

Home Oxygen Use to Treat Cluster Headache (CH) (NCD 240.2.2)

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[↪ Terms and Conditions](#)

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Related Medicare Advantage Policy Guidelines

- [Home Use of Oxygen \(NCD 240.2\)](#)
- [Home Use of Oxygen in Approved Clinical Trials \(NCD 240.2.1\)](#)

Related Medicare Advantage Coverage Summaries

- [Durable Medical Equipment \(DME\), Prosthetics, Corrective Appliances/Orthotics \(Non-Foot Orthotics\) and Medical Supplies Grid](#)
- [Oxygen for Home Use](#)

Policy Summary

[↪ See Purpose](#)

Overview

Cluster headache (CH), as described in Harrison’s “Principles of Internal Medicine” 16th edition, is an episodic (most common), or chronic unilateral headache syndrome that begins with one to three short-lived headaches per day over many weeks followed by a period of remission. There may be a regular recurrence in the vast majority of attacks. When it becomes chronic, it is characterized by the absence of sustained periods of remission. Generally the cause is unknown but associations can occur with alcohol use which is the only known dietary trigger of CH. There are other triggers such as strong odors (mainly solvents and cigarette smoke) and napping. CH is also characterized by unilateral, excruciating pain principally in ocular, frontal, and temporal areas, as well as ipsilateral lacrimation, conjunctival injection, photophobia, and nasal stuffiness. Attacks may happen at precise hours, especially at night.

The medical literature includes anecdotal reports of the use of 100% normobaric oxygen for the treatment of CH. Oxygen is an odorless, colorless gas at room temperature. It can be delivered in a chamber, by compressed air, via oxygen concentrator, or other method. Though often thought of as harmless, oxygen use has been noted to have adverse effects including blindness, pulmonary fibrosis, and suppression of the drive to breathe in patients who have advanced chronic obstructive lung disease. Oxygen is also known to increase fire risk in certain environments. There are a number of drug treatments for CH, including but not limited to IV and sublingual sumatriptan. Effective prophylactic drugs include prednisone, lithium, Methysergide, ergotamine, sodium valproate, and verapamil. At present, there is no curative treatment.

Guidelines

Nationally Covered Indications

Effective for claims with dates of services on or after January 4, 2011, the Centers for Medicare & Medicaid Services (CMS) believes that the available evidence suggests that the home use of oxygen to treat CH is promising and supports further research under §1862(a)(1)(E) of the Social Security Act (the Act) through the Coverage With Study Participation (CSP) form of Coverage With Evidence Development (CED).

The home use of oxygen to treat CH is covered by Medicare only for beneficiaries with CH participating in an approved prospective clinical study comparing normobaric 100% oxygen (NBOT) with at least one clinically appropriate comparator for the treatment of CH. The clinical study must address one or more aspects of the following questions:

- Prospectively, compared to individuals with cluster headache who do not receive NBOT, do Medicare beneficiaries with CH who receive NBOT have improved outcomes as indicated by:
 - Pain relief
 - Time to pain relief
 - Durability of pain relief
- Prospectively, among Medicare beneficiaries with cluster headache, which method of oxygen delivery provides the most benefit as indicated by:
 - Pain relief
 - Time to pain relief
 - Durability of pain relief
- Prospectively, among Medicare beneficiaries with cluster headache, what other factors, if any, predict the patient's response to 100% oxygen therapy as indicated by:
 - Pain relief
 - Time to pain relief
 - Durability of pain relief

Only those beneficiaries diagnosed with the condition of cluster headache are eligible for participation in a clinical study. CMS adopts the diagnostic criteria used by the International Headache Society to form a definitive diagnosis of CH. Therefore, the home use of oxygen to treat CH is covered by Medicare only when furnished to Medicare beneficiaries who have had at least five severe to very severe unilateral headache attacks lasting 15-180 minutes when untreated. (Intensity of pain: Degree of pain usually expressed in terms of its functional consequence and scored on a verbal 5-point scale: 0=no pain; 1=mild pain, does not interfere with usual activities; 2=moderate pain, inhibits but does not wholly prevent usual activities; 3=severe pain, prevents all activities; 4=very severe pain. It may also be expressed on a visual analogue scale.

<http://img.medscape.com/article/742/580/VAS.pdf>.)

The headaches must be accompanied by at least one of the following findings:

- Ipsilateral conjunctival injection and/or lacrimation; or
- Ipsilateral nasal congestion and/or rhinorrhea; or
- Ipsilateral eyelid edema; or
- Ipsilateral forehead and facial sweating; or
- Ipsilateral miosis and/or ptosis; or
- A sense of restlessness or agitation.

The clinical study must adhere to the following standards of scientific integrity and relevance to the Medicare population:

- The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.
- The research study is well supported by available scientific and medical information or it is intended to clarify or establish the health outcomes of interventions already in common clinical use.
- The research study does not unjustifiably duplicate existing studies.
- The research study design is appropriate to answer the research question being asked in the study.
- The research study is sponsored by an organization or individual capable of executing the proposed study successfully.
- The research study is in compliance with all applicable Federal regulations concerning the protection of human subjects found at 45 CFR Part 46. If a study is regulated by the Food and Drug Administration (FDA), it must be in compliance with 21 CFR parts 50 and 56.
- All aspects of the research study are conducted according to appropriate standards of scientific integrity (see <http://www.icmje.org>).
- The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED coverage.
- The clinical research study is not designed to exclusively test toxicity or disease pathophysiology in healthy individuals. Trials of all medical technologies measuring therapeutic outcomes as one of the objectives meet this standard only if the

disease or condition being studied is life threatening as defined in 21 CFR § 312.81(a) and the patient has no other viable treatment options.

