# NCA - Home Use of Oxygen and Home Oxygen Use to Treat Cluster Headaches (CAG-00296R2) - Decision Memo

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# Decision Summary

The Centers for Medicare & Medicaid Services (CMS) is finalizing changes to two separate, but medically related, National Coverage Determinations (NCDs). Given new information in the peer-reviewed medical literature, we are removing the NCD for Home Oxygen Use to Treat Cluster Headache (CH) (240.2.2). We are also revising the NCD for Home Use of Oxygen (240.2). We summarize these changes below and fully explain our rationale in the Analysis section of this NCD decision memorandum.

CMS is removing NCD 240.2.2 in the Medicare NCD Manual, ending coverage with evidence development (CED), and allowing the Medicare Administrative Contractors (MACs) to make coverage determinations regarding the use of home oxygen and oxygen equipment for CH.

CMS also is modifying NCD 240.2, Home Use of Oxygen, in the Medicare NCD Manual to expand patient access to oxygen and oxygen equipment in the home, and to permit contractors to cover the use of home oxygen and oxygen equipment in order to treat CH and other acute conditions.

The scope of this decision does not include any consideration of Home Use of Oxygen in Approved Clinical Trials, identified in section 240.2.1 of the NCD Manual. Additionally, the scope of the decision does not include any consideration of hyperbaric oxygen for any indication, currently identified in section 20.29 of the NCD Manual.

See Appendices B and C for the expected NCD Manual language.

CMS sought comments on our proposed decisions consistent with the public process established by §1862(l) of the Social Security Act. We are responding to public comments in this final decision memorandum.

# Decision Memo

TO: Administrative File: CAG-00296R2

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SUBJECT: Decision to Remove National Coverage Determination for Home Oxygen Use to Treat Cluster Headache (NCD 240.2.2)
and to Modify National Coverage Determination for Home Use of Oxygen (NCD 240.2)

DATE: September 27, 2021

## I. Decision

The Centers for Medicare & Medicaid Services (CMS) is finalizing changes to two separate, but medically related, National Coverage Determinations (NCDs). Given new information in the peer-reviewed medical literature, we are removing the NCD for Home Oxygen Use to Treat Cluster Headache (CH) (240.2.2). We are also revising the NCD for Home Use of Oxygen (240.2). We summarize these changes below and fully explain our rationale in the Analysis section of this NCD decision memorandum.

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## II. Background

Throughout this document we use acronyms, some of which are not defined as they are presented in direct quotations. Please find below a list of these acronyms and corresponding full terminology:

CED – Coverage with Evidence Development
CH - cluster headache
CCH – chronic cluster headache
CMS - Centers for Medicare & Medicaid Services
CMN – Certificate of Medical Necessity
CSP - Coverage with Study Participation
DME – durable medical equipment
ECH – episodic cluster headache
MAC – Medicare Administrative Contractor
NBOT - normobaric oxygen therapy

NCA - National Coverage Analysis
NCD - National Coverage Determination
US - United States

*Introduction*

CHs are headaches grouped under the category of trigeminal autonomic cephalalgias. CHs are manifested by attacks of severe unilateral pain. This pain, which at times is so excruciating that these headaches are known as 'suicide headaches', is located either singularly or in combination in the orbital, supraorbital, or temporal areas of the face. CHs commonly last for 15–180 minutes and usually occur from once every other day to eight times a day. The pain is associated with ipsilateral conjunctival injection, lacrimation, nasal congestion, rhinorrhoea, forehead and facial sweating, miosis, ptosis and/or eyelid edema, and/or with restlessness or agitation. Age at onset for CHs is usually 20–40 years. Men experience CHs three times more often than women (May, 2005; May, 2020; Headache Classification Committee of the International Headache Society, 2018).

The lifetime prevalence of CH for adults of all ages is approximately 0.1 percent. Though some patients have a single bout of this disorder, CHs also exhibit two different types of continuing patterns. The episodic form of CH is the most common, affecting 80 to 90 percent of patients. It is characterized by periods of attacks (clusters or bouts) and periods of remission. On average, a cluster period lasts 2 to 12 weeks while remissions can last up to 12 months or longer. When not in a bout, patients are usually asymptomatic. In the chronic form of the disorder, attacks occur without significant periods of remission. The chronic form of CH is diagnosed after a year without remission, or if a remission has lasted less than three months. Chronic CHs may present primarily or evolve from the episodic type. (May, 2005; May, 2020; Headache Classification Committee of the International Headache Society, 2018).

The treatment of CH can be divided into that which is acute (used to abort the exquisitely painful headache at the time it occurs) or preventative (May, 2020). Though medications may be helpful to some individuals, since 1952, oxygen has been used to treat the acute attacks of CHs (Geerlings, Haane & Koehler, 2011). Home oxygen therapy provides air that contains more oxygen than normal to a patient through a mask or tube connected to a device in a patient's home. Home oxygen therapy is used to treat a variety of conditions. In 2011, CMS issued a NCD for Home Oxygen Use to Treat CH (240.2.2). At that time, CMS concluded that the evidence did not demonstrate that the home use of oxygen to treat CH improved health outcomes in Medicare beneficiaries, though the Agency was supportive of further research on the topic.

The primary goal of this National Coverage Analysis (NCA) was to examine the evidence developed in the last decade regarding the response to oxygen therapy of those individuals who attempt to acutely abort their CH with this medical gas. Importantly though, ending CED for coverage of home oxygen for the treatment of CH, also necessitated a review of 240.2 NCD for Home Use of Oxygen to determine if this policy impedes patient access to oxygen therapy in the home for the treatment of acute conditions, be they CHs or other illnesses (e.g. COVID -19). This NCD, effective since October 27, 1993 arguably provides for home oxygen therapy only if the patient is in the 'chronic stable state.' We note that since the inception of the Public Health Emergency (PHE) due to the COVID 19 pandemic, CMS has begun to permit health care services to increase the capacity of the American health care system outside the setting of the traditional inpatient hospital, including the treatment of acute illnesses. (CMS Press Release, November 25, 2020). The ability to provide home oxygen has been crucial to treatment of patients during the pandemic.

In summary, CMS opened this NCA to examine first, if coverage of oxygen in the home for CH, is reasonable and necessary under the Medicare program. Secondly, CMS reviewed the NCD for Home Use of Oxygen (240.2) to determine if this policy impedes patient access to oxygen therapy in the home for the treatment of CH or for any other acute condition.

## III. History of Medicare Coverage

CMS has provided formal coverage of home oxygen since the 1980s. In 2006, CMS reconsidered NCD 240.2 and issued a final NCD providing Medicare coverage of home oxygen and oxygen equipment under the durable medical equipment (DME) benefit (see §1861(s)(6) of the Social Security Act) only for patients with significant chronic hypoxemia[1] who meet the medical documentation, laboratory evidence, and health conditions specified elsewhere in the NCD. The policy is codified in section 240.2 of the Medicare NCD Manual (Pub. 100-03).

In 2011, CMS issued a NCD for Home Oxygen Use to Treat CH (240.2.2). At that time, CMS concluded that the evidence did not demonstrate that the home use of oxygen to treat CH improved health outcomes in Medicare beneficiaries. Therefore, the home use of oxygen to treat CH was not found to be reasonable and necessary under 1862(a)(1)(A) of the Act. However CMS believed that the available evidence suggested that the home use of oxygen to treat CH was promising and supported further research under §1862(a)(1)(E) of the Social Security Act through the Coverage With Study Participation (CSP) form of Coverage With Evidence Development (CED). Therefore the NCD covered the home use of oxygen for CH for beneficiaries participating in an approved prospective clinical study comparing 100% normobaric oxygen therapy (NBOT) with at least one clinically appropriate comparator for the treatment of CH. The policy is codified in section 240.2.2 of the Medicare NCD Manual (Pub. 100-03).

### A. Current Request

CMS received a formal reconsideration request for NCD 240.2.2 Home Oxygen Use to Treat CH from The Alliance for Headache Disorders Advocacy. The formal request letter can be viewed via the tracking sheet for this NCA on the CMS website at https://www.cms.gov/medicare-coverage-database/details/nca-tracking-sheet.aspx?NCAId=301. In addition to the formal request specific to the home use of oxygen for CH, lessons learned from the COVID-19 public health emergency have compelled us to review NCD 240.2 to ensure that our coverage policies do not impede patient access to oxygen in appropriate circumstances.

### B. Benefit Category

Medicare is a defined benefit program. For an item or service to be covered by the Medicare program, it must fall within one of the statutorily defined benefit categories outlined in the Social Security Act. Medicare has recognized the home use of oxygen as a supply of durable medical equipment (DME), which is referenced in section 1861(s)(6) of the Social Security Act. Thus, the home use of oxygen falls within the DME benefit category.

## IV. Timeline of Recent Activities

| Date | Actions Taken |
|---|---|
| August 17, 2020 | CMS opens an NCA and the Initial 30-day public comment period begins. |
| September 16, 2020 | First public comment period ends. CMS receives 200 comments. |
| July 2, 2021 | Proposed decision memorandum posted. 30-day public comment period begins. |
| August 1, 2021 | Second public comment period ends. CMS receives 150 comments. |

## V. Food and Drug Administration (FDA) Status

FDA regulates Oxygen, USP as a designated medical gas under sections 575-576 of the Federal Food, Drug, and Cosmetic Act. FDA regulates oxygen concentrators and certain equipment and delivery systems required for providing oxygen therapy as medical devices.

## VI. General Methodologic Principles

When making NCDs, CMS generally evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service falling within a benefit category is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member. The critical appraisal of the evidence enables us to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for beneficiaries. An improved health outcome is one of several considerations in determining whether an item or service is reasonable and necessary.

A detailed account of the methodological principles of study design that the agency utilizes to assess the relevant literature on a therapeutic or diagnostic item or service for specific conditions can be found in Appendix A.

