CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-03 Medicare National Coverage Determinations	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 130	**Date: January 14, 2011**
	Change Request 7235

SUBJECT: Home Oxygen Use to Treat Cluster Headache (CH)

I. SUMMARY OF CHANGES: After careful reconsideration, effective for claims with dates of service on and after January 4, 2011, Medicare will allow for coverage of home use of oxygen to treat Medicare beneficiaries diagnosed with CH when beneficiaries are enrolled in clinical studies that are approved by CMS for the purpose of gaining further evidence. This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 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: January 4, 2011
IMPLEMENTATION DATE: February 15, 2011

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
N	1/Table of Contents
N	1/240.2.2/Home Oxygen Use to Treat Cluster Headache (CH) - Effective January 4, 2011

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; Contractor activities are to be carried out within their operating budgets.

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

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

Attachment - Business Requirements

Pub. 100-03	Transmittal: 130	Date: January 14, 2011	Change Request: 7235

SUBJECT: Home Oxygen Use to Treat Cluster Headache (CH)

Effective Date: **January 4, 2011**

Implementation Date: February 15, 2011

I. GENERAL INFORMATION

A. Background: Medicare has a National Coverage Determination (NCD) on the home use of oxygen (240.2 dated October 1993) that states it is reasonable and necessary for patients with significant hypoxemia, as evidenced by a blood gas study or a measurement of arterial oxygen saturation. In March 2006, an internally generated NCD at Publication (Pub.) 100-03, chapter 1, section 240.2.1, led to coverage with study participation for those beneficiaries who did not qualify for coverage based on the initial criteria for hypoxemia established in NCD Pub. 100-03,Chapter 1, section 240.2. This expansion in coverage requires that beneficiaries be enrolled subjects in clinical trials sponsored by the National Heart, Lung, and Blood Institute. Current national policy states that the home use of oxygen is reasonable and necessary for only those patients diagnosed with significant hypoxemia in conjunction with certain health conditions.

In April 2010, the Centers for Medicare & Medicaid Services (CMS) received an external request from the American Headache Society and the American Academy of Neurology requesting an NCD to determine if home oxygen therapy is reasonable and necessary for Medicare patients diagnosed with cluster headache (CH). The requestors asked that CMS issue a revision to its current national coverage policy that would add CH as a covered indication for home oxygen therapy.

B. Policy: After careful reconsideration, effective for claims with dates of service on and after January 4, 2011, Medicare will allow for coverage of home use of oxygen to treat Medicare beneficiaries diagnosed with CH when beneficiaries are enrolled in clinical studies that are approved by CMS for the purpose of gaining further evidence. Medicare will allow for coverage of the following:

Beneficiaries with CH participating in an approved prospective clinical study comparing normobaric 100% oxygen with at least one clinically appropriate comparator for the treatment of CH. The clinical study must address whether home use of oxygen improves Medicare beneficiaries' health outcomes and is subject to the criteria as outlined in Pub. 100-03, of the NCD Manual, chapter 1, section 240.2.2.

NOTE: Contractors shall use existing clinical trial coding conventions to help identify on a claim that the Home use of Oxygen for CH was provided pursuant to a Medicare-approved clinical study under CED, in addition to the ICD-9-CM diagnosis codes for CH (339.00, cluster headache syndrome unspecified, 339.01, cluster headache episodic, and 339.02, cluster headache, chronic), HCPCS code E1399, durable medical equipment, miscellaneous, and place of service (POS) 12, home. The 8-digit clinical trial number is optional.

NOTE: Currently, there are no clinical trials approved or pending approval for the home use of oxygen for CH. CMNs are not required in the context of this clinical trial setting. This is a Part B DME benefit only.