- The clinical research study is registered on the ClinicalTrials.gov website by the principal sponsor/investigator prior to the enrollment of the first study subject.
- The research study protocol specifies the method and timing of public release of all prespecified outcomes to be measured including release of outcomes if outcomes are negative or study is terminated early. The results must be made public within 24 months of the end of data collection. If a report is planned to be published in a peer reviewed journal, then that initial release may be an abstract that meets the requirements of the International Committee of Medical Journal Editors (<http://www.icmje.org>). However a full report of the outcomes must be made public no later than three (3) years after the end of data collection.
- The research study protocol must explicitly discuss subpopulations affected by the treatment under investigation, particularly traditionally underrepresented groups in clinical studies, how the inclusion and exclusion criteria effect enrollment of these populations, and a plan for the retention and reporting of said populations on the trial. If the inclusion and exclusion criteria are expected to have a negative effect on the recruitment or retention of underrepresented populations, the protocol must discuss why these criteria are necessary.
- The research study protocol explicitly discusses how the results are or are not expected to be generalizable to the Medicare population to infer whether Medicare patients may benefit from the intervention. Separate discussions in the protocol may be necessary for populations eligible for Medicare due to age, disability or Medicaid eligibility.

Consistent with section 1142 of the Social Security Act, AHRQ supports clinical research studies that CMS determines meet the above-listed standards and address the above-listed research questions.

The diagnosis code(s) for the qualifying cluster headache condition must be included on the claim (reference ICD-10 Codes listed below). The diagnosis code Z00.6 must also be included on the claim for cluster headache if the beneficiary is enrolled in an approved study.

For cluster headache claims there must be information in the medical record justifying:

- Participation in an approved study
- The qualifying diagnosis code(s)

For cluster headache claims, the “clinicaltrials.gov” identifier number of the CMS approved clinical trial must be included on each claim. Claims for oxygen used for the treatment of cluster headaches that meet the approved clinical trial and diagnosis requirements described in the Coverage Indications, Limitations and/or Medical Necessity section of Local Coverage Determinations and Articles must be submitted with the Q0 (Q-zero) modifier. Claims for oxygen used for cluster headaches that do not meet these criteria must not use this modifier.

Nationally Non-Covered Indications

Effective for claims with dates of service on and after January 4, 2011, CMS believes that the evidence does not demonstrate that the home use of oxygen to treat CH improves health outcomes in Medicare beneficiaries with CH. Therefore, the home use of oxygen to treat CH is not reasonable and necessary under 1862(a) (1) (A) of the Act unless provided in the context of an approved clinical study under CED.

Other

This decision does not modify the existing requirements for coverage of the home use of oxygen currently identified in sections 240.2 and 240.2.1 of this manual. Additionally, the scope of the decision does not include any consideration of hyperbaric oxygen for any indication.

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
E0441	Stationary oxygen contents, gaseous, 1 month's supply = 1 unit

Modifier	Description
QF	Prescribed amount of oxygen exceeds 4 liters per minute (LPM) and portable oxygen is prescribed
QG	Prescribed amount of oxygen is greater than 4 liters per minute (LPM)
CED Only	
Q0	Investigational clinical service provided in a clinical research (Outpatient only)

Condition Code	Description
CED Only	
30	Qualifying clinical trial

Place of Service Code	Description
12	Home

Diagnosis Code	Description
Primary	
G44.001	Cluster headache syndrome, unspecified, intractable
G44.009	Cluster headache syndrome, unspecified, not intractable
G44.011	Episodic cluster headache, intractable
G44.019	Episodic cluster headache, not intractable
G44.021	Chronic cluster headache, intractable
G44.029	Chronic cluster headache, not intractable
Secondary	
Z00.6	Encounter for examination for normal comparison and control in clinical research program
CED Only	
Z00.6	Encounter for examination for normal comparison and control in clinical research program

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 240.2.2 Home Oxygen Use to Treat Cluster Headache \(CH\)](#)

Reference NCDs: [NCD 240.2 Home Use of Oxygen](#), [NCD 240.2.1 Home Use of Oxygen in Approved Clinical Trials](#)

CMS Local Coverage Determinations (LCDs) and Articles

LCD	Article	Contractor	DME MAC
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; § 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 130, Change Request 7235, Dated 01/14/2011 \(Home Oxygen Use to Treat Cluster Headache \(CH\)\)](#)

[Transmittal 2465, Change Request 7820, Dated 05/11/2012 \(Assigned Codes for Home Oxygen Use for Cluster Headache \(CH\) in a Clinical Trial \(ICD-10\)\)](#)

MLN Matters

[Article MM5790, Use of an 8-Digit Registry Number on Clinical Trial Claims](#)

[Article MM7235, Revised, Home Oxygen Use to Treat Cluster Headache \(CH\)](#)

[Article MM7820, Assigned Codes for Home Oxygen Use for Cluster Headache \(CH\) in a Clinical Trial \(ICD-10\)](#)

[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 MPG139.05

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.

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*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](#).