## VII. Evidence

### A. Introduction

This section provides a summary of the evidence we considered during our review. The evidence reviewed to date includes the published medical literature on the use of oxygen therapy for the treatment of CH. For this NCA, we reviewed the published medical literature in the form of clinical trials, systematic reviews and guidelines from 2011 to the present to determine if the home use of oxygen therapy for the treatment of CH is reasonable and necessary. We also reviewed the need for revisions to NCD 240.2 based on our findings related to CH.

### B. Discussion of Evidence

1. Evidence Question

Our review and analysis of the evidence concerning the clinical utility of oxygen therapy for CH and thus, whether home oxygen therapy for CH is reasonable and necessary to treat Medicare beneficiaries, is guided by the following question:

*Is the evidence sufficient to conclude that the home use of oxygen improves health outcomes in Medicare beneficiaries with CH?*

#### 2. External Technology Assessment

CMS did not request an external technology assessment (TA) on this issue.

#### 3. Internal Technology Assessment

*Literature Search Methods*

We searched EMBASE and MEDLINE for clinical investigations, systematic reviews and guidelines, using key words which included CH and oxygen. We also assessed all literature suggestions provided to us by

commenters. Furthermore, bibliographies of pertinent review articles and clinical investigations were hand searched.

For the purpose of this analysis, we reviewed literature related to CH published since the prior NCD (2011). Clinical trials were sought that described placebo controlled, prospective comparative trials of the use of oxygen for the treatment of CH, delivered in any setting. We considered results that were based on original data collected to obtain the original goal of the study, meaning that post hoc analyses were not considered. Our search for guidelines relating to the treatment of CH with oxygen therapy was limited to those of the United States.

Evidence that discussed multiple management strategies of CH were retained in our analysis as long as there was a defined subgroup of investigations or considerations that met our inclusion criteria. This additional information regarding non-oxygen management strategies for CH is not reflected in this document as we considered it to be outside the scope of this national coverage analysis.

**Randomized and Semi-randomized Controlled Trials**

*Petersen AS, Barloese MC, Lund NL, Jensen RH. Oxygen therapy for cluster headache. A mask comparison trial. A single-blinded, placebo-controlled, crossover study. Cephalalgia. 2017; 37(3):214-224. doi: 10.1177/0333102416637817. Epub 2016 Jul 11. PMID: 27013239.*

The purpose of this single-blinded, semirandomized, placebo-controlled, crossover inpatient study was to investigate possible differences in effect between three types of masks in the acute treatment of CH. Patients trialed a random sequence of a simple facemask (SM), an O2ptimaskTM (OM) and a demand valve oxygen mask (DVO), always succeeded by DVO with placebo. (The DVO delivers oxygen according to respiration rate and tidal volume [flow-rate: 0–200 l/min], and thus the DVO is not limited to a specific flowrate but delivers oxygen according to demand. The DVO ensures a FiO2 of 100%.). The placebo treatment (21% oxygen and 79% nitrogen) was placed last in the sequence so that in the case of patients suffering fewer than four attacks, they would have tried as many of the active masks as possible. To eliminate a possible effect of the previous treatment and the risk of treating a rebound headache, the treatments were separated by a minimum of three hours. Blinding of the mask type used was not possible, but patients were blinded to the contents of the gas cylinders. Patients inhaled 100% oxygen delivered by one of the three face masks for 15 min at the beginning of a CH attack and placebo for one attack. After 15 minutes, the patient was offered rescue medication or could choose to continue the trial therapy.

The study was performed with subjects in hospital to ensure optimal therapy compliance, instruction and attack observation. The inclusion criteria were age between 18 and 65 years (mean age 45) and the CH diagnosis was made according to International Classification of Headache Disorders, second edition (ICHD-II) criteria. Originally, only those individuals with episodic cluster headaches (ECH) were admitted into the study. However, criteria changed during the trial to include both chronic cluster headaches (CCH) and ECH patients in order to increase recruitment.

Fifty-seven subjects were included in the trial and 42 patients (20 ECH, 22 CCH) received treatment for at least one attack. Seventy-six percent (76%) of the subjects who received trial therapy had previously used oxygen for treatment of their CH; 20% of the patients reported absolute pain reduction, fifty-one percent reported some effect and 29% described only a slight response to oxygen.

Only 10 CH patients had multiple attacks and reached the point of placebo use (i.e. were treated for four CH attacks). The primary endpoint was a two-point reduction of pain on a five-point rating scale within 15 minutes.

There were no significant differences between masks in the primary endpoints. After 15 minutes, 48% of patients had a two-point decrease using the DVO compared to 45% with placebo (p=0.867). After 30 minutes 68% were pain free or had pain relief using DVO and 45% by placebo (p=0.061).

The authors concluded that the primary endpoint of pain relief at 15 minutes was non-significant between masks. A high placebo rate with the DVO mask was also noted.

**Systematic Review/ Professional Society Statement/ Guidelines**

*Beithon J, Gallenberg M, Johnson K, Kildahl P, Krenik J, Liebow M, Linbo L, Myers C, Peterson S, Schmidt J, Swanson J. Institute for Clinical Systems Improvement. Diagnosis and Treatment of Headache. Updated January 2013.*

This guideline discusses the headache disorders most commonly seen in primary care offices. The Institute for Clinical Systems Improvement (ICSI) staff, in consultation with the work group and a medical librarian, conducted a literature search to identify systematic reviews, randomized clinical trials, meta-analysis, other guidelines, regulatory statements and other pertinent literature on the topic. This literature was evaluated based on the GRADE methodology by work group members. When needed, an outside methodologist was consulted. Then the work group used this information to develop or revise clinical flows and algorithms, write recommendations, and identify gaps in the literature. All decisions made by the work group were done using a consensus process.

ICSI's medical group members and sponsors review each guideline as part of the revision process. This feedback is used by and responded to by the work group as part of their revision work. Final review and approval of the guideline is done by ICSI's Committee on Evidence-Based Practice. This committee is made up of practicing clinicians and nurses, drawn from ICSI member medical groups.

This guideline is targeted to patients age 12 years and older who present with headache. The literature search for this guideline was divided into two stages to identify systematic reviews, (stage I) and randomized controlled trials, meta-analysis and other literature (stage II) from June 2010 through July 2012.

This guideline recommends that for the acute treatment of cluster headaches, clinicians should utilize inhaled oxygen at a rate of 7-15 L/min, stating it is highly effective when delivered at the beginning of an attack with a non-rebreathing facial mask (7-15 L/min). Additionally the guideline states most patients will obtain relief within 15 minutes.

*Bennett MH, French C, Schnabel A, Wasiak J, Kranke P, Weibel S. Normobaric and hyperbaric oxygen therapy for the treatment and prevention of migraine and cluster headache. Cochrane Database Syst Rev. 2015;(12):CD005219. Published 2015 Dec 28. doi:10.1002/14651858.CD005219.pub3*

The purpose of this systematic review (SR) was to examine the efficacy and safety of NBOT in the acute treatment of CH. This work updated a similar review of the topic which examined literature and other sources of information available to May, 2008. In the current SR, the following databases were searched up to mid- June 2015: CENTRAL (the Cochrane Library), MEDLINE, EMBASE, and CINAHL. Also bibliographies of relevant journals were assessed and researchers were queried to identify trials. Randomized controlled trials in patients with CH comparing NBOT with all comparators, including hyperbaric oxygen, other active therapies, placebo (sham) interventions, or no treatment were considered for inclusion into the SR.

The authors found four studies that evaluated NBOT. Investigations included patients of any age and sex. Three trials compared NBOT to sham therapy or ergotamine tartrate for CH (145 participants). One trial, in which only two participants were diagnosed with CH, compared NBOT to sham for a mixed group of headaches. This trial was also the only pertinent RCT of this SR not included in the analysis of NCD for Home Oxygen Use to Treat CH (240.2.2), effective 2011. This clinical trial was not germane to this National Coverage Analysis due to the limited numbers of relevant subjects.

The authors of the SR stated that they had "some confidence" that NBOT can terminate a CH. They found no evidence that NBOT could prevent CH. They did note that oxygen therapy for CH appeared

safe. They further stated that, "It is generally accepted that about 70% of patients will receive significant relief…" from NBOT. However they also expressed concern that the studies upon which these conclusions were founded were not based on sound sample size calculations for expected differences. The authors believed there is a case for confirming the apparent effectiveness of NBOT for CH in a study with sufficient power to produce valid conclusions.

*Robbins MS, Starling AJ, Pringsheim TM, Becker WJ, Schwedt TJ. Treatment of Cluster Headache: The American Headache Society Evidence-Based Guidelines. Headache. 2016;56(7):1093-1106. doi:10.1111/head.12866*

The purpose of this systematic review was to appraise the available evidence for the acute and prophylactic treatment of CH, and provide an update of the 2010 American Academy of Neurology (AAN) endorsed systematic review. To develop these guidelines, the American Headache Society (AHS) Guidelines Committee assembled a panel of AHS members with expertise in CH and guideline development. Medline, PubMed, and EMBASE databases were searched for double blind, randomized controlled trials of any treatment versus placebo/sham or versus another treatment of CH in persons, at least 18 years of age. Research published between 1950 and November, 2015, was considered.

Since the publication of the 2010 AAN review, the authors found no new data from randomized, double-blind, controlled trials that contributed to the determination of the efficacy or safety of oxygen for the acute treatment of CH.

[Note: The 2010 AAN assessment was included in NCD for Home Oxygen Use to Treat CH (240.2.2), effective 2011. The update contains no pertinent new literature.]