NOTE: There are no updates to the Claims Processing Manual at this time. Contractors should refer to the business requirements below, as well as general clinical trial billing requirements at Pub. 100-03, chapter 1, section 310, and Pub. 100-04, chapter 32, section 69.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7235.1	Effective for claims with dates of service on and after January 4, 2011, Medicare will allow for coverage of home use of oxygen for treatment of CH only for Medicare beneficiaries who are diagnosed with CH and enrolled in an approved clinical trial under CED as specified at Pub. 100-03, NCD Manual chapter 1, section 240.2.2.		X								
7235.2	Contractors shall pay claims with dates of service on or after January 4, 2011, for home use of oxygen for the treatment of CH ONLY if they contain all of the following: -HCPCS code E1399 -CH ICD-9-CM diagnosis code(s) 339.00, 339.01, or 339.02 -Clinical Trial ICD-9-CM diagnosis code V70.7 -Clinical Trial Procedure Code Modifier Q0 -POS 12 (home) 8-digit clinical trial number (optional)		X								
7235.3	Contractors shall deny claims for dates of service on and after January 4, 2011, for home use of oxygen for the treatment of CH that do not contain all of the coding included in BR 7235.2 above using the following messages: CARC 50 - These are non-covered services because this is not deemed a 'medical necessity' by the payer. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present. RARC N386 - This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at http://www.cms.hhs.gov/mcd/search.asp. If you do not have web access, you may contact the contractor to request a copy of the NCD.		X								

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
	Group Code - Patient Responsibility (PR) if ABN/HINN given, otherwise Contractual Obligation (CO) MSN 16.77 – This service/item was not covered because it was not provided as part of a qualifying trial/study. (Este servicio/artículo no fue cubierto porque no estaba incluido como parte de un ensayo clínico/estudio calificado.)										
7235.4	For home oxygen for the treatment of CH claims with dates of service between January 4, 2011, and the implementation date of this CR, contractors shall perform necessary adjustments only when affected claims are brought to their attention.		X								

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
7235.5	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.		X								

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below: N/A

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space: NA

V. CONTACTS

Pre-Implementation Contact(s): Sarah Meisenberg, (coverage), 410-786-5323, sarah.meisenberg@cms.hhs.gov, Pat Brocato-Simons (coverage), 410-786-0261, patricia.brocatosimons@cms.hhs.gov, Bobbett Plummer, DME Clams Processing, 410-786-3321, Bobbett.plummer@cms.hhs.gov.

Post-Implementation Contact(s): Appropriate CMS RO

VI. FUNDING

Section A: For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers*:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: *For Medicare Administrative Contractors (MACs),* include the following statement:

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.

Medicare National Coverage Determinations Manual

Chapter 1, Part 4 (Sections 200 – 310.1)

Coverage Determinations

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(Rev.130, Issued: 01-14-11)

240.2.2 – Home Oxygen Use to Treat Cluster Headache (CH) (Effective January 4, 2011)

240.2.2 – Home Oxygen Use to Treat Cluster Headache (CH) – (Effective January 4, 2011)

(Rev. 130, Issued: 01-14-11, Effective: 01-04-11, Implementation: 02-15-11)

A. General

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.

B. 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:

1. *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:*

    a. *Pain relief*
    b. *Time to pain relief*
    c. *Durability of pain relief*

2. *Prospectively, among Medicare beneficiaries with cluster headache, which method of oxygen delivery provides the most benefit as indicated by:*

    a. *Pain relief*
    b. *Time to pain relief*
    c. *Durability of pain relief*

3. *Prospectively, among Medicare beneficiaries with cluster headache, what other factors, if any, predict the patient's response to 100% oxygen therapy as indicated by:*

    a. *Pain relief*
    b. *Time to pain relief*
    c. *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://ihs-classification.org/en/02_klassifikation/06_glossar/?letter=i.)

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

1. *ipsilateral conjunctival injection and/or lacrimation; or*
2. *ipsilateral nasal congestion and/or rhinorrhea; or*
3. *ipsilateral eyelid edema; or*
4. *ipsilateral forehead and facial sweating; or*
5. *ipsilateral miosis and/or ptosis; or*
6. *a sense of restlessness or agitation.*

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

a. *The principal purpose of the research study is to test whether a particular intervention potentially improves the participants' health outcomes.*
b. *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.*
c. *The research study does not unjustifiably duplicate existing studies.*
d. *The research study design is appropriate to answer the research question being asked in the study.*
e. *The research study is sponsored by an organization or individual capable of executing the proposed study successfully.*
f. *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.*
g. *All aspects of the research study are conducted according to appropriate standards of scientific integrity (see http://www.icmje.org).*
h. *The research study has a written protocol that clearly addresses, or incorporates by reference, the standards listed here as Medicare requirements for CED coverage.*
i. *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.*
j. *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.*
k. *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.*
l. *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.*
m. *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.

C. 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 (see section B. above).

D. 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.

(This NCD last reviewed January 2011.)