

Medicare for Cluster Headache

a significant gap in patient care

Oxygen Therapy



Cluster Headache

- Cluster headaches are characterized by an intense one-sided pain centered by the eye or temple. The pain lasts for one to two hours on average and may recur several times in a day
- The pain transcends by far the distress of the more common tension-type headache and even that of a migraine headache.
- Cluster headaches afflict less than 0.5% of the population
- Approximately 80% of cluster headaches are classified as episodic, affecting the patient for 2-3 months of the year; the remaining 20% are considered chronic with no reprieve.

Source: 2016, <http://medical-dictionary.thefreedictionary.com/cluster+headache>



Current State

- The NCD for the Home Use of Oxygen to Treat Cluster Headache (CH), released by CMS in January 2011, concludes that the **currently available evidence does not demonstrate that the home use of oxygen to treat CH improves health outcomes** among Medicare beneficiaries. Absent such evidence, CMS has concluded that additional clinical research is appropriate under Coverage with Evidence Development (CED). The NCD specifies that home use of oxygen to treat CH is covered for beneficiaries with CH participating in an approved prospective clinical study comparing normobaric 100% oxygen (NBOT) with at least one clinically appropriate comparator for the treatment of CH. Source: <https://www.cms.gov/Medicare/Coverage/>

- *There is, in fact, no patent protection or financial opportunity for any organization to undertake the proposed NCD study*
- *100% of neurologists who specialize in headache disorders prescribe high-flow oxygen therapy as a firstline acute treatment*



Healthcare considers O2 essential

- The standard treatment of acute attacks of cluster headache is inhalation of 100% oxygen.

[Cephalalgia](#). 1995 Oct;15 Suppl 15:33-6

Treatment of cluster headache: clinical trials

- Inhaled normobaric oxygen is an essential abortive treatment of cluster headache. Recognition of its efficacy for cluster headache goes back a half a century

Trigeminal Autonomic Cephalalgias (M Matharu, Section Editor)

[Current Pain and Headache Reports](#)

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- A total of 109 patients treated 4 CH attacks with either oxygen (12 L/min) or inhaled air, given via a facial mask for 15 minutes. Oxygen was significantly superior to placebo with regards to the primary end point (elimination of pain or "adequate pain relief" at 15 minutes—78% vs 20%, with oxygen and air, respectively). As opposed to triptans, oxygen can be given to patients with a history of cardiovascular or cerebrovascular disease.

Cluster Headache—Acute and Prophylactic Therapy

Avi Ashkenazi, MD; Todd Schwedt, MD

[Headache](#). 2011;51(2):272-286



Expert Opinion

- “Normobaric oxygen is an **effective treatment of acute CH attacks** in the majority of patients. It is well tolerated and has virtually **no AEs**. As opposed to triptans, there is **no limitation to the number of times per day it can be used**. A proper technique of use is crucial for good results with oxygen therapy. The patient should be instructed to use the oxygen via a non-rebreathable mask, at a rate of 7-10 L/min, in a sitting position, for at least 15-20 minutes. Patients may increase the flow rate up to 15 L/min if needed. The optimal flow rate should be determined individually for each patient.

Cluster Headache—Acute and Prophylactic Therapy
Headache 2011;51:272-286 American Headache Society
Avi Ashkenazi, MD; Todd Schwedt, MD



Clinical Studies Prove Safety and Efficacy

- **High-Flow Oxygen for Treatment of Cluster Headache: A Randomized Trial**

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- *JAMA*. 2009;302(22):2451-2457. doi:10.1001/jama.2009.1855

Objective To ascertain whether high-flow inhaled oxygen was superior to placebo in the acute treatment of cluster headache.

- **Design, Setting, and Patients** A double-blind, randomized, placebo-controlled crossover trial of 109 adults (aged 18-70 years) with cluster headache as defined by the International Headache Society. Patients treated 4 headache episodes with high-flow inhaled oxygen or placebo, alternately. Patients were randomized to the order in which they received the active treatment or placebo. Patients were recruited and followed up between 2002 and 2007 at the National Hospital for Neurology and Neurosurgery, London, England.