*The Primary Care Management of Headache Work Group, Department of Veterans Affairs/Department of Defense. VA/DoD Clinical Practice Guideline for the Primary Care Management of Headache. Version 1.0 – 2020; accessed at https://www. https://www.healthquality.va.gov/guidelines/pain/headache/VADoDHeadacheCPGFinal508 on 12/18/2020.*

This clinical practice guideline (CPG) is intended to provide primary care providers (PCPs) with a framework by which to evaluate, treat, and manage the individual needs and preferences of patients with CH, thereby leading to improved clinical outcomes. The subject matter experts who produced this document developed evidence-based clinical practice recommendations to be used by providers within the Department of Veterans Affairs (VA) and Department of Defense (DoD) healthcare systems as well as those within the community who treat individuals within the VA and DoD. Those who worked on the CPG used the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system to assess the quality of the evidence base and assign a strength for each recommendation. When a near-final draft of the guideline was agreed upon, the draft was sent out for peer review and comment. The peer reviewers comprised individuals working within the VA and DoD healthcare systems and experts from relevant outside organizations designated by the Work Group members. Additionally a small (and potentially non-generalizable) patient focus group was held to further understand the perspectives of patients who are receiving treatment for headache within the VA and/or DoD healthcare systems.

The CPG notes that first-line treatment of CH includes oxygen therapy and that it has been established as safe and often found to be effective in aborting CH in the clinical setting. However, the CPG identified very little evidence for the use of NBOT in acute CH and stated that the evidence is inconsistent for being pain-free after treatment. Confidence in the quality of the evidence was very low. In summary, the CPG notes there is insufficient evidence to recommend for or against oxygen therapy for the acute treatment of primary headache, a classification which includes CH.

**Public Comment**

Public comments sometimes cite the published clinical evidence and give CMS useful information. Public comments that give information on unpublished evidence such as the results of individual practitioners or patients are less rigorous and therefore less useful for making a coverage determination.

CMS uses the initial public comments to inform its proposed decision. CMS responds in detail to the public comments on a proposed decision when issuing the final decision memorandum. All comments that were submitted without personal health information may be viewed in their entirety by using the following link https://www.cms.gov/medicare-coverage-database/details/nca-view-public-comments.aspx?NCAId=301&ExpandComments=n&type=Open&bc=AAgAAAAACAAA&.

**Initial Comment Period: 8/17/2020 – 9/16/2020**

During the initial 30-day public comment period CMS received 200 comments. Of these 200 comments, 42 were not published on the CMS website due to excessive personal health information content; however, all comments were considered for this proposed decision.

We received 188 comments related to CH and all of the commenters supported coverage of the use of home oxygen to treat CH. Most of the commenters supporting coverage of home oxygen for CH expressed that high-dose oxygen is a safe and effective non-pharmacologic treatment option for patients suffering from CH that is preferable to pharmacological treatments. Most of the commenters also mentioned that home oxygen is a cost-effective treatment option for CH.

The majority of comments related to CH (131) were provided by commenters that did not specify their titles and/or organizations, but wrote of personal experience or family and friends who experience CH. There were 56 comments submitted by neurologists, other healthcare professionals and providers, as well as professional associations, societies and advocacy organizations, including the Alliance for Headache Disorders Advocacy, Cluster Busters, the American Headache Society, the Spinal SF Leak Foundation, and the American Cluster Headache Chronic Pain Association. An additional group comment was submitted by the Coalition for Headaches and Migraine Patients that included 257 co-signers.

There were 12 comments submitted related to the NCD for Home Use of Oxygen (NCD 240.2). All 12 commenters supported CMS reconsidering this NCD. Several commenters recommended that CMS expand coverage for home oxygen to include both acute respiratory conditions and other non-respiratory illnesses that affect oxygen saturation levels, such as pneumonia patients, bronchitis, or any other acute condition, including exacerbation of chronic conditions. Several commenters requested various revisions to the medical documentation and laboratory evidence sections. Recommendations included but are not limited to: remove the Certificate of Medical Necessity (CMN) requirement for home oxygen and instead use Standard Written Orders/Clinical Data Element Templates; minimize the requirement for patients to try other alternative treatments prior to being prescribed oxygen; remove the term "chronic stable state"; and change recertification and testing requirements. Several commenters recommended changes to the covered blood gas group definitions and one commenter requested that CMS cover the services of respiratory therapists under home oxygen.

Of the comments for NCD 240.2 Home Use of Oxygen, several were submitted by DME suppliers, providers and professional associations and societies, including the Council for Quality Respiratory Care, American Association for Homecare. Additional group comments were submitted by American College of Chest Physicians with 11 co-signers that included Alpha-1 Foundation, American Association for Respiratory Care, American Lung Association, American Thoracic Society, COPD Foundation, Dorney Koppel Foundation, Pulmonary Fibrosis Foundation, Respiratory Compromise Institute. Respiratory Health Association and the US COPD Coalition.

**Second Comment Period: 7/02/2021 – 8/02/2021**

During the second 30-day public comment period CMS received 150 comment submissions. Of these 150 comment submissions, 36 were not published on the CMS website because they contained personal health information; however, all comments were considered for this decision.

Of the 150 total comments, 134 included comments on CH. All of the commenters supported removing NCD 240.2.2, and generally supported removing barriers to coverage for CH in NCD 240.2. While a few commenters supported the proposal to allow coverage determinations for CH to be made by the local MACs, other commenters disagreed with local coverage, instead requested a national decision that provided coverage. Most commenters additionally requested that CMS base coverage on diagnosis alone and that CMS make clear that blood oxygen tests are not required for CH. As in the first comment period, most of the commenters supporting coverage of home oxygen for CH expressed that high-dose oxygen is a safe and effective non-pharmacologic treatment option for patients suffering from CH that is preferable to pharmacological treatments. Many of the commenters also mentioned that home oxygen is a cost-effective treatment option for CH.

Of the 134 comments related to CH, the majority (101) were provided by commenters who wrote of personal experience or family and friends who experience CH. Four commenters representing durable medical equipment suppliers and associations commented regarding CH, including the American Association for Homecare, Home Medical Equipment & Services Association of New England, VGM Group, Inc. and VieMed. There were 29 comments regarding CH submitted by neurologists, other healthcare professionals, and providers/hospitals/hospital systems; as well as professional associations, societies and advocacy organizations, including the Alliance for Headache Disorders Advocacy, Cluster Busters with 12 co-signer organizations, the American Headache Society jointly with the American Migraine Foundation, the American Academy Family Physicians, Miles for Migraine, and U.S. Pain Foundation.

Of the 150 total comments received, 24 included comments related to the NCD for Home Use of Oxygen (NCD 240.2). All 24 commenters agreed with the proposal to expand national coverage of the home use of oxygen. Of special note was the agreement by many commenters of the broader definition of exercise and removing the limiting language referring to the chronic stable state and the need for the patient to have unsuccessfully tried alternative therapies prior to the use of oxygen in the home. Several commenters requested further explanation of the "time of need" related to timing of clinical laboratory tests. Several commenters wished to know how to distinguish between acute and chronic patients in regards to recertification. Commenters also remarked on the proposed recertification process for beneficiaries with conditions unrelated to hypoxemia, specifically those that are acute. Several commenters expressed concern that the documentation which demonstrates the reasonable and necessary characteristics of home oxygen was not proposed in detail in this NCD, but is at MAC discretion. While many commenters supported the concept of removing the requirement for the CMN from the NCD, many commenters also expressed concern at the perceived subjectiveness of using the medical record to document medical necessity. They requested that CMS rely upon other documentation such as the practitioner's prescription to establish medical necessity of home oxygen and oxygen equipment, as is done with coverage and reimbursement for pharmaceutical products, or the DMEPOS templates and clinical data elements which CMS designed to assist providers with data collection and medical record documentation to support coverage of selected items and services. Some commenters also requested that the requirement for the CMN be retained in this NCD, if CMS does not delineate specific documentation criteria and formats.

The 24 comments for NCD 240.2 Home Use of Oxygen, were submitted by DME suppliers, physicians and other health care professionals, providers/hospitals and professional associations, societies, and advocacy organizations including; the Council for Quality Respiratory Care, American Association for Homecare, American College of Chest Physicians (with 9 co-signers, American Association of Nurse Practitioners, American Association for Respiratory Care, American Academy of Family Physicians, Medicare Councils for DME MAC Jurisdictions A, B, C and D, MAMES DME Supplier Consortium, Home Medical Equipment & Services Association of New England, VGM Group, Inc.,

VieMed, Apria Healthcare, Lincare, Advacare Home Services, McAbee Medical, Jim's Pharmacy & Home Health, Columbine Medical Equipment, Wilkes Apothecary LLC.

Articles, websites and other types of information were submitted with public comments. We have added the relevant new evidence in our evidence review section.

**Home Oxygen and Oxygen Equipment for Cluster Headache**

*Comment*: Many comments were received from patients with cluster headaches and their family members who provided us with a narrative of their experiences with this disorder.

*Response*: We thank these commenters for sharing with us the frank and sincere accounts of the burden this condition imposes.

*Comment*: All commenters agreed with our proposal to remove the barriers to treatment of cluster headaches with home oxygen, by ending coverage with evidence development in NCD 240.2.2. However, few agreed with revising NCD 240.2 to allow the local MACs to determine the reasonable and necessary coverage of home use of oxygen for patients with CH and other conditions that are unrelated to hypoxemia. Instead they desired national coverage for home oxygen for patients with these conditions.

*Response*: We appreciate the support for our policy changes. To further emphasize and clarify that conditions unrelated to hypoxemia may be covered, we have added language in the final NCD to clarify this point. MACs may determine reasonable and necessary coverage of home oxygen and oxygen equipment for patients who do not exhibit hypoxemia as defined in Section B of the NCD Manual. The language will be included in the manual, see Appendix C.

*Comment*: Many commenters have requested clarification that measurements of blood oxygen are not required in patients with cluster headaches.

*Response*: We agree that measurements of blood oxygen are not relevant to CH. However, we are not making an NCD for CH patients and the reasonable and necessary determination will be made by the local MACs.

*Comment*: Commenters objected to our proposed policy that the MAC may determine reasonable and necessary coverage of home oxygen and oxygen equipment for patients with CH. These commenters stated that all beneficiaries diagnosed with cluster headaches should be afforded home oxygen and oxygen equipment coverage based on diagnosis alone, and that the coverage should be provided through a NCD and not through local determination by the MACs.

