July 29, 2021

Re: Proposed Decision Memo on Home Use of Oxygen and Oxygen Use to Treat Cluster Headaches (CH) (CAG-00296R2)

The undersigned organizations appreciate the opportunity to offer comments in response to the Centers for Medicare & Medicaid Services (CMS) Proposed Decision Memo for Home Use of Oxygen and Home Oxygen Use to Treat Cluster Headaches **(CAG-00296R2)**.
CMS proposes to remove National Coverage Determination (NCD) 240.2.2 and allow the Medicare Administrative Contractors (MAC) to determine the appropriate use of oxygen and oxygen equipment for cluster headaches while concurrently revising NCD 240.2 to expand coverage for home use of oxygen. CMS is also seeking comment on the specific language to be included in the NCD Manual based on the revisions in the proposed decision memo.

COMMENTS:
We would like to express our support and appreciation for the inclusion of the following modifications:

1. We applaud CMS for its decision to expand coverage to include short- and long-term use of supplemental oxygen for acute and chronic respiratory conditions and to provide coverage for conditions unrelated to hypoxemia, especially recognizing the increased need for oxygen for many acute conditions, including those individuals who require oxygen upon discharge from the hospital due to COVID.
2. Allowing maximum flexibility of the treating practitioner to determine clinically appropriate oxygen use based on medical need, without the patient having to first try and fail other therapeutic alternatives, is an important change and one that can help improve overall patient care. Requiring that a patient try and fail alternative treatments prior to the provision of supplemental oxygen puts the patient at unnecessary risk, and we support the recommendation that this language be removed.
3. We are supportive of CMS's proposed recertification changes for those individuals who are not hypoxemic or who demonstrate continued improvement from an acute disease. We agree with CMS's assessment that many patients recovering from an acute illness may not need long-term supplemental oxygen use. Limiting initial coverage to the shorter of 90 days or a physician prescription, while at the same time allowing the treating practitioner to continue supplemental oxygen use if it is determined within 60-90 days after the equipment is placed in the "home" where renewal is medically necessary, can result in improved utilization and cost savings.
4. We concur with the proposal to eliminate references to "chronic stable state" and to replace it with "time of need." This gives the treating practitioner the ability to determine when the need for oxygen outside the hospital setting will improve the patient's condition, which has been limited due to the current restrictions. The language to be included in the manual states: "For those patients whose initial oxygen prescription does not originate during an inpatient hospital stay, the time of need would be during the

period **when the treating practitioner notes signs and symptoms of illness that can be relieved by oxygen (emphasis added)** in the patient who is to be treated at home." We caution how this may be interpreted by the MACs. Our reading of the language implies that "notes signs and symptoms" is the initial assessment of the patient's need for supplemental oxygen by the treating practitioner. We ask CMS to clarify this understanding in the final decision memo.

5. In our comments submitted in September 2020, we supported the removal of the Certificate of Medical Necessity (CMN) and recommended that the Clinical Data Element Order Template currently on the CMS website be used in its place. Although we agree with CMS's rationale to eliminate the CMN documentation as burdensome, we believe the electronic template is an important tool in validating the medical record for audit purposes and encourage CMS to require its use in lieu of the CMN. We are concerned that without this fail-safe, patient access could be an issue if left to the discretion of the Durable Medical Equipment MACs.
6. We applaud CMS's proposal to remove the specific list of examples included in the section related to Conditions for Which Oxygen Therapy May be Covered in NCD 240.1. Although the list was never intended to be inclusive as CMS suggests, it has caused confusion in the past, and we support removal of the examples, thereby allowing patients suffering from any medical condition to receive supplemental oxygen if it is determined to be medically necessary.

RECOMMENDATIONS:

We support the major changes outlined in CMS's proposed decision memo, and we believe consideration should be given to further revisions in the final decision memo. Our recommendations and rationale for additional changes are listed below:

1. **Eliminate "home" from the NCD and retitle it to read "Outpatient Use of Supplemental Oxygen."**
   Rationale: As indicated in previous comments, the term "home use of oxygen" implies that it can only be used within the "four walls of a home." This can be confusing and does not reflect today's standards for supplemental oxygen use outside the inpatient hospital setting. Oxygen is frequently utilized away from the home while performing the usual activities of daily living that require exertion and may increase the need for supplemental oxygen. We feel it is important to provide clinically appropriate supplemental oxygen support for any patient who has a disease characterized by both acute and chronic hypoxemia, regardless of location of need.

