

Home Use of Oxygen in Approved Clinical Trials (NCD 240.2.1)

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- Related Medicare Advantage Policy Guidelines**
- [Continuous Positive Airway Pressure \(CPAP\) Therapy for Obstructive Sleep Apnea \(OSA\) \(NCD 240.4\) and Other Respiratory Assist Devices \(RAD\)](#)
 - [Home Oxygen Use to Treat Cluster Headache \(CH\) \(NCD 240.2.2\)](#)
 - [Home Use of Oxygen \(NCD 240.2\)](#)

- Related Medicare Advantage Coverage Summaries**
- [Durable Medical Equipment \(DME\), Prosthetics, Corrective Appliances/Orthotics \(Non-Foot Orthotics\) and Medical Supplies Grid](#)
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Policy Summary

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Overview

Oxygen is a colorless, odorless gas that comprises 21 percent of the atmospheric gases at sea level. Historically, long term supplemental oxygen has been administered in higher than atmospheric concentrations to patients with chronic hypoxemia, generally resulting from cardiac and/or pulmonary disease. The need for supplemental oxygen is assessed by direct or indirect measurement of the partial pressure of oxygen (conventionally expressed in millimeters of mercury, mmHg) and the oxygen saturation of hemoglobin in arterial blood (expressed as a percent). Chronic oxygen therapy is generally administered via nasal cannulae, face mask, or tracheostomy, from a stationary or portable oxygen tank or an oxygen concentrator.

The medical literature documents health benefits as well as serious adverse events associated with supplemental oxygen use. In this light, it is clear that the decision to initiate, continue, or discontinue the use of supplemental oxygen should be guided by high quality scientific evidence.

Guidelines

Nationally Covered Indications

Effective for services performed on or after March 20, 2006 the home use of oxygen is covered for those beneficiaries with arterial oxygen partial pressure measurements from 56 to 65 mmHg or oxygen saturation at or above 89% who are enrolled subjects in clinical trials approved by the Centers for Medicare & Medicaid Services and sponsored by the National Heart, Lung & Blood Institute (NHLBI).

Oxygen for participants in a Long Term Oxygen Therapy (LTOT) Trial is provided under special coverage rules. Reimbursement is only available for beneficiaries who are enrolled in an approved clinical trial. CMS maintains a list of policies that require study

participation as a condition of coverage on the CMS web site. For each policy the approved studies are listed and a link provided to the study on the clinicaltrials.gov web site. The clinicaltrials.gov identifier number required on each claim is listed on this site.

Claims for LTOT Trial participants that meet the approved clinical trial and testing requirements described in the Coverage Indications, Limitations and/or Medical Necessity section of the Local Coverage Determinations and Articles must be submitted with the Q0 (Q-zero) modifier. Claims for oxygen that do not meet these criteria must not use this modifier.

Other

This policy does not alter Medicare coverage for items and service that may be covered or non-covered according to the existing national coverage determination for the home use of oxygen provided outside the context of approved clinical trials (National Coverage Determination Manual, section 240.2 and 310.1).

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

Coding Clarification: CMS, as part of the national coverage determination (NCD) may determine coverage of an item or service only in the context of a clinical study. The clinical trial identifier number is required for all items/services provided in relation to participation in a clinical trial, clinical study, or registry that may result from coverage with evidence development (CED). Specifically, include the clinical trial identifier number if:

- The beneficiary is enrolled in an approved clinical trial; and
- The claim is for the investigational item or service, and/or,
- The costs are related to the investigational item or service, and/or
- The costs are related to routine care for the condition in the clinical trial.

See the related [MLN Matters](#).

HCPCS Code	Description
E0424	Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0425	Stationary compressed gas system, purchase; includes regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing (Not covered by Medicare)
E0430	Portable gaseous oxygen system, purchase; includes regulator, flowmeter, humidifier, cannula or mask, and tubing (Not covered by Medicare)
E0431	Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing
E0433	Portable liquid oxygen system, rental; home liquefier used to fill portable liquid oxygen containers, includes portable containers, regulator, flowmeter, humidifier, cannula or mask and tubing, with or without supply reservoir and contents gauge
E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing
E0435	Portable liquid oxygen system, purchase; includes portable container, supply reservoir, flowmeter, humidifier, contents gauge, cannula or mask, tubing and refill adaptor (Not covered by Medicare)
E0439	Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, & tubing
E0440	Stationary liquid oxygen system, purchase; includes use of reservoir, contents indicator, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing (Not covered by Medicare)