*Response*: NCDs are made through an evidence-based process, with opportunities for public participation. In the case of cluster headaches, the literature reviewed described the health outcomes resulting from the treatment of cluster headaches with oxygen. As noted in our evidence review we found only one new (since 2011) comparative study of the use of oxygen in the treatment of CHs (Petersen et al., 2017). In that single-blinded, semirandomized, placebo-controlled, crossover study, data was provided comparing the use of DVO masks administering 100% oxygen versus air (21% oxygen and 79% nitrogen) to patients with CH. No significant differences were found in the provision of these different gases through DVO masks for the relief of the pain of CH at 15 and 30 minutes. Rather than accept this finding as suggesting that the provision of DVO supplied 100% oxygen is no different than DVO supplied room air in the treatment of CHs, we concluded that the small sample size (n = 10) prevented a definitive statement regarding the utility/non-utility of DVO supplied oxygen in the care of patients with this condition.

Of added interest to this article, was the authors' report that before the trial, oxygen treatment was used by 76% of the patients who received trial therapy. Only 20% of the patients reported absolute pain reduction. Fifty-one percent reported some effect and 29% described only a slight response to oxygen.

Furthermore, as noted in our analysis, the data obtained from the international Cluster Headache Questionnaire, the largest CH survey performed at the time of its publication with 1604 respondents from over 50 countries, revealed only 54% (582/1082) of respondents reported complete or very effective treatment of oxygen for their CH. Of the 139 respondents 65 years and older, oxygen was reported as completely effective or very effective in 56% of respondents. The clinical report of this Questionnaire also discussed that previous research has found that patients may not prefer oxygen treatment as it may be inconvenient. Oxygen may also take longer for full effect than other treatments and the headaches may return when the oxygen is stopped. Whether or not this is due to logistic concerns is unknown, but it has been documented that half of patients who were prescribed oxygen for their CHs never received proper training in the management of this medical gas and less than half of prescriptions may specify a flow rate or mask type. (Pearson et al., 2019).

As we have stated, we recognize that the literature confirms there is benefit to the use of oxygen therapy for some individuals with CH. But, as demonstrated by the evidence, at the current time, a significant number of beneficiaries with cluster headaches will not find oxygen useful. These results emphasize the need to consider the individualized nature of this treatment, including patient life style preferences. This conclusion also conforms to stakeholder comments we have received in the past that advise us that patients with CH typically have unique characteristics to their disorder, as well as varying comorbidities and concomitant treatments.

We believe that in order to make home oxygen and oxygen equipment available to those individuals with CH for whom it is reasonable and necessary, the evidence demonstrates that it is appropriate to remove the national barriers to its coverage for the treatment of CHs in the home and allow decisions regarding coverage to be made at the local level. This NCD reconsideration has accomplished the removal of barriers to the use of home oxygen and oxygen equipment by individuals with CHs through (1) removing the requirement that the home use of oxygen to treat CH is covered by Medicare only for beneficiaries participating in an approved prospective clinical study; (2) removing the rebuttable presumption that those individuals who do not experience hypoxemia/severe lung disease as defined in this NCD have no need for home oxygen; (3) removing the requirement for the prior use of alternative treatment before oxygen in the home can be used and (4) allowing home oxygen coverage in beneficiaries with acute, short term need for this medical gas. Considering the new evidence that fit within the parameters of our review, we have concluded that for some patients, the use of home oxygen may be useful to produce a significant reduction in the pain of their CHs. Given the gaps in the current evidence, however, allowing Medicare contractors to make the reasonable and necessary decisions provides the best mechanism to make home oxygen available to patients with cluster headache.

*Comment*: Two commenters objected to the evidence review performed by CMS regarding cluster headaches, stating it was incomplete, selective and inconsistent with current medical literature.

*Response*: We disagree. The parameters of the evidence review performed by CMS were carefully thought out to answer the question we posed for this NCA and were consistent with our standards for evidence review that are outlined in Appendix A. We believe that these parameters allowed for a fair examination of the literature.

In developing and reconsidering NCDs, CMS reviews clinical evidence to determine, among other things, whether the item or service is reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member for the affected Medicare beneficiary population. At the time National Coverage Determination (NCD) for Home Oxygen Use to Treat Cluster Headache (CH) (240.2.2) was written (Jan, 2011), CMS believed that the evidence did not demonstrate that the home use of oxygen to treat CH improves health

outcomes in Medicare beneficiaries with CH, and therefore its use was not reasonable and necessary under 1862(a)(1)(A) of the Act. Instead, the home use of oxygen to treat CH could be provided only 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). Our current evidence review, based on literature published since NCD 240.2.2 was first effective, has reversed that decision, and concluded that the use of home oxygen may be useful to some individuals in order to significantly reduce the pain experienced during their CHs.

We appreciate and take into consideration expert opinion and public comments. In addition to the literature found during our own search efforts, we also review articles and websites provided to us by external stakeholders. We acknowledge that a commenter presented us with a Guideline we had not previously seen and which we have now added to our Evidence section. However this evidence was not sufficient to identify a specific patient population for whom the home use of oxygen would be a reasonable and necessary treatment for patients with CH.

Although we are not making a national coverage determination to cover home oxygen for patients with cluster headaches, we are removing national restrictions that have created barriers to coverage based on the available evidence.

*Comment*: One commenter thought a statement in the proposed decision memo meant that there was sufficient evidence for CMS to formally state support of coverage for home oxygen for CH rather than providing coverage discretion to the MACs. In the proposed decision a sentence stated:"*Therefore we propose to remove NCD 240.2.2, and allow the MACs to determine coverage for the use of home oxygen as a treatment option for CH, without the need for further clinical trials."*

*Response*: We regret that the commenter has misunderstood this sentence. As we have stated, we recognize that the literature confirms there is benefit to the use of oxygen therapy for some individuals with CH and therefore we believe it appropriate to remove CED and allow the MACs to determine coverage for the use of home oxygen as a treatment option for CH. But as demonstrated by the evidence, at the current time, a significant number of beneficiaries with cluster headaches will not find oxygen useful.

We recognize that much still remains to be learned concerning CHs and its potential treatment modalities. For instance, literature which we reviewed but did not meet our inclusion criteria, revealed that future research investigating flow rates of oxygen (Dirkx, Haane & Koehler, 2018) may be informative in this domain. Another interesting concept considered by McLeod, Andrasik, Packard & Miller, (2002) as well as Petersen et al, (2017), is the use of cold room air to control the pain of cluster headaches. Though these topics are just two examples of potential inquiry in this field, we believe they indicate the importance of ongoing investigation for this exquisitely painful condition.

*Comment*: Many commenters argued that CMS does not appreciate that it is not feasible for patients with CH to travel to a practitioner's office or ED to receive oxygen therapy within the time frame of an acute CH episode. Additionally, many commenters took issue with our use of the words "selected patients" in analysis of the evidence related to CH in Section VIII (Analysis) of the proposed decision memorandum.

*Response*: CMS recognizes that some individuals experiencing a cluster headache seek out emergency room treatment. However, we also know this potential avenue for treatment is not always possible, nor frankly desirable for patients. As explained above, we are removing current restrictions in our NCD that may have prevented coverage of home use of oxygen for some patients with CH.

In order to avoid any further misunderstanding, we have revised the language used in the analysis. Specifically, we have removed the word "selected" from the final decision memorandum Section VIII (Analysis) and replaced it with

"some", indicating (as we have noted), that the available literature findings show that oxygen treatment is not always helpful nor necessarily desired by all individuals with cluster headache. Therefore home oxygen and oxygen equipment may not be reasonable and necessary treatment for all beneficiaries with CH.

**Home Use of Oxygen and Oxygen Equipment (NCD 240.2)**

*Comment*: Many commenters agreed with the proposal to expand national coverage of home use of oxygen and to expand patient access to this treatment. Of special note was the agreement by many commenters of the broader definition of exercise and the removal of limiting language referring to the chronic stable state and the need for the patient to have unsuccessfully tried alternative therapies prior to the use of oxygen in the home.

*Response*: We thank commenters for their support. This NCD reconsideration has accomplished the removal of barriers to the use of home oxygen and oxygen equipment by individuals through (1) removing the rebuttable presumption that those individuals who do not experience hypoxemia/severe lung disease as defined in this NCD have no need for home oxygen; (2) removing the language referring to the chronic stable state; (3) removing the requirement for the prior use of alternative treatment before oxygen in the home can be used; and (4) allowing home oxygen coverage in beneficiaries with acute, short term need for this medical gas.

Additionally, providing the MACs discretion to cover home oxygen and oxygen equipment for individuals who do not exhibit hypoxemia will allow them to make decisions based on the unique physiologic, cognitive and/or functional symptoms of individual patients, that are improved by oxygen therapy.

*Comment*: Several commenters stated that home oxygen should be specified as an option for the treatment of obstructive sleep apnea.

*Response*: We thank the commenters, but specific treatment options for obstructive sleep apnea are beyond the scope of this NCD.

*Comment*: Several commenters expressed concern that the documentation which demonstrates the reasonable and necessary characteristics of home oxygen was not proposed in detail in this NCD.

*Response*: We proposed to remove the language related to medical documentation requirements from this NCD. Documentation requirements are more appropriately addressed in other manuals and guidance, not a NCD, and CMS may choose to address this issue in the future. The purpose of a NCD is to identify whether or not a particular item or service is covered nationally under Title XVIII.

*Comment*: While many commenters supported the concept of removing the requirement for the CMN from the NCD, many commenters also expressed concern at the perceived subjectiveness of using the medical record to document medical necessity. They requested that CMS rely upon other documentation such as the practitioner's prescription to establish medical necessity of home oxygen and oxygen equipment, as is done with coverage and reimbursement for pharmaceutical products, or the DMEPOS templates and clinical data elements which CMS designed to assist providers with data collection and medical record documentation to support coverage of selected items and services. Some commenters also requested that the requirement for the CMN be retained in this NCD, if CMS does not delineate specific documentation criteria and formats.

