



**OPEN COMMENT PERIOD ON:**

**Home Use of Oxygen and Home Oxygen Use to Treat Cluster Headaches (CAG-00296R2)**

*Submitted electronically to*

July 30<sup>th</sup>, 2021

The Honorable Chiquita Brooks-LaSure  
Administrator  
U.S. Centers for Medicare & Medicaid Services  
200 Independence Avenue, SW  
Washington, DC 20201

Dear Administrator Brooks-LaSure,

The American Headache Society (AHS) and the American Migraine Foundation (AMF) appreciate the opportunity to submit a public comment to advocate for coverage of home use oxygen therapy for the acute treatment of cluster headache attacks by Medicare and Medicaid beneficiaries.

For 60 plus years, AHS has been and continues to be the leading professional society of health care providers dedicated to the study and treatment of migraine, cluster and other headaches, as well as face pain. With over 1400 members and associates, the Society's education, research, and advancement programs engage medical professionals throughout their careers, from the world's most sought after thought leaders to those at the beginning of their professional work in headache medicine. Working alongside AHS, AMF advocates for, supports, educates, and engages over 40 million Americans who suffer the debilitating effects of headache diseases, including cluster headache. Founded by AHS in 2010, the AMF strives to mobilize a community for patient support and advocacy, as well as drive and support impactful research that translates into treatment advances.

This letter is a response to the proposed decision memo for home use of oxygen and home oxygen use to treat cluster headaches (CAG-00296R2) of July 2, 2021. This memo highlights significant progress for the coverage of home use oxygen for the acute treatment of cluster headache attacks for Medicare and Medicaid beneficiaries. We are supportive and appreciative that home use oxygen for the treatment of cluster headache attacks is now a coverable benefit. Thank you.

However, additional clarifications and changes are recommended before the policy is finalized.

1. All Medicare patients with a cluster headache diagnosis should be eligible for insurance covered home use oxygen, not just "select" patients.
  - o Home use oxygen for the acute treatment of cluster headache attacks is a first line therapy as recommended by evidence-based guidelines from both AHS and the American Academy of Neurology. There have been two Class I studies, Fogan et al. and Cohen et al., demonstrating that 100% high flow oxygen for up to 15 minutes during an attack is better than placebo. In both studies,

oxygen was well tolerated with no serious adverse events. Guidelines have indicated that, based on available evidence, there is a Level A evidence for home use 100% high flow oxygen for the acute treatment of cluster headache attacks.

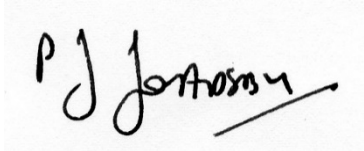
- In addition, a large patient experience study with 2,193 subjects, 60% from the United States, demonstrating 77% of patients with cluster headache reported oxygen therapy to be effective, safe, and very well tolerated. In fact, 91% of patients with cluster headache reported that there were no adverse effects of oxygen therapy. This is strong evidence that oxygen therapy for cluster headache is safe. We would also like to highlight the impressively large sample size for this cluster headache study given that cluster headache is a rare disease with a lifetime prevalence of about one in 1000 people.
  - In all the above studies, there is no evidence or indication that home use oxygen is not safe for patients with a diagnosis of cluster headache.
  - The proposed decision memo expresses concern over study sample size and the mix of both international and national data. However, these well designed studies have appropriate sample sizes for a rare disease and inclusion of a wide breadth of patients (international and national) increases the generalizability of data thus increasing validity.
  - **The above professional society guidelines and large patient experience study emphasizes the medical necessity that ALL Medicare patients with a cluster headache diagnosis be eligible for home use oxygen therapy.**
2. The coverage determination should be made at the CMS/National level and not moved down to the individual Medicare Administrative Contractors (MAC).
    - MACs would establish their independent Local Coverage Determination (LCD) policies which may impact the consistency of coverage for patients with cluster headache which may expand healthcare disparities. Coverage determination, based on high levels of evidence for a first-line therapy that is safe and effective for a rare disease that is highly disabling, needs to be made at the CMS/National level to ensure equal ethical coverage for all Medicare and Medicaid beneficiaries.
  3. For the acute treatment of cluster headache attacks with home-use oxygen, blood gas studies should not be required prior to approval for insurance coverage.

We strongly support coverage of home use oxygen therapy for the acute treatment of cluster headache attacks by Medicare and Medicaid beneficiaries. Cluster headache (known as ‘suicide headache’) is a severe pain disorder with devastating suffering along with employment, social and emotional consequences. Oxygen therapy has been demonstrated to be safe and effective. The use of oxygen is a highly recommended first line therapy for cluster headache attacks by AHS guidelines. This recommendation is backed by high quality clinical trials and an increasing breadth of positive published patient experience.

From the patient perspective, having access to home oxygen therapy can be life changing, and for many it can be lifesaving. Cluster headaches are estimated to affect up to 1 million Americans, and despite the characteristic symptoms of the attacks and the incredibly high disability that they cause, it can take up to 7 years for a patient to be correctly diagnosed. And yet there is a simple, inexpensive, and highly effective, safe treatment available, but all too often, because of insurance coverage restrictions, this therapy has been unavailable. In a survey of patients living with cluster headache conducted by the American Migraine Foundation, it was found that 74% of patients who had tried oxygen for the acute treatment of their attacks reported it to be effective/very effective, yet 41% of patients who were prescribed home oxygen were denied this treatment modality by their insurance company. Not surprisingly, patient comments reflected their disappointment with the inability to obtain this highly effective treatment. When you factor in the high suicidality rates of this disease (approximately 60% of sufferers contemplate taking their own lives), limiting access to treatment is inhumane and unethical. The AMF stands together with AHS in advocating for our patients so that they may receive, without restrictions, the treatment that they deserve.

For the reasons outlined above, the American Headache Society and the American Migraine Foundation respectfully requests that CMS provide the above recommended clarifications and revisions prior to finalization of the policy to all all Medicare and Medicaid beneficiaries with the diagnosis of cluster headache to have access to home-use oxygen.

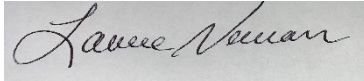
On behalf of the American Headache Society and the American Migraine Foundation,



Peter Goadsby, MD, PhD, FAHS, AHS President



Amaal Starling, MD, FAHS, AHS Advocacy  
Committee Chair



Lawrence Newman MD, FAHS, AMF Chair

#### References:

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- Fogan L. Treatment of cluster headache. A double-blind comparison of oxygen v air inhalation. *Arch Neurol.* 1985;42:362–363
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