

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 11587	Date: September 8, 2022
	Change Request 12877

SUBJECT: Revision to National Coverage Determination (NCD) 240.2 (Home Use of Oxygen) to Align to 1834(a)(5)(E) of the Social Security Act

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to revise 240.2 of the National Coverage Determination (NCD) Manual, Publication (Pub.) 100-03, Chapter 1, Part 4, and to inform the Medicare Administrative Contractors (MACs) of the changes associated with this NCD, effective September 27, 2021, as amended July 8, 2022.

On September 27, 2021, the Centers for Medicare & Medicaid Services (CMS) revised NCD 240.2 (Home Use of Oxygen) and NCD 240.2.2 (Home Oxygen Use for Cluster Headache). On February 10, 2022, CMS issued Transmittal 11263 to implement the revised coverage policies in Change Request (CR) 12607. On May 23, 2022, CMS rescinded Transmittal 11263 and replaced it with Transmittal 11429, to extend the implementation date of CR 12607 to January 3, 2023. All other information in Transmittal 11429 remained the same as in Transmittal 11263.

On July 8, 2022, CMS reconsidered and amended NCD 240.2 narrowly in order to conform the period of initial coverage described in section D with the specific time period specified in §1834(a)(5)(E) of the Social Security Act. Specifically, CMS amended the period of initial coverage for patients in section D of NCD 240.2 from 120 days to 90 days, in order to align with the 90-day statutory time period. No other part of NCD 240.2 was reconsidered or amended. Since §1834(a)(5)(E) of the Social Security Act was the continuous controlling authority, the coverage policies in NCD 240.2 remain effective as of September 27, 2021.

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

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

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

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EFFECTIVE DATE: September 27, 2021

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I. GENERAL INFORMATION

A. Background: On September 27, 2021, the Centers for Medicare & Medicaid Services (CMS) revised NCD 240.2 (Home Use of Oxygen) and NCD 240.2.2 (Home Oxygen Use for Cluster Headache). On February 10, 2022, CMS issued Transmittal 11263 to implement the revised coverage policies in Change Request (CR) 12607. On May 23, 2022, CMS rescinded Transmittal 11263 and replaced it with Transmittal 11429, to extend the implementation date of CR 12607 to January 3, 2023. All other information in Transmittal 11429 remained the same as in Transmittal 11263.

B. Policy: On July 8, 2022, CMS reconsidered and amended NCD 240.2 narrowly in order to conform the period of initial coverage described in section D with the specific time period specified in §1834(a)(5)(E) of the Social Security Act. Specifically, CMS amended the period of initial coverage for patients in section D of NCD 240.2 from 120 days to 90 days, in order to align with the 90-day statutory time period. No other part of NCD 240.2 was reconsidered or amended. Since §1834(a)(5)(E) of the Social Security Act was the continuous controlling authority, the coverage policies in NCD 240.2 remain effective as of September 27, 2021.

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	
12877.1	Effective for claims with dates of service on or after September 27, 2021, contractors shall be aware that the MAC may determine reasonable and necessary coverage of oxygen therapy and oxygen equipment in the home for patients who are not described in section B or precluded by section C of NCD 240.2. Initial coverage for patients with other conditions may be limited to the shorter of 90 days or the number of days included in the practitioner prescription at MAC discretion.				X					

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
	Oxygen coverage may be renewed if deemed medically necessary by the MAC.									

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
12877.2	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:

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

V. CONTACTS

Pre-Implementation Contact(s): Patricia Brocato-Simons, 410-786-0261 or patricia.brocato-simons@cms.hhs.gov , Daniel Feller, 410-786-6913 or Daniel.Feller@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.11587; Issued: 09-08-22; 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

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 *I*:

- 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

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

The MAC may determine reasonable and necessary coverage of oxygen therapy and oxygen equipment in the home for patients who are not described in section B or precluded by section C of this NCD. Initial coverage for patients with other conditions may be limited to the shorter of **90** 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 *was* last *reviewed July 2022*.)

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