*Response*: The benefit category under which home oxygen and oxygen equipment falls is that of durable medical equipment. Though the oxygen contents of the home equipment are available by prescription (as is a drug), payment is made for this supply because it is necessary for the effective use of durable medical equipment (i.e. the home

oxygen equipment). For any DMEPOS to be covered by Medicare, the patient's medical record must contain sufficient documentation of the patient's condition to substantiate the necessity for the type and quantity of the items ordered and for the frequency of use or replacement (if applicable). The supplier should also obtain as much documentation from the patient's medical record as they determine they need, in order to assure themselves that coverage criteria for an item have been met. The CMN and/or order alone may not always contain sufficient information to paint a complete clinical picture that allows the reviewer to make a medical necessity determination. The templates and clinical data elements are intended to be a helpful guide to the practitioner, but are voluntary.

Note that the term "renewed" now appears in the NCD and has replaced the term "recertification." We had concern that using the term recertification could be interpreted as referencing the CMN although the CMN requirement has been removed from the NCD.

*Comment*: Several commenters wished to know how to distinguish between acute and chronic patients in regards to recertification. Commenters also remarked on the proposed recertification process for beneficiaries with conditions unrelated to hypoxemia, specifically those that are acute. A few commenters stated that a re-evaluation by the treating practitioner should suffice as justification for the medical need if oxygen is required beyond 90 days. Several also stated the re-evaluation should be allowed to occur within ranges such as 30-120 days from the initial date of therapy, instead of the proposed 60-90 days. The commenters suggested that this wider range will allow more time for the treating practitioner to determine appropriate forms of therapy in addition to allowing time for the beneficiary to be seen and evaluated if the practitioner's scheduling capabilities become challenging.

*Response*: As suggested by our analysis, and for the purposes of NCD 240.2, acute conditions, including acute on chronic exacerbations of illness, are conditions that both represent a recent change in patient symptomatology and are reasonably expected to improve in the short term with intervention. Therefore, long term use of oxygen for these conditions would not be expected. Chronic conditions are those that are ongoing. Therefore, long term use of oxygen for chronic conditions is expected.

We agree that the time frame of initial coverage for patients who present with a short term need of oxygen can be extended to the shorter of 120 days or the number of days included in the treating practitioner prescription, instead of 60-90 days as proposed. Given the experience with the PHE, we believe that the extra time is still within the parameters of a short term illness and might be needed to allow beneficiaries to return to their treating practitioners to be properly evaluated for continuation or discontinuation of oxygen.

As a result, we have changed the NCD Manual language in Appendix C, section D to recognize that MACs may limit the initial coverage of home oxygen for patients who do not exhibit hypoxemia to the shorter of 120 days or the number of days included in the practitioner prescription. Oxygen coverage may be renewed if medically necessary, at MAC discretion. It is also within their discretion to request the information from the treating practitioner that demonstrates a beneficiary's continuing need for home oxygen and oxygen equipment. Specifically, it is within their discretion to request repeat blood oxygen measurements upon any change of patient condition or any renewal of oxygen and oxygen equipment. We anticipate that most patients who require oxygen but do not demonstrate hypoxemia will be recovering from acute conditions. As we stated in our analysis, we expect most patients (excluding those with CH) recovering from acute diseases that have required the use of home oxygen and oxygen equipment, to no longer have need for this medical gas after three months of global treatment of their condition.

For beneficiaries who do exhibit hypoxemia as defined in Appendix C, Section B, we have not specified time periods for national coverage.

In the case of the Medicare beneficiary with cluster headache, a diagnosis that is made independent of blood oxygen levels, the coverage of home oxygen and oxygen equipment for the treatment of this disorder is at MAC discretion,

as is its renewal.

**Timing of Clinical Laboratory Tests**

*Comment*: Several commenters requested clarification as to the meaning of "the time of need".

*Response*: Because we are removing all references to the 'chronic stable state', we are also updating the 1993 language that described the timing of qualifying blood oxygen studies for hospital inpatients but did not fully describe the timing of qualifying blood oxygen for those patients whose prescription for oxygen did not result from an inpatient hospital stay. For these beneficiaries, we proposed to require qualifying blood oxygen studies be performed at the 'time of need'. The 'time of need' means during the patient's illness when the presumption is that the provision of oxygen in the home setting will improve the patient's condition, whether that condition represents a long term chronic illness or an expected short term recovery from an acute disorder.

**Measuring Blood Oxygen Levels**

*Comment*: Several commenters requested that arterial blood gas studies not be the only method by which blood oxygen levels may be measured.

*Response*: We agree that arterial blood gas studies performed by needlestick are not necessarily needed to establish hypoxemia or other oxygen need. A measurement of arterial oxygen saturation obtained by ear or pulse oximetry, is also acceptable for this purpose, 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. We have clarified the language in the NCD manual at Section B.

*Comment*: One commenter requested that CMS remove the language related to variations in oxygen measurements and patient characteristics found at the end of NCD proposed Section B. Other commenters stated that because the readings from pulse oximeters might provide a variation among beneficiaries being tested based on certain conditions such as ethnicity, they are concerned that this may result in MACs using their discretion to deny claims based on these test results. Therefore, these commenters requested CMS use only objective criteria for pulse oximetry requirements for the provision of home oxygen.

*Response*: The referenced language is long-standing language found in the 1993 NCD at Section D.3.d. We proposed two changes to this information: 1) adding "a patient's skin pigmentation" to the example factors, and 2) moving the language from 1993 NCD Section D.3.d (Health Conditions/Covered Blood Gas Values/Variable Conditions that May Affect Blood Gas Values) to its new placement at end of Section B (Nationally Covered Indications).

We believe it important to retain the language when considering the provision of home oxygen and oxygen equipment to all patients who may need it. Pulse oximetry is commonly used as a criterion to determine medical necessity of this DME. As discussed in the decision memorandum section VIII (Analysis, subsection Health Disparities), the FDA states that there are individual variations among patients when tested with pulse oximeters and therefore the device reading should always be considered an estimate of oxygen saturation, in part because various patient factors may affect the exactness of this measurement. As it has been in the past, it is Medicare's expectation that treating practitioners as well as MACs are aware of these factors and realize that pulse oximeter readings can provide misleading results if considered in isolation. Instead, the values obtained from a pulse oximeter reading should be analyzed together with pertinent information gathered from the patient's history, physical examination and previous medical course, in order to ascertain the correct path of treatment for any individual.

**Respiratory Therapy**

*Comment*: A few commenters expressed differing opinions about whether CMS should retain in the NCD the longstanding paragraph about noncoverage of respiratory therapist visits to beneficiaries using oxygen and oxygen equipment in their homes under the DME benefit. One commenter agreed that the language should be removed from the NCD because respiratory therapist services in the home are covered under a different benefit category, while another commenter recommended that CMS retain the paragraph about noncoverage of these professional services in the NCD as an acknowledgement or cross-reference to their benefit category.

*Response*: As the DME benefit for home use of oxygen does not include clinical services, we believe it is best not to include reference to respiratory therapist services in this NCD.

**Physicians vs Treating Practitioner Terminology**

*Comment*: One commenter noted that though we attempted to ensure that patients who choose nurse practitioners and other Medicare qualified clinicians as their providers of choice are able to maintain access to medically necessary treatments of home oxygen, we did not consistently replace the term "attending physician" with the term "treating practitioner" in this policy.

*Response*: We thank the commenter for bringing this to our attention and have corrected our oversight.

**Other**

*Comment*: Several commenters provided suggestions regarding coding, billing/payment, titration methodology, pediatric patients,and equipment classification as these topics related to delivering home oxygen.

*Response*: These comments are outside the scope of this NCD.

*Comment*: One commenter desired the language regarding portable oxygen be removed form the NCD.

*Response*: Language regarding the coverage of portable oxygen serves to describe coverage criteria for those for whom it is reasonable and necessary. Therefore we believe it is prudent to retain the language as proposed.

**VIII. CMS Analysis**

*Introduction*
NCDs are determinations by the Secretary with respect to whether or not a particular item or service is covered nationally by Medicare (§1869(f)(1)(B) of the Act). In order to be covered by Medicare, an item or service must fall within one or more benefit categories contained within Part A or Part B, and must not be otherwise excluded from coverage. Moreover, with limited exceptions, the expenses incurred for items or services must be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (§1862(a)(1)(A) of the Act).

The Supreme Court has recognized that "[t]he Secretary's decision as to whether a particular medical service is 'reasonable and necessary' and the means by which she implements her decision, whether by promulgating a generally applicable rule or by allowing individual adjudication, are clearly discretionary decisions." *Heckler v. Ringer*,

466 U.S. 602, 617 (1984). See also, *Almy v. Sebelius*, 679 F.3d 297, 303-04 (4th Cir. 2012) ("The Medicare statute preserves this discretion for the Secretary, leaving it to her judgment whether to proceed by implementing an NCD, by allowing regional contractors to adopt an LCD, or by deciding individual cases through the adjudicative process."); *International Rehabilitative Services Inc. v. Sebelius*, 688 F.3d 994, 1001 (9th Cir. 2012) ("But while the agency may make coverage determinations via up-front rules, it is not required to do so; rather, the agency has discretion in whether to make coverage determinations by up-front rulemaking or by case-by-case adjudication.")

