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Comments on CMS Proposed Decision Memo for Home Use of Oxygen and Home Use to Treat Cluster Headaches (CAG-00296R2) Posted July 2, 2021

I. Introduction

The American Association for Homecare (AAHomecare) is pleased to submit comments on the Centers for Medicare and Medicaid Services' (CMS') Proposed Decision Memo for Home Use of Oxygen and Home Use to Treat Cluster Headaches (CAG-00296R2). AAHomecare is the national association representing DMEPOS suppliers, manufacturers, and other stakeholders in the homecare community. Our members are proud to be part of the continuum of care that assures Medicare beneficiaries receive cost effective, safe and reliable home care products and services, including home oxygen equipment and related services. Our members serve approximately 80 percent of all Medicare home oxygen patients across the country. In light of this, we are uniquely qualified to comment on CMS' proposed decision memo.

II. CMS Proposed Decision Memo

In its proposed Decision Memo, CMS proposes to remove the current national coverage determination (NCD) at section 240.2.2 of the Medicare NCD Manual (CMS Pub. 100-03). CMS also proposes to modify its NCD for Home Use of Oxygen at section 240.2 of the Medicare NCD Manual to expand patient access to oxygen and oxygen equipment in the home, and to permit the DME MACs to cover the use of home oxygen and oxygen equipment to treat cluster headaches and to treat other acute conditions.

III. Summary of Comments

AAHomecare appreciates CMS' recognition that, since the onset of the COVID-19 public health emergency (PHE), "the ability to provide home oxygen has been crucial to treatment of patients during the pandemic," and that "the ability to provide home oxygen was crucial for many patients." (CMS Proposed Decision Memo, Sections II and VI). As a result of our members' experience with patients both before the pandemic as well as patients with COVID-19 who have needed supplemental oxygen therapy, we fully support CMS' proposal to expand coverage for oxygen and oxygen equipment in the home for short- and long-term use, and for patients with both acute and chronic conditions. We also support CMS' proposal to remove the requirement for a beneficiary to have tried and failed alternative therapies. We support, with caveats explained in the following paragraph, CMS' proposal that could improve the documentation requirements by eliminating the use of the oxygen certificate of medical necessity (CMN).

While we appreciate CMS' proposal to expand coverage to include acute and chronic patients and remove the CMN requirement, we have serious concerns about the apparent lack of objective data that would be used to support a patient's medical need. Without clear and objective criteria, medical review audits will be continue to be based upon a subjective review of the medical record, which is wholly within the control of the prescriber, and for which the prescriber has no financial or other incentive to document consistent with Medicare's traditional detailed requirements. We therefore strongly recommend that the prescription, or the standard written order (SWO) be the sole required documentation of medical need. If CMS chooses to require additional documentation, we strongly recommend that CMS make mandatory for hospital systems and physicians a revised version of the clinical data element template (CDE) for home oxygen. The home oxygen CDE, modified to be consistent with the revised oxygen NCD, would incorporate all required elements of the SWO. If CMS chooses to not make mandatory the home oxygen CDE, then we support continued use of the CMN, as long as CMS allows the medical need details (such as test results) on the CMN to substantiate a beneficiary's medical need for home oxygen. To protect patient access, it is imperative that medical necessity be based on objective documentation and not left to the discretion of contractors reviewing medical records.

A. Comments.

1. Support Expanded Coverage for Patients with Acute Conditions

AAHomecare fully supports CMS' proposal to expand coverage of home oxygen therapy to beneficiaries with acute and chronic conditions, for short- and long-term therapy. We concur with CMS' statement that "this expansion is appropriate as it will remove the limitation on reasonable and necessary treatments with home oxygen and oxygen equipment for beneficiaries." As became evident during the COVID-19 PHE, this will also give physicians more options to provide the best course of treatments. We also support CMS' proposed expansion of coverage for cluster headaches.

2. Medical Need Documentation Must be Clear and Objective (Section B)

AAHomecare supports CMS' proposal to eliminate the CMN as it is currently only utilized as a billing tool and is not used to demonstrate medical need. The CMN is a burdensome requirement for both oxygen suppliers and prescribers who must complete this document. Oxygen suppliers often have difficulty meeting the CMN requirement because many of the forms are returned incomplete from prescribers and then require multiple communications between the prescriber and supplier to have it completed accurately.

While we agree that the NCD is not the appropriate venue to detail documentation requirements, ***we recommend that CMS/DME MACs implement clear and objective documentation requirements consistent with the final oxygen NCD.*** Like prescription drugs that are dispensed based on a valid physician prescription, the medical need for oxygen should be determined by the physician and a valid SWO should be sufficient to document medical need for acute or chronic

patients. ***AAHomecare also recommends that CMS require a new SWO to document a beneficiary's medical need beyond 90 days for patients with acute conditions.***

AAHomecare has serious concerns about a potential shift from using objective criteria to subjective criteria to determine medical need for home oxygen. The proposed Decision Memo alludes to potential contractor discretion, but if contractor discretion becomes the standard without being replaced by the SWO and/or the objective CDE template, the uncertainty of whether medical record documentation meets subjective criteria may produce unintended consequences on the back end with potential unfounded negative outcomes in audit findings. ***We therefore strongly urge CMS and the DME MACs to rely upon objective criteria to determine medical need.***