Intervention Inhaled oxygen at 100%, 12 L/min, delivered by face mask, for 15 minutes at the start of an attack of cluster headache or high-flow air placebo delivered alternately for 4 attacks.

Main Outcome Measures The primary end point was to render the patient pain free, or in the absence of a diary to have adequate relief, at 15 minutes. Secondary end points included rendering the patient pain free at 30 minutes, reduction in pain up to 60 minutes, need for rescue medication 15 minutes after treatment, overall response to the treatment and overall functional disability, and effect on associated symptoms.

Results Fifty-seven patients with episodic cluster headache and 19 with chronic cluster headache were available for the analysis. For the primary end point the difference between oxygen, 78% (95% confidence interval, 71%-85% for 150 attacks) and air, 20% (95% confidence interval, 14%-26%; for 148 attacks) was significant (Wald test, $\chi^2_5 = 66.7$, $P < .001$). There were no important adverse events.



Additional Expert Reports and Studies

- Extracranial vascular responses to sublingual nitroglycerin and oxygen inhalation in cluster headache patients. [Headache](#). 1985;25:70-74. Drummond PD, Anthony M.
- Oxygen inhibits neuronal activation in the trigeminocervical complex after stimulation of trigeminal autonomic reflex, but not during direct dural activation of trigeminal afferents. [Headache](#). 2009;49:1131-1143. Akerman S, Holland PR, Lasalandra MP, et al.
- Normobaric and hyperbaric oxygen therapy for migraine and cluster headache. [Cochrane Database](#) Syst Rev. 2008;3:CD005219. Bennett MH, French C, Schnabel A, et al.
- Response of cluster headache attacks to oxygen inhalation. [Headache](#). 1981;21:1-4. Kudrow L.
- Treatment of cluster headache. A double-blind comparison of oxygen v air inhalation. [Arch Neurol](#). 1985;42:362-363. Fogan L.
- High oxygen flow rates for cluster headache. [Neurology](#). 2004;63:593. Rozen TD.
- High-flow oxygen for treatment of cluster headache: A randomized trial. [JAMA](#). 2009;302:2451-2457. Cohen AS, Burns B, and Goadsby PJ.
- Treatment of a cluster headache patient in a hyperbaric chamber. [Headache](#). 1989;29:109-110. Weiss LD, Ramasastry SS, and Eidelman BH.
- Hyperbaric oxygen therapy in cluster headache [Pain](#). 1993; 52:243-245. Di Sabato F, Fusco BM, Pelaia P, et al.
- Hyperbaric oxygen treatment of active cluster headache: A double-blind placebo-controlled cross-over study. [Cephalalgia](#). 2002;22:730-739. Nilsson Remahl AI, Ansjon R, Lind F, et al.

Medicare Approved Treatment Options

● Acute/abortive

- Sumatriptan succinate injection 6mg x 9/mo.
- Sumatriptan tablet (note: ineffective for CH due to duration of attack vs. route of administration)

● Preventive

- There are currently no approved preventive medications for CH
- Some off-label medications provide partial relief (verapamil, lithium, sodium valproate, gabapentin, topiramate, etc.)

Unmet Medical Need

- Cluster patients average 3.5 severe attacks/day, 20 days/month
 - Triptans are limited to 2 uses/day, 6/wk
 - Medicare only allows 9 triptans/mo
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- The average patient is left untreated for >40% of severe HA events every day, >90% in a month
 - Patients with cardiovascular or cerebrovascular conditions are contraindicated for triptans
 - Many patients resort to using welder's oxygen and/or self-medicating
 - Quality of Life is poor, many become disabled

Financial Impact of current Medicare coverage

- Triptan cost: \$639/mo meeting 10% of need
vs. \$200/mo. for home oxygen meeting 100% of need
- Disability cost:
 - Median US income is \$46,481 per year
 - Average SSDI payment is \$1166/mo (\$13,992/yr)
 - Results is a \$32,489 economic loss per year per person

Recommendations

- Based on *healthcare expertise, clinical study evidence* of efficacy and safety, and anecdotal evidence of an *improved quality of life* that reduces the incidence of *disability*, we strongly urge the **CMS to reconsider its position on Medicare coverage for home high-flow oxygen for cluster headache**