*Home Use of Oxygen Use to Treat Cluster Headaches (NCD 240.2.2)*

The 2011 NCD for Home Oxygen Use to Treat CH (240.2.2), notes that the available evidence suggested the home use of oxygen to treat CH was promising and therefore supported further research under §1862(a)(1)(E) of the Social Security Act (the Act) through the CSP form of CED. Consequently, Medicare would provide coverage of the home use of oxygen for beneficiaries with CH, only when participating in an approved prospective clinical study comparing normobaric 100% oxygen with at least one clinically appropriate comparator for the treatment of that condition. To date, no research protocols studying the home use of oxygen for the treatment of CH have been submitted to CMS under NCD 240.2.2. Based on conversations with stakeholders, we have been informed that clinical studies have been conducted and new evidence has been developed outside the context of CED as reviewed below. Stakeholders have informed us that patients with CH typically have unique characteristics to their disorder, comorbidities and concomitant treatments. To that end, stakeholders, including the requester, have noted that the current CED clinical study requirements, while well intentioned, are challenging to implement for this treatment due to patient characteristics and care settings. Based on stakeholder feedback, we do not anticipate that any CED protocols will be submitted for review in the near future due to the difficulty in enrolling an appropriately defined study population.

For this reconsideration, we reviewed the current evidence for home use of oxygen to treat CH, which consisted of five published articles (one comparative trial, two SR and two guidelines).

The goal of research performed by Petersen et al.(2017) was to study possible differences in effect between three types of mask delivery systems of oxygen in the acute treatment of CH. While doing so, they provided data comparing the use of DVO masks administering 100% oxygen versus air (21% oxygen and 79% nitrogen) to patients with CH. No significant differences were noted in the provision of these different gases through DVO masks for the relief of the pain of CH at 15 and 30 minutes. However, the small sample size (n = 10) precludes a definitive statement regarding the utility/non-utility of oxygen in the care of patients with this condition.

Bennett et al. (2015), conducted a SR to examine the efficacy and safety of NBOT in the acute treatment of CH. Of the four studies noted, three had been previously considered in the 2011 NCD that determined the evidence did not demonstrate that the home use of oxygen to treat CH improved health outcomes in Medicare beneficiaries. The one clinical trial published since 2011 mentioned in this systematic review studied only two individuals with CH, precluding our use of it to supply new information. Additionally, Bennett et al. (2015) highlighted that the early articles that concluded oxygen was useful for the treatment of CH, may have been based upon inappropriately sized sample populations, thereby casting doubt as to the strength of evidence associated with the use of oxygen therapy for the treatment of CH.

In a similar vein, CPGs from the VA/DoD (2020) determined that there was insufficient evidence to recommend for or against oxygen therapy for the acute treatment of primary headaches, a classification that includes CH. Taken as a whole then, the current evidence for the generalized use of oxygen for the treatment of CH reflects stakeholder comments about the small study sample sizes and difficulty enrolling well defined patients in clinical studies.

However, we recognize that the literature confirms there is benefit to the use of oxygen therapy for some individuals

with CH. For example, data obtained from the international Cluster Headache Questionnaire, with 1604 respondents from over 50 countries (with 80.5% reported from the United States, the United Kingdom, and Canada) demonstrated that 54% of respondents (582/1082), reported complete or very effective treatment of oxygen for their CH. Of the 139 respondents 65 years and older, oxygen was reported as completely effective or very effective in 56% (Pearson, Burish, Shapiro, Yan and Schor, 2019). As noted in the CPGs of the VA/DoD (2020), though the Workgroup considered the quality of evidence to be very low, the use of inhaled oxygen, along with triptans, was considered to be first-line treatment. If successful then, oxygen in itself would be "optimum therapy" for the treatment of CH. Consequently, we believe that some Medicare beneficiaries who suffer CH, will receive meaningful pain relief from oxygen therapy. Therefore we are removing NCD 240.2.2, to allow the MACs to determine coverage for the use of home oxygen as a treatment option for CH, without the need for further CED clinical trials. The MACs are structured to be able to take into account individualized patient factors, particularly when the overall prevalence of the disease is small, as it is in this patient population and as further research evolves.

*Home Use of Oxygen (NCD 240.2)*

Because we are removing NCD 240.2.2, we are also modifying the 1993 NCD 240.2, Home Use of Oxygen, in order to allow appropriate patient access to oxygen and oxygen equipment in the home when its use is reasonable and necessary to treat certain Medicare beneficiaries, including those with CH. In doing so, we believe these modifications also address lessons learned during the COVID-19 public health emergency. Since the inception of the Public Health Emergency (PHE) due to the COVID-19 pandemic, CMS has permitted waivers for health care services to increase the capacity of the American health care system outside the setting of the traditional inpatient hospital (CMS Press Release, November 25, 2020). Many patients with COVID-19 developed low oxygenation and needed oxygen as part of their treatment outside the usual treatment settings. The ability to provide home oxygen was crucial for many patients. Specifically, we are expanding the coverage of oxygen and oxygen equipment in the home for short as well as long term use in both acute and chronic diseases of respiratory and non-respiratory origin, as is medically necessary. As mentioned above, we realize that the policy changes we are making will expand coverage of oxygen and oxygen equipment to beneficiaries with other conditions besides CH. We believe that this expansion is appropriate as it will remove limitations on reasonable and necessary treatments with home oxygen and oxygen equipment for beneficiaries. As seen during the PHE, this will also give treating practitioners more options to provide the best course of treatments, as is discussed further on in Section VIII of this document.

Below we outline the changes to the pertinent sections of the 1993 NCD 240.2. See Appendix B for the NCD Manual language for NCD 240.2.2. See Appendix C for the NCD Manual language NCD 240.2.

*General Statement of formatting changes*
We have reformatted the 1993 NCD 240.2 into the sections now more commonly used in NCDs: A (General); B (Nationally Covered Indications); C (Nationally Noncovered Indications); and D (Other). The chart below outlines the re-organization of NCD 240.2 into "modern" NCD format (see Appendix C for draft NCD Manual language).

| **Section Letter Designations** | **1993 NCD 240.2 Section Headings** | **2021 Revised NCD 240.2 Section Headings** |
|---|---|---|
| A | General | General |
| B | Medical Documentation | Nationally Covered Indications<br>(Includes portions of previous sections for Laboratory Evidence, Covered Blood Gas Values, Groups I and II and Variable Factors) |

| | | |
|---|---|---|
| C | Laboratory Evidence | Nationally Noncovered Indications<br>(Includes former section D2 Conditions for which oxygen therapy may not be covered) |
| D | Health Conditions | Other (includes former section E for Portable Oxygen Systems) |
| D1 | Conditions for Which Oxygen Therapy May be Covered | N/A |
| D2 | Conditions for Which Oxygen Therapy May not be Covered | N/A |
| D3 | Covered Blood Gas Values:<br>(a) Group 1<br>(b) Group 2<br>(c) Group 3<br>(d) Variable Factors | N/A |
| E | Portable Oxygen Systems | N/A |
| F | Respiratory Therapists | N/A |

N/A = not applicable

*Section A (General)*

Section A of the 1993 NCD 240.2 provides a broad summary of coverage of home use of oxygen which indicates that oxygen and oxygen equipment will only be covered for individuals with hypoxemia.[2] We have revised Section A to more accurately reflect the current scope of the NCD. In the reconsideration of NCD 240.2, as noted above, we are modifying the coverage of home use of oxygen to permit expanded coverage for beneficiaries beyond the condition of chronic hypoxemia. Therefore, we are modifying Section A to reflect this change.

*Section B, Medical Documentation*

We are removing all of the language in Section B of the 1993 NCD 240.2 entitled Medical Documentation. The main purpose of a NCD is to determine if items and services are reasonable and necessary for Medicare beneficiaries and will be covered (or non-covered) nationally under title XVIII. CMS makes this determination by using an evidence based process which is responsive to comments of external stakeholders. Determining appropriate documentation is not always part of the evidence-based analysis.

As part of CMS effort to reduce provider burden, we are removing the oxygen CMN requirement from the NCD. CMNs are claim attachment forms developed in the 1990s to augment medical review. At that time, the CMS DME claims systems had very limited editing capabilities and only basic information was included on the claim form. The CMN forms captured information needed for medical necessity determinations. Currently however, the claims

processing system is more sophisticated and can secure information that may corroborate the medical necessity for home oxygen. Sophisticated audits of the medical record may also accomplish the same goal. Therefore the CMN for home oxygen is no longer necessary as part of the NCD.

We also acknowledge that in removing Section B medical documentation of the 1993 NCD 240.2, we are removing the following non-documentation requirement for home oxygen therapy: "*The treating physician's prescription or other medical documentation must indicate that other forms of treatment (e.g., medical and physical therapy directed at secretions, bronchospasm and infection) have been tried, have not been sufficiently successful, and oxygen therapy is still required. While there is no substitute for oxygen therapy, each patient must receive optimum therapy before long-term home oxygen therapy is ordered."* We believe it is clinically appropriate to remove this requirement because there are clinical circumstances for which this policy requirement is not relevant. For example, treatment of CH in the otherwise healthy patient may not require other therapies. As noted in the CPG of the VA/DoD, the use of inhaled oxygen may be first line therapy for CH in some patients and if successful, is then in itself "optimum therapy." Therefore retaining a requirement for the prior use of alternative treatment may needlessly prolong patient symptoms and suffering in the individual with CH who does successfully respond to oxygen therapy. Similarly, we believe that it is clinically inappropriate to withhold oxygen in the home for hypoxemic patients while awaiting the results of other therapeutic measures to take effect. Though we believe it is the responsibility of the treating practitioner to evaluate any patient who requires oxygen in order to provide other therapeutic interventions as necessary, relief of signs and symptoms of respiratory insufficiency with supplemental oxygen, if reasonable and necessary, is paramount.

*Section C (Laboratory Evidence)(Finalized as part of Section B (Nationally Covered Indications): General Expansion of Coverage and Removal of 'Chronic Stable State' Condition Criterion*

Section C of the 1993 NCD 240.2 similarly describes medical documentation requirements which we are removing for the same reasons as described above. Specifically, we are removing in the fifth paragraph of Section C (proposed as Section B), the sentence, "*A/B MACs (B) may accept an attending physician's statement of recent hospital test results for a particular patient, when appropriate, in lieu of copies of actual hospital records.*" This is a statement of a medical documentation requirement to demonstrate that a particular item or service meets a reasonable and necessary standard. Documentation requirements such as this are more appropriately addressed in other manuals and guidance documents, not a NCD.