   The description of "home" in the current NCD language can be a barrier to full understanding of the need for portable oxygen. There is a clearly defined, relatively small number of patients with certain very severe diseases (eg, interstitial lung disease, pulmonary hypertension, post-COVID pulmonary disease, bullous emphysema, etc) that cause profound hypoxemia that is refractory to correction on an outpatient basis with the commonly supplied oxygen systems. Portable oxygen units that provide a reasonably long duration of high oxygen concentrations are needed on an outpatient basis to supply essential needs and for the usual activities of daily living.

2. **Revise coverage and payment criteria by establishing a classification system based on clinical needs.**
   Rationale: By removing the CMN, CMS has the opportunity to revise oxygen coverage and payment decisions based on the standard of care and not solely based on the criteria of "continuous flow/liters per minute." Setting forth categories that accurately reflect the patient's need for supplemental oxygen, based on the physician assessment,

is needed to bring policies up to date along with the other changes CMS is proposing. The following is an example of a physician-ordered equipment classification that could meet this need:

Category 1 (Stationary System Only) – Use of oxygen limited to patients who are sleep-only, clinically moribund, or bedbound, or to activities limited to less than a 50-foot radius. Example: A stationary concentrator with a 50-foot oxygen hose and a compressed gas cylinder for emergency backup for power outage or stationary device failure.

Category 2 (Transportable System) – Limited/occasional mobility outside of a 50-foot radius (e.g., medical appointment, religious services, family visits). Example: A stationary concentrator with a 50-foot hose, plus an as-needed supply of compressed gas cylinders (e.g., E cylinder on a wheeled cart).

Category 3 (Ambulatory System) – Support for exercise/exertion or for continuous use, also including need for frequent ambulation. Example: An "ambulatory delivery system" is defined as a small device that is "portable," allowing the beneficiary to move about freely while carrying or rolling a lightweight unit without assistance and with enough ease to perform medically required exercise/exertion or their usual activities of daily living for the required duration. An example would be a portable oxygen concentrator (POC) or lightweight containers filled from a transfilling concentrator.

Category 4 (Refractory Hypoxemia) – This is the group with profound hypoxemia refractory to commonly used oxygen systems described in the previous categories, requiring higher flow rates, high concentrations of supplemental oxygen, and portability.

3. **Utilize oximetry to determine the appropriate device setting(s) that should be ordered to provide adequate oxygen saturations at rest and during usual activities of daily living: "Titrate to Saturate."**
   Rationale: Once the appropriate clinical category and optimal delivery device and accessories have been determined, every patient should be titrated to an adequate oxygen saturation on the device(s) they will be using while at rest and during the activities they will perform daily. For example, a setting of 2 liters per minute on one device may not provide the same oxygen delivery to a patient on a different type of device on a similar setting. The delivery may also be different if the device is set to intermittent flow versus continuous flow. Upon initiation of supplemental oxygen therapy, and periodically thereafter, the setting(s) on every oxygen delivery system prescribed should be adjusted to provide adequate oxygen saturation for the patient at rest and during their usual activities of daily living. This may require a different setting on their stationary system and portable systems.

4. **The NCD for oxygen is based on data derived from studies of adults, and we suggest that the NCD not be used to establish standards of care for children.**

5. **The use of oxygen during sleep should be assessed while using positive airway pressure (PAP) devices for those with sleep-disordered breathing, and as per the rest of the document, supplemental oxygen approval does not require a total time of desaturation.**

6. **We would like to again point out that while "service" is not part of the NCD process, we recognize and support that the services of a respiratory therapist are**

part of the standard of care in the clinical assessment, education, treatment, and care of individuals who require supplemental oxygen.

We appreciate the opportunity to comment on the proposal and your consideration of inclusion of our recommendations. We would also look forward to the opportunity to have further meetings with CMS to discuss how these issues could be addressed.

- American Association for Respiratory Care
- American College of Chest Physicians
- American Lung Association
- American Thoracic Society
- Allergy & Asthma Network
- COPD Foundation
- Dorney-Koppel Foundation
- Pulmonary Fibrosis Foundation
- Respiratory Health Association
- US COPD Coalition