The current Medicare oxygen NCD states the “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.” (p. 19 of NCD 240.2). We support defining the test to be used as an arterial blood gas (ABG) or pulse oximetry. CMS appears to have concerns in the proposed Decision Memo that pulse oximetry tests may under-report low oxygen saturation levels. ***We therefore recommend that CMS and/or the DME MACs clarify the oximetry test results ranges that would qualify a beneficiary with acute or chronic health conditions requiring supplemental oxygen therapy.***

If Medicare insists on requiring medical need documentation beyond the SWO, AAHomecare supports the use of a single, simplified, modified version of the CMS CDE template for home oxygen therapy. The CDE includes all required elements of the SWO. The CDE elements assist suppliers and providers with meeting all the documentation requirements for home oxygen. CMS would need, however, to require hospital systems and prescribers to implement the CDE templates within their respective electronic health record (EHR) systems to meet all the documentation requirements. If such a CDE requirement cannot be implemented on a timely basis, we recommend that the SWO along with any required documentation of testing be sufficient to meet the billing and qualification requirements to document medical need. Of course, the current draft CDE for home oxygen would need to be revised based upon the final revised oxygen NCD.

DME MACs' LCD, as well as their LCA, “Standard Documentation Requirements for All Claims Submitted to DME MACs” (A55426) must be revised to be consistent with this NCD. The current version of A55426 contains multiple references to the CMN and other documentation that would need to be updated if the proposed NCD is finalized.

3. Laboratory Evidence (Section C)

Chronic Stable State: AAHomecare fully supports CMS' proposal to remove all references and instructions in the NCD regarding the clinical criterion “chronic stable state,” to enable patients with certain diseases to better recover from an acute illness. This term is no longer relevant as CMS proposes to expand coverage for patients with acute conditions.

“Time of Need”: AAHomecare requests that CMS clarify the term “time of need.” In its proposed Decision Memo, CMS states,

The “time of need” means during the patient’s illness when the presumption is that the provision of oxygen will improve the patient’s condition in the home setting, 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 (such as individuals with CH), the time of need would logically be during 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.

AAHomecare recommend that CMS clarify “time of need” as the date the therapy is ordered to initiate oxygen therapy.

Pulse Oximetry Tests: We are concerned about CMS’ apparent questioning of the utility of pulse oximetry tests, given that this test provides clear objective data to determine a beneficiary’s medical need. CMS must establish clear and objective clinical criteria to establish medical necessity, as explained above. AAHomecare therefore requests that CMS clarify the oximetry test results range that would qualify a beneficiary with acute issues and the range of oximetry test results that would qualify a beneficiary with chronic health issues.

We strongly suggest limiting oxygen testing requirements to either (1) SpO2 or PaO2 at rest or during activity (without the need for a formal exercise study), or (2) SpO2 overnight. Additionally, for oxygen prescribed for hospital discharge, if more than one arterial blood gas or pulse oximetry test is performed during a beneficiary’s hospital stay, the test result obtained closest to the hospital discharge date should be evidence of the need for home oxygen therapy.

4. Health Conditions (Section D)

AAHomecare agrees with CMS’ recognition 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 appreciate CMS’ statement in the proposed Decision Memo that respiratory function can be impaired from various causes, not just lung disease.

AAHomecare fully supports CMS’ statement in the proposed Decision Memo that “the NCD should allow for maximum flexibility to clinically appropriately provide coverage of home oxygen and oxygen equipment, regardless of duration of need.” We also support CMS’ proposed elimination of examples of medical conditions that may require the use of home oxygen, because they inappropriately limit coverage. While CMS states that it wishes to provide “maximum flexibility to clinically appropriately provide coverage of home oxygen and oxygen equipment,” CMS also appears to provide the MACs with discretion to limit that flexibility. We are concerned

with CMS' statement that "[t]he MAC may determine the reasonable and necessary coverage of home oxygen and oxygen equipment for patients with conditions unrelated to hypoxemia," given the proposed NCD's clear direction that it is the prescriber who determines medical need for oxygen. Any MAC interpretation, for example in an LCD, to limit the NCD language, would be inappropriate and inconsistent with the clear direction in the proposed NCD to rely upon the prescriber to determine medical need.

AAHomecare further agrees with CMS' proposal to remove the current requirement that the beneficiary must have unsuccessfully tried alternative therapies prior to the use of oxygen in the home, and CMS' statement that it is the responsibility of the treating practitioners to fully evaluate the patient and what they require. This underscores our recommendation that the SWO be used as the determinant of medical need.

For patients with acute conditions, CMS proposes that the coverage may be renewed when a treating practitioner determines within 120 days of initiating treatment that the patient exhibits a continuing need for oxygen. ***We recommend that CMS clarify in the final NCD that this renewal of medical need can be documented by the prescriber in a new SWO.***

5. Portable Oxygen

The current home oxygen NCD 240.2, Section E, contains verbiage related to portable oxygen systems. ***We recommend that CMS eliminate all references to portable oxygen in the NCD because the NCD is about the national coverage criteria for home oxygen therapy, of which portable oxygen is a subset.*** There is simply no need to separately specify portable oxygen in the NCD.

B. Conclusion

Thank you for the opportunity to comment. Please contact me at kimb@aaahomecare.org if you have any questions.

Sincerely,



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VP, Regulatory Affairs