However, Section C of the 1993 NCD 240.2 also describes clinical criteria required to demonstrate that home oxygen was reasonable and necessary for the Medicare beneficiary. We are revising these clinical criteria to increase access to home oxygen for beneficiaries with CH and other clinical conditions, when appropriate.

We are removing all references and instructions regarding the "chronic stable state," in the 1993 NCD 240.2. "Chronic stable state" is used in the NCD to describe illness or disease that is "not during a period of an acute illness or an exacerbation of their underlying disease." The characteristics of CH do not fit an illness or disease in its "chronic stable state," because home oxygen is used to abort acute symptoms of CH, which in most cases would be expected to occur in bouts of relatively short duration (as compared to the symptoms of a life long chronic disease) and therefore only require short bursts of oxygen. Further, by removing the clinical criterion of "chronic stable state" we also expand the availability of home use of oxygen to individuals with resolving respiratory diseases who may benefit from oxygen in the short term (e.g. weeks instead of lifetime) as they recover from an acute, curable illness. In a singular illustration of such a point, we note patients who may be recovering from COVID-19 associated pneumonia, but who do not or who no longer require hospitalization, may be cautiously managed to a satisfactory health outcome at home when oxygen therapy is available for relatively short periods of time (Cohen, 2020; Sardesai I, Grover J, Garg M, et al., 2020). We believe this is clinically appropriate and therefore we are removing the requirement that home oxygen only be covered for those in the 'chronic stable state'; and instead provide home use of oxygen for patients with medical need of any duration, both for acute or chronic diseases, as it is medically

necessary.

Because we are removing all references to the 'chronic stable state', we also have required in Section B of the NCD Manual that qualifying blood oxygen studies be performed at the time of need. The 'time of need' means during the patient's illness when the presumption is that the provision of oxygen in the home setting will improve the patient's condition, whether that condition represents a long term chronic illness or an expected short term recovery from an acute disorder. For an inpatient hospital patient, this would ordinarily be (as stated in the 1993 NCD) within 2 days of discharge. For those patients whose initial oxygen prescription does not originate during an inpatient hospital stay, the time of need would logically be during the period when the treating practitioner notes signs and symptoms of illness that may be relieved by oxygen in the patient who is to be treated at home.

*Section D (Health Conditions) (portions Finalized in Section B (Nationally Covered Indications), Section C (Nationally Non-covered Indications), and D (Other))*

As described below, we have rewritten Section D of the 1993 NCD 240.2 to conform to the changes above.

Section D.1 of the 1993 NCD 240.2 (Conditions for Which Oxygen May Be Covered) provides the conditions and clinical criteria for which oxygen therapy may be covered and includes a list of specific examples of severe lung disease and hypoxia-related symptoms. We believe that by listing examples, which were not meant to be all-inclusive, we may have caused some to interpret the coverage determination more narrowly than intended. Furthermore, as stated above, CMS recognizes that oxygen therapy in the home may be medically necessary to treat not just respiratory conditions, but also non-respiratory conditions for certain beneficiaries. We noted above, for example, that it may be medically necessary to cover home oxygen therapy in order to diminish or terminate the exquisite pain of CH, a condition unrelated to the function of the lungs. Even when oxygen therapy is required to support respiratory needs, the etiology of that need may be due to causes other than lung disease. For example, chronic liver disease has long been known to be associated with respiratory symptoms and hypoxia for which the administration of supplemental oxygen may be appropriate (Maicao, Balakrishnan & Fallon, 2014). Moreover, as noted above, the NCD should allow for maximum flexibility to clinically appropriately provide coverage of home oxygen and oxygen equipment, regardless of duration of need. Therefore, we are removing the introduction to section D "Health Conditions" and Section D.1 (Conditions for which Oxygen May be Covered) of the 1993 NCD 240.2 including all examples of medical conditions that may require the use of home oxygen. This change reinforces that patients suffering from any medical condition, be it of respiratory or non-respiratory origin, may receive home oxygen and oxygen equipment for the duration of illness, be it short or long term, if this service is otherwise reasonable and necessary.

We also made the conforming change noted above removing the need for the patient to have unsuccessfully tried alternative therapies prior to the use of oxygen in the home (bullet D.3 of the 1993 NCD 240.2). As noted above, oxygen may be used as first line therapy for the treatment of CH if determined reasonable and necessary by the MACs. We deleted this bullet because we believe it may be an obstacle to ensuring the opportunity for local coverage discretion for the treatment of this condition, when appropriate. However, we again emphasize that it is the responsibility of the treating practitioner to fully evaluate the patient who requires oxygen and provide other therapeutic interventions as necessary.

We are moving Section D.2 of the 1993 NCD 240.2 (Conditions for Which Oxygen Therapy Is Not Covered) to new Section C (Nationally Noncovered Indications). Under subsection D2 of the 1993 NCD 240.2, Conditions for Which Oxygen Therapy Is Not Covered (New Section C, National Noncovered Indications), we also are clarifying bullet 4 to reflect that CMS recognizes that respiratory function can be impaired from various causes, not all of which involve primary lung disease. We want to ensure Medicare patients receive medically necessary treatments. Therefore, we are revising bullet 4 to indicate that CMS will cover home oxygen for terminal illnesses that affect the ability to

breathe, not withstanding the etiology of the disease process.

Further, for those patients who exceed the SPO2 and/or oxygen saturation values of the Group I and II individuals described in Section B (section D of the 1993 NCD 240.2), coverage of home oxygen is at the discretion of the MACs for the reasons discussed above. Therefore we have revised the language in Group III in section D.3.c of the 1993 NCD 240.2 and (here as new section D (Other)) removed the current reference to Group III and the definition including the rebuttable presumption of noncoverage. We replaced it with the following sentence: *The MAC may determine reasonable and necessary coverage of home oxygen and oxygen equipment for patients who are not described in Section B or precluded by Section C*. Conditions encompassed by this statement may include CH. This statement also includes other disease states that demonstrate arterial pO2 levels at or above 60 mm Hg, or arterial blood oxygen saturation at or above 90%. The discretion provided to the MACs allows them to make decisions regarding coverage based on the unique physiologic, cognitive and/or functional symptoms of individual patients, that are improved by oxygen therapy.

For those individuals who do not exhibit hypoxemia as defined in Section B of the NCD we proposed that initial coverage be limited to the shorter of 90 days or the number of days included in the practitioner prescription. For this subset of patients, we also proposed oxygen coverage may be renewed if medically necessary when a treating practitioner determines within 60-90 days after the DME has been initially placed in the home that the patient exhibits a continuing need for oxygen. This period of time was chosen because clinically, we expect most patients (excluding those with CH) recovering from acute diseases that have required the use of home oxygen, to no longer have need for this medical gas. However, based on experience with the PHE, we find it appropriate that the time frame of initial coverage for patients with relatively short term conditions who do not exhibit hypoxemia, i.e. those described in Section D, is limited to the shorter of 120 days or the number of days included in the practitioner prescription. Oxygen coverage may be renewed if medically necessary, at MAC discretion. We believe that the extra time is still within the parameters of a short term illness and might be needed to allow beneficiaries to return to their treating practitioners to be properly evaluated for continuation or discontinuation of oxygen.

For beneficiaries who do exhibit hypoxemia as defined in Appendix C, Section B, we have not specified time periods of coverage.

Additionally, in Covered Blood Gas Values, section D.3.a of the 1993 NCD 240.2 (finalized as section B), we note the term 'exercise' in the requirements for Group I patients, in the past, may have been interpreted by some narrowly. We interpret the term exercise more broadly to include either the functional performance of the patient (e.g. ambulation, accomplishment of ADLs, stair climbing, dressing, eating, etc.) or a formal exercise test (e.g. 6 minute walk test, etc.), as preferred by the treating practitioner. Given the burden that respiratory illnesses places on the patient during everyday activities, the need for oxygen can be evaluated during the execution of these routine pursuits.

Based on the discussion below regarding health disparities, we also are modifying section D.3.d of the 1993 NCD 240.2 (Variable Factors That May Affect Blood Gas Values) in order to add the patient's skin pigmentation to the list of factors that may account for variations in oxygen measurement. Additionally, the subheading is removed and the language is moved to the end of proposed Section B, Nationally Covered Indications. Finally, we also are removing Section F from the 1993 NCD 240.2 concerning Respiratory Therapists. As the DME benefit does not include clinical services, we believe that having this section as part of the NCD is not necessary.

*Health Disparities*

Pulse oximetry can be a useful means to estimate blood oxygen levels. However, the FDA states that there are individual variations among patients when tested with pulse oximeters and therefore the device reading should

always be considered an estimate of oxygen saturation. For example, if an FDA-cleared pulse oximeter reads 90%, then the true oxygen saturation in the blood is generally between 86-94%. Pulse oximeter accuracy is highest at saturations of 90-100%, intermediate at 80-90%, and lowest below 80% (FDA, 2021).

Patient factors may affect the exactness of this measurement. For example, literature has reported that there are differences in the accuracy of the pulse oximeter readings when the information obtained from these devices is compared between persons who identified their race as Black or White. Though many of the individuals who identified themselves as Black did demonstrate accurate pulse oximeter values, their risk of experiencing occult hypoxemia (defined as an arterial oxygen saturation of <88% determined by arterial blood gas studies despite an oxygen saturation of 92 to 96% on pulse oximetry) was reported to be nearly three times that of individuals who designated themselves as White (Sjoding, 2020).

