Medicare for Cluster Headache
a significant gap in patient care

Oxygen Therapy
Topics Covered in this Presentation

- Disease Description and Statistics
- Current State: Medicare Denial of Coverage
- Expert Opinion
- Clinical Studies
- Gap in Medical Care
- Cost to US Taxpayers
- Recommendations
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