HCPCS Code	Description
E0441	Stationary oxygen contents, gaseous, 1 month's supply = 1 unit
E0442	Stationary oxygen contents, liquid, 1 month's supply = 1 unit
E0443	Portable oxygen contents, gaseous, 1 month's supply = 1 unit
E0444	Portable oxygen contents, liquid, 1 month's supply = 1 unit
E0445	Oximeter device for measuring blood oxygen levels noninvasively
E0446	Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories (Not covered by Medicare)
E0447	Portable oxygen contents, liquid, 1 month's supply = 1 unit, prescribed amount at rest or nighttime exceeds 4 liters per minute (LPM) (Effective 01/01/2019)
E1390	Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate
E1391	Oxygen concentrator, dual delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate, each
E1392	Portable oxygen concentrator, rental
E1405	Oxygen and water vapor enriching system with heated delivery
E1406	Oxygen and water vapor enriching system without heated delivery
K0738	Portable gaseous oxygen system, rental; home compressor used to fill portable oxygen cylinders; includes portable containers, regulator, flowmeter, humidifier, cannula or mask, and tubing
Accessories	
A4575	Topical hyperbaric oxygen chamber, disposable (Not covered by Medicare)
A4606	Oxygen probe for use with oximeter device, replacement
A4608	Transtracheal oxygen catheter, each
A4615	Cannula, nasal
A4616	Tubing (oxygen), per foot
A4617	Mouth piece
A4619	Face tent
A4620	Variable concentration mask
A7525	Tracheostomy mask, each
A9900	Miscellaneous DME supply, accessory, and/or service component of another HCPCS code
E0455	Oxygen tent, excluding croup or pediatric tents
E0555	Humidifier, durable, glass or autoclavable plastic bottle type, for use with regulator or flowmeter
E0580	Nebulizer, durable, glass or autoclavable plastic, bottle type, for use with regulator or flowmeter
E1352	Oxygen accessory, flow regulator capable of positive inspiratory pressure
E1353	Regulator
E1354	Oxygen accessory, wheeled cart for portable cylinder or portable concentrator, any type, replacement only, each
E1355	Stand/rack
E1356	Oxygen accessory, battery pack/cartridge for portable concentrator, any type, replacement only, each
E1357	Oxygen accessory, battery charger for portable concentrator, any type, replacement only, each
E1358	Oxygen accessory, dc power adapter for portable concentrator, any type, replacement only, each (Not Covered by Medicare)

Modifier	Description
EY	No physician or other licensed health care provider order for this item

Modifier	Description
QE	Prescribed amount of oxygen is less than 1 liter per minute (LPM)
QF	Prescribed amount of oxygen is greater than 4 liter per minute (LPM) and portable oxygen is also prescribed
QG	Prescribed amount of oxygen is greater than 4 liters per minute (LPM) and portable oxygen is not prescribed
QH	Oxygen conserving device is being used with an oxygen delivery system
RA	Replacement of a DME item
RR	Rental (use the RR modifier when DME is to be rented)
CED Only	
Q0	Investigational clinical service provided in a clinical research (Outpatient only)

Condition Code	Description
CED Only	
30	Qualifying clinical trial

Diagnosis Code	Description
CED Only	
Z00.6	Encounter for examination for normal comparison and control in clinical research program (In any position)

Questions and Answers

1	Q:	Have you verified the CPT/HCPCS code(s) on your claim may have limited coverage under CED (Coverage with Evidence Development)?
	A:	<ul style="list-style-type: none"> If no, clinical trial number, modifier Q0 and diagnosis code Z00.6 should not be submitted. If yes, the three requirements listed above are required. Claims without the required information will be denied.

References

CMS National Coverage Determinations (NCDs)

[NCD 240.2.1 Home Use of Oxygen in Approved Clinical Trials](#)

Reference NCDs: [NCD 240.2 Home Use of Oxygen](#), [NCD 240.2.2 Home Oxygen Use to Treat Cluster Headaches \(CH\)](#)

CMS Local Coverage Determinations (LCDs) and Articles

L33797 Oxygen and Oxygen Equipment	A52514 Oxygen and Oxygen Equipment - Policy Article	CGS	AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV
		Noridian	AK, AS, AZ, CA, CT, DC, DE, GU, HI, IA, ID, KS, MA, MD, ME, MO, MP, MT, ND, NE, NH, NJ, NV, NY, OR, PA, RI, SD, UT, VT, WA, WY

CMS Benefit Policy Manual

[Chapter 15: § 110 Durable Medical Equipment - General](#)

CMS Claims Processing Manual

[Chapter 10: § 10B Services to Include on the Claim for Home Health Benefits, § 10.1.10.4 Claim Submission and Processing](#)
[Chapter 20: § 30.6 Oxygen and Oxygen Equipment, § 60 Payment for Delivery and Service Charges for Durable Medical Equipment, § 100.2.3 Evidence of Medical Necessity for Oxygen, § 100.2.3.1 Scheduling and Documenting Recertifications of Medical Necessity for Oxygen, § 100.2.3.2 HHA Recertification for Home Oxygen Therapy, § 100.2.3.3 Contractor Review of Oxygen Certifications, § 130.6 Billing for Oxygen and Oxygen Equipment, § 130.6.1 Oxygen Equipment and Contents Billing Chart](#)

CMS Transmittal(s)

[Transmittal 57, Change Request 4389, Dated 05/26/2006 \(Home Use of Oxygen in Approved Clinical Trials\)](#)
[Transmittal 961, Change Request 4389, Dated 05/26/2006 \(Home Use of Oxygen in Approved Clinical Trials\)](#)

MLN Matters

[Article MM5790, Use of an 8-Digit Registry Number on Clinical Trial Claims](#)
[Article MM8401, Revised, Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims](#)
[Article SE1344, Further Information on Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims](#)

Guideline History/Revision Information

Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

Date	Summary of Changes
04/01/2021	Template Update <ul style="list-style-type: none">Reformatted policy; transferred content to new template
12/09/2020	Supporting Information <ul style="list-style-type: none">Updated <i>References</i> section to reflect the most current information; no change to guidelinesArchived previous policy version MPG142.05

Purpose

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers' submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as NCDs, LCDs, LCAs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

Terms and Conditions

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines use Current Procedural Terminology (CPT®), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT® or other sources are for definitional purposes only and do not imply any right to reimbursement or guarantee claims payment.

Medicare Advantage Policy Guidelines are the property of UnitedHealthcare. Unauthorized copying, use, and distribution of this information are strictly prohibited.

*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the [Administrative Guide](#).