It is important for both patients and providers to be aware of the limitations of pulse oximeters, particularly when these devices are used to either diagnose or treat conditions that require the ongoing monitoring of the patient's health status as oxygen is used in the home. All manifestations of an individual's disease state and physical characteristics should be considered in their assessment, including signs and symptoms of cognitive and physical dysfunction, potential laboratory abnormality, and variability of device readings. The discretion provided to the MACs in this NCD should provide home oxygen coverage for all individuals who require it.

*Technical Changes*

Based on the above mentioned reformatting into an A-D structure, we made several conforming technical changes. The language of Section E (Portable Oxygen Systems) of the 1993 NCD 240.2 has been moved to Section D (Other) because it reflects local coverage discretion. We also removed from this language the bulleted sentences referencing the 1993 sections of the NCD and the sentence related to medical documentation, in conformance with the general standard of removing medical documentation language throughout the NCD.

## IX. Conclusion

CMS is finalizing changes to two separate, but medically related, NCDs. Given new information in the peer-reviewed medical literature, we are removing NCD for Home Oxygen Use to Treat CH (240.2.2). We are also revising NCD for Home Use of Oxygen (240.2). We summarize these changes below and fully explain our rationale in the Analysis section of this decision memorandum.

CMS is removing NCD 240.2.2 in the Medicare NCD Manual, ending coverage with evidence development (CED), and allowing the Medicare Administrative Contractors (MACs) to make coverage determinations regarding the use of home oxygen and oxygen equipment for CH.

CMS also is modifying NCD 240.2, Home Use of Oxygen, in the Medicare NCD Manual to expand patient access to oxygen and oxygen equipment in the home, and to permit contractors to cover the use of home oxygen and oxygen equipment in order to treat CH and other acute conditions.

The scope of this decision does not include any consideration of Home Use of Oxygen in Approved Clinical Trials, identified in section 240.2.1 of the NCD Manual. Additionally, the scope of the decision does not include any consideration of hyperbaric oxygen for any indication, currently identified in section 20.29 of the NCD Manual.

See Appendices B and C for NCD Manual language.

## APPENDIX A

### General Methodological Principles of Study Design

(Section VI of the Decision Memorandum)

When making national coverage determinations, CMS evaluates relevant clinical evidence to determine whether or not the evidence is of sufficient quality to support a finding that an item or service is reasonable and necessary. The overall objective for the critical appraisal of the evidence is to determine to what degree we are confident that: 1) the specific assessment questions can be answered conclusively; and 2) the intervention will improve health outcomes for patients.

We divide the assessment of clinical evidence into three stages: 1) the quality of the individual studies; 2) the generalizability of findings from individual studies to the Medicare population; and 3) overarching conclusions that can be drawn from the body of the evidence on the direction and magnitude of the intervention's potential risks and benefits.

The methodological principles described below represent a broad discussion of the issues we consider when reviewing clinical evidence. However, it should be noted that each coverage determination has its unique methodological aspects.

**Assessing Individual Studies**

Methodologists have developed criteria to determine weaknesses and strengths of clinical research. Strength of evidence generally refers to: 1) the scientific validity underlying study findings regarding causal relationships between health care interventions and health outcomes; and 2) the reduction of bias. In general, some of the methodological attributes associated with stronger evidence include those listed below:

- Use of randomization (allocation of patients to either intervention or control group) in order to minimize bias.
- Use of contemporaneous control groups (rather than historical controls) in order to ensure comparability between the intervention and control groups.
- Prospective (rather than retrospective) studies to ensure a more thorough and systematical assessment of factors related to outcomes.
- Larger sample sizes in studies to demonstrate both statistically significant as well as clinically significant outcomes that can be extrapolated to the Medicare population. Sample size should be large enough to make chance an unlikely explanation for what was found.
- Masking (blinding) to ensure patients and investigators do not know to that group patients were assigned (intervention or control). This is important especially in subjective outcomes, such as pain or quality of life, where enthusiasm and psychological factors may lead to an improved perceived outcome by either the patient or assessor.

Regardless of whether the design of a study is a randomized controlled trial, a non-randomized controlled trial, a cohort study or a case-control study, the primary criterion for methodological strength or quality is to the extent that differences between intervention and control groups can be attributed to the intervention studied. This is known as internal validity. Various types of bias can undermine internal validity. These include:

- Different characteristics between patients participating and those theoretically eligible for study but not participating (selection bias).
- Co-interventions or provision of care apart from the intervention under evaluation (performance bias).
- Differential assessment of outcome (detection bias).

- Occurrence and reporting of patients who do not complete the study (attrition bias).

In principle, rankings of research design have been based on the ability of each study design category to minimize these biases. A randomized controlled trial minimizes systematic bias (in theory) by selecting a sample of participants from a particular population and allocating them randomly to the intervention and control groups. Thus, in general, randomized controlled studies have been typically assigned the greatest strength, followed by non-randomized clinical trials and controlled observational studies. The design, conduct and analysis of trials are important factors as well. For example, a well-designed and conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size. The following is a representative list of study designs (some of that have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

Randomized controlled trials
Non-randomized controlled trials
Prospective cohort studies
Retrospective case control studies
Cross-sectional studies
Surveillance studies (e. g. , using registries or surveys)
Consecutive case series
Single case reports

When there are merely associations but not causal relationships between a study's variables and outcomes, it is important not to draw causal inferences. Confounding refers to independent variables that systematically vary with the causal variable. This distorts measurement of the outcome of interest because its effect size is mixed with the effects of other extraneous factors. For observational, and in some cases randomized controlled trials, the method in that confounding factors are handled (either through stratification or appropriate statistical modeling) are of particular concern. For example, in order to interpret and generalize conclusions to our population of Medicare patients, it may be necessary for studies to match or stratify their intervention and control groups by patient age or co-morbidities.

Methodological strength is, therefore, a multidimensional concept that relates to the design, implementation and analysis of a clinical study. In addition, thorough documentation of the conduct of the research, particularly study selection criteria, rate of attrition and process for data collection, is essential for CMS to adequately assess and consider the evidence.

**Generalizability of Clinical Evidence to the Medicare Population**

The applicability of the results of a study to other populations, settings, treatment regimens and outcomes assessed is known as external validity. Even well-designed and well-conducted trials may not supply the evidence needed if the results of a study are not applicable to the Medicare population. Evidence that provides accurate information about a population or setting not well represented in the Medicare program would be considered but would suffer from limited generalizability.

The extent to that the results of a trial are applicable to other circumstances is often a matter of judgment that depends on specific study characteristics, primarily the patient population studied (age, sex, severity of disease and presence of co-morbidities) and the care setting (primary to tertiary level of care, as well as the experience and specialization of the care provider. Additional relevant variables are treatment regimens (dosage, timing and route of administration), co-interventions or concomitant therapies, and type of outcome and length of follow-up.

The level of care and the experience of the providers in the study are other crucial elements in assessing a study's external validity. Trial participants in an academic medical center may receive more or different attention than is typically available in non-tertiary settings. For example, an investigator's lengthy and detailed explanations of the potential benefits of the intervention and/or the use of new equipment provided to the academic center by the study sponsor may raise doubts about the applicability of study findings to community practice.

Given the evidence available in the research literature, some degree of generalization about an intervention's potential benefits and harms is invariably required in making coverage determinations for the Medicare population. Conditions that assist us in making reasonable generalizations are biologic plausibility, similarities between the populations studied and Medicare patients (age, sex, ethnicity and clinical presentation) and similarities of the intervention studied to those that would be routinely available in community practice.

A study's selected outcomes are an important consideration in generalizing available clinical evidence to Medicare coverage determinations. One of the goals of our determination process is to assess health outcomes. These outcomes include resultant risks and benefits such as increased or decreased morbidity and mortality. In order to make this determination, it is often necessary to evaluate whether the strength of the evidence is adequate to draw conclusions about the direction and magnitude of each individual outcome relevant to the intervention under study. In addition, it is important that an intervention's benefits are clinically significant and durable, rather than marginal or short-lived. Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits.

If key health outcomes have not been studied or the direction of clinical effect is inconclusive, we may also evaluate the strength and adequacy of indirect evidence linking intermediate or surrogate outcomes to our outcomes of interest.

**Assessing the Relative Magnitude of Risks and Benefits**

Generally, an intervention is not reasonable and necessary if its risks outweigh its benefits. Health outcomes are one of several considerations in determining whether an item or service is reasonable and necessary. CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes, and laboratory or radiographic responses. The direction, magnitude, and consistency of the risks and benefits across studies are also important considerations. Based on the analysis of the strength of the evidence, CMS assesses the relative magnitude of an intervention or technology's benefits and risk of harm to Medicare beneficiaries.

## APPENDIX B

**Medicare National Coverage Determinations Manual**

*Draft*
*This NCD is subject to formal revisions and formatting changes prior to the release of the final NCD contractor instructions and publication in the Medicare National Coverage Determinations Manual.*

**Table of Contents**
**(Rev.)**

*Effective September 27, 2021 the Centers for Medicare and 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.*

**APPENDIX C**

**Medicare National Coverage Determinations Manual**

*This NCD is subject to formal revisions and formatting changes prior to the release of the final NCD contractor instructions and publication in the Medicare National Coverage Determinations Manual.*

**Table of Contents**

**(Rev.)**



## 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 NCD*. This prohibition does not extend to the results of blood gas test*s* 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 *(EKG)*, 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 MAC 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

*CMS will not cover oxygen and home oxygen equipment 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 $PO_2$ 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 home oxygen and oxygen equipment for patients who are not described in Section B or precluded by Section C. 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. Oxygen coverage may be renewed if medically necessary.*

*MAC may 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 reviewed September 2021.)*

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

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[1] Hypoxemia: abnormally low levels of oxygen in the blood.

[2] Section A of NCD 240.2 (effective 10/27/1993) states: Medicare coverage of home oxygen and oxygen equipment under the DME benefit (see §1861(s)(6) of the Social Security Act) is considered reasonable and necessary only for patients with significant hypoxemia who meet the medical documentation, laboratory evidence, and health conditions …"

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