

The Honorable Seema Verma
Administrator
U.S. Centers for Medicare & Medicaid Services
200 Independence Avenue, SW
Washington, DC 20201

September 14, 2020

Dear Administrator Verma,

The Coalition for Headache and Migraine Patients (CHAMP) appreciates the opportunity to comment on CMS' National Coverage Analysis (NCA) Tracking Sheet for Home Use of Oxygen and Home Oxygen Use to Treat Cluster Headaches (CAG-00296R2). CHAMP is a coalition of 21 participants: 13 non-profit organizations, five patient opinion leaders, and three migraine communications companies. Our mission is to improve the lives of people with migraine, cluster and other headache diseases by aligning coalition participants and empowering patient voices. CHAMP works to ensure that patients are supported, patient advocates are empowered, and headache diseases are better managed.

We submit the following data from the *CHAMP Headache Disease Patient Access Survey* as further evidence to overturn the CMS Decision Memo for National Coverage Determination (NDC), which denies coverage of home use of high-flow oxygen therapy for the acute treatment of cluster headache attacks for Medicare and Medicaid beneficiaries.

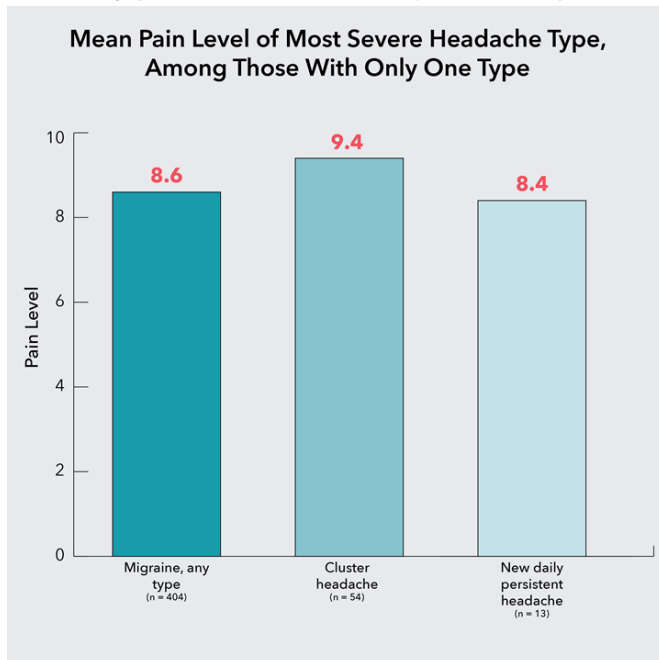
Cluster headache is one of the most painful types of headache. It occurs in cyclical patterns or bouts of frequent attacks, known as cluster periods, which can last from weeks to months (*mayoclinic.org*). High-flow oxygen therapy has been established as the standard of care for the acute treatment of cluster headache in adults. (*Kudrow L. Response of cluster headache attacks to oxygen inhalation. Headache 1981;21:1–4.; Fogan L. Treatment of cluster headache: a double blind comparison of oxygen v. air inhalation. Arch Neurol 1985;42:362–363.; Cohen A, Burns B, Goadsby P. High flow oxygen for treatment of cluster headache. JAMA 2009;302:2451–2457.; Dirks, H.T., et al., Oxygen treatment for cluster headache attacks at different flow rates: a double-blind, randomized, crossover study. J Headache Pain 2018;19:94.*) In addition, survey studies have found no difference in its efficacy, tolerability or safety in adults aged < 65 years vs. adults aged ≥ 65 years. (*Rozen TD, Fishman RS, Inhaled Oxygen and Cluster Headache Sufferers in the United States: Use, Efficacy and Economics: Results From the United States Cluster Headache Survey. Headache. 2011;51:191-200.; Pearson SM, Burish MJ, Shapiro RE, Yan Y, Schor LI. Effectiveness of oxygen and other acute treatments for cluster headache: Results from the Cluster Headache Questionnaire, an international survey. Headache. 2019;59:235-249.*)

In late 2019 and early 2020, CHAMP conducted an anonymous survey that reached 3,514 people. Of those, 2,037 met survey eligibility requirements and completed the survey. Of the eligible completer sample, 468 (23%) self-reported having received a diagnosis of cluster headache (*Coalition for Headache and Migraine Patients. (2019-2020). CHAMP Headache Disease Patient Access Survey [Unpublished raw data]*).

From this survey, we submit new, unpublished data with respect to the relative severity of cluster headache pain, current and past usage of pharmacological treatments, satisfaction with current treatment plan, and insurance coverage barriers experienced.

Relative Severity of Pain During a Cluster Attack

Our survey asked respondents to rate the pain level of their most severe headache types on a scale from 1 to 10. We compared ratings among those with one headache type. Cluster headache patients mean rating (9.4) was higher than both migraine (mean 8.6, $p < 0.001$) and new daily persistent headache (mean 8.4, $p < 0.01$).



Note: Although we asked this question for other headache types, there was insufficient sample to report it among those with tension-type headache or post-traumatic headache for whom that was their only headache type.

Pharmacological Treatments Tried

When living with a condition as painful as cluster headache, every moment closer to relief is all consuming. People living with cluster headache have used or are currently using a large number of separate pharmacological treatments. Our survey showed that almost 40% of respondents have previously used or are currently using more than 10 separate pharmacological treatments to treat their cluster attacks.

Table 1 - Number of separate pharmacological treatments respondents with a cluster headache diagnosis previously used or are currently using to treat their headaches

	Number	Percentage
0	#	#
1-3	58	12.4
4-6	126	26.9

7-10	98	20.9
11-20	100	21.4
21-49	54	11.5
50+	28	6.0

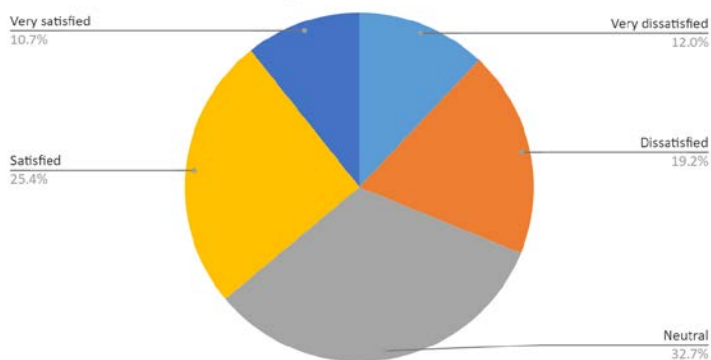
Notes: # - Too few cases to report

Item was capped at 50+ treatments on survey

Level of Satisfaction with Current Treatment

Respondents were asked to rate their level of satisfaction with their current headache disease treatment plan considering all pharmacological and non-pharmacological treatment options. Despite trying so many different treatments, on average, 31.2% said they were either very dissatisfied or dissatisfied with their overall current headache disease treatment plan, while another 32.7% reported neutral satisfaction. Only about a third of people with cluster headache are satisfied with their current treatment.

Satisfaction with current headache treatment plan, among those with a cluster headache diagnosis



Reported Treatment Access Barriers

Our survey respondents defined high-flow oxygen therapy as both pharmacological and non-pharmacological treatments. Here are some examples of barriers experienced by survey respondents that may be related to high-flow oxygen therapy. Almost 72% reported high cost as a barrier to accessing a prescribed treatment and 54% reported that obtaining insurance approval prevented them from gaining access to a prescribed treatment.

Furthermore, our survey showed that high numbers of cluster patients have had trouble accessing treatments or been denied treatments altogether. 82% of those with Medicare reported an issue accessing treatments because of a prior authorization, while 76% reported being denied treatment.

Conclusion

CHAMP believes it is essential for CMS to cover home use of high-flow oxygen therapy for cluster headache patients. Our data shows that cluster headache is an extremely painful disease and patients are often forced to try many different medications to find any kind of relief, with only about a third being satisfied with their current treatments. High-flow oxygen therapy has been established as the standard of care for years and continues to be proven as safe and effective regardless of age. Cluster patients face an uphill battle against a complicated neurological disease; they need all the help they can get.

We strongly urge you to reconsider and overturn the CMS Decision Memo for National Coverage Determination (NCD) [CAG-00296R] to permit coverage of home use of oxygen for the treatment of cluster headache attacks by Medicare and Medicaid beneficiaries. As private insurance coverage decisions are also often impacted by the coverage decisions of CMS, we request CMS lead by example and provide more options to those living with cluster headache.

CHAMP appreciates the opportunity to provide input during the open comment period. If you have questions, please contact Meghan Buzby, Director of Advocacy, Coalition for Headache and Migraine Patients, at 410-404-9482 or meghan.buzby@headachemigraine.org.

Sincerely,

Kevin Lenaburg
Executive Director, CHAMP
On behalf of the CHAMP coalition

CHAMP Participants

American Migraine Foundation
Association of Migraine Disorders
Chronic Migraine Awareness
Clusterbusters
Cluster Headache Support Group
The Daily Headache
Danielle Byron Henry Migraine Foundation
Golden Graine
The Headache & Migraine Policy Forum
HealthyWomen
Hope for Migraine Community
Migraine Again
Migraine.com
MigrainePal
The Migraine Diva
Migraine World Summit
Miles for Migraine

National Headache Foundation
Patient Advocate Foundation
US Pain Foundation