - 03.1	Effective for claims with dates of service on or after September 27, 2021, Medicare will no longer have a national coverage policy for home oxygen use to treat cluster headaches. Contractors shall be aware that in the absence of an NCD, coverage determinations are made by the Medicare Administrative Contractors, as allowed and described in Subsection D of Section 240.2 Home Use of Oxygen of the Medicare NCD Manual (Pub 100-03). Section 240.2.2 (Home Oxygen Use to Treat Cluster Headache (CH)) of the Medicare National Coverage Determinations Manual (Pub 100-03), Chapter 1, Part 4.				X							
12607 - 03.2	Effective for claims with dates of service on or after September 27, 2021, contractors shall be aware that 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 Section 240.2 Home Use of Oxygen of the Medicare National Coverage Determinations Manual (Pub 100-03), Chapter 1, Part 4. Coverage is subject to the conditions and requirements described in the revised NCD.				X							
12607 - 03.3	Effective for claims with dates of service on or after September 27, 2021, contractors shall be aware that oxygen therapy and oxygen equipment is not covered in the home for: <ul style="list-style-type: none"> • Angina pectoris in the absence of hypoxemia • Breathlessness without cor pulmonale or evidence of hypoxemia 				X							

Number	Requirement	Responsibility									
		A/B MAC			D M E M A C	Shared-System Maintainers				Other	
		A	B	H H H		F I S S	M C S	V M S	C W F		
	<ul style="list-style-type: none"> Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities Terminal illnesses unless they affect the ability to breathe <p>Section 240.2 Home Use of Oxygen of the Medicare National Coverage Determinations Manual (Pub 100-03), Chapter 1, Part 4.</p>										
12607 - 03.4	<p>Effective for claims with dates of service on or after September 27, 2021, contractors shall be aware that coverage determinations are made by the Medicare Administrative Contractors for coverage of oxygen therapy and oxygen equipment in the home for patients who do not exhibit hypoxemia, as defined in the revised NCD, and are not excluded as non-covered, as described in the revised NCD. Section 240.2 Home Use of Oxygen of the Medicare National Coverage Determinations Manual (Pub 100-03), Chapter 1, Part 4.</p>				X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility									
		A/B MAC			D M E M A C	C E D I					
		A	B	H H H							
12607 - 03.5	<p>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.</p>				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): Daniel Feller, 410-786-6913 or Daniel.Feller@cms.hhs.gov , Patricia Brocato-Simons, 410-786-0261 or patricia.brocatosimons@cms.hhs.gov , Heather Hostetler, 410-786-7515 or heather.hostetler@cms.hhs.gov , Wanda Belle, 410-786-7491 or wanda.belle@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

240.2 – Home Use of Oxygen

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

A. General

When used in the home, oxygen and oxygen equipment can make meaningful contributions to the treatment of patients with both acute and chronic conditions who require the medical gas on either a short- or long-term basis.

B. Nationally Covered Indications

Effective September 27, 2021, 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 below.

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*. *Such a test is usually in the form of a measurement of the partial pressure of oxygen (PO₂) in arterial blood.* A measurement of arterial oxygen saturation obtained by ear or pulse oximetry, however, is also acceptable when ordered and evaluated by *the treating practitioner* and performed under his or her supervision or when performed by a qualified provider or supplier of laboratory services. A durable medical equipment (DME) supplier is not considered a qualified provider or supplier of laboratory services for purposes of *this National Coverage Determination (NCD)*. This prohibition does not extend to the results of blood gas tests conducted by a hospital certified to do such tests.

When the arterial blood gas and the oximetry studies are both used to document the need for home oxygen therapy and the results are conflicting, the arterial blood gas study is the preferred source of documenting medical need.

Required qualifying arterial blood gas or oximetry studies must be performed at the time of need. The time of need is defined as during the patient's illness when the presumption is that the provision of oxygen in the home setting will improve the patient's condition. For an inpatient hospital patient the time of need is within 2 days of discharge. For those patients whose initial oxygen prescription does not originate during an inpatient hospital stay, the time of need is during the period when the treating practitioner notes signs and symptoms of illness that can be relieved by oxygen in the patient who is to be treated at home.

Patients exhibiting hypoxemia are defined using the clinical criteria below:

Group 1:

- An arterial PO₂ at or below 55 mm Hg, or an arterial oxygen saturation at or below 88%, taken at rest, breathing room air; *or*
- An arterial PO₂ at or below 55 mm Hg, or an arterial oxygen saturation at or below 88%, taken during sleep for a patient who demonstrates an arterial PO₂ at or above 56 mm Hg, or an arterial oxygen saturation at or above 89%, while awake; or a greater than normal fall in oxygen level during sleep (a decrease in arterial PO₂ more than 10 mm Hg, or decrease in arterial oxygen saturation more than 5%) associated with symptoms or signs reasonably attributable to hypoxemia (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia). In either of these cases, coverage is provided only for use of oxygen during sleep, and then only one type of unit will be covered. Portable oxygen, therefore, would not be covered in this situation; *or*,

- An arterial PO₂ at or below 55 mm Hg or an arterial oxygen saturation at or below 88%, taken during exercise *[defined as either the functional performance of the patient or a formal exercise test]*, for a patient who demonstrates an arterial PO₂ at or above 56 mm Hg, or an arterial oxygen saturation at or above 89%, during the day while at rest. In this case, supplemental oxygen is provided for during exercise if the use of oxygen improves the hypoxemia that was demonstrated during exercise when the patient was breathing room air.

Group II: Coverage is available for patients whose arterial PO₂ is 56-59 mm Hg or whose arterial blood oxygen saturation is 89%, if there is:

- Dependent edema suggesting congestive heart failure; *or*,
- Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVFL); *or*,
- Erythrocythemia with a hematocrit greater than 56%.

In reviewing the arterial PO₂ levels and the arterial oxygen saturation percentages specified above, the *Medicare Administrative Contractors (MACs)* must take into account variations in oxygen measurements that may result from such factors as the patient's age, *the patient's skin pigmentation*, the altitude level, or the patient's decreased oxygen carrying capacity.

C. Nationally Non-Covered Indications

Effective September 27, 2021, the Centers for Medicare & Medicaid Services will not cover oxygen therapy and oxygen equipment in the home in the following circumstances:

- Angina pectoris in the absence of hypoxemia. This condition is generally not the result of a low oxygen level in the blood, and there are other preferred treatments; *or*,
- Breathlessness without cor pulmonale or evidence of hypoxemia. Although intermittent oxygen use is sometimes prescribed to relieve this condition, it is potentially harmful and psychologically addicting; *or*,
- Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities. There is no evidence that increased PO₂ improves the oxygenation of tissues with impaired circulation; *or*,
- Terminal illnesses *unless they* affect the *ability to breathe*.

D. Other

Effective September 27, 2021, the MAC may determine reasonable and necessary coverage of oxygen therapy and oxygen equipment in the home for patients who are not described in subsection B or precluded by subsection C of this NCD. Initial coverage for patients with other conditions may be limited to the shorter of 120 days or the number of days included in the practitioner prescription at MAC discretion. Oxygen coverage may be renewed if deemed medically necessary by the MAC.

MACs may also allow beneficiaries who are mobile in the home and would benefit from the use of a portable oxygen system in the home to qualify for coverage of a portable oxygen system either (1) by itself, or, (2) to use in addition to a stationary oxygen system.

(This NCD last revised September 2021.)

(See §280.1 and the Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §110.)

240.2.2 Home Oxygen Use to Treat Cluster Headache

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

Effective September 27, 2021, the Centers for Medicare & Medicaid Services removed the national coverage determination (NCD) for home oxygen use to treat cluster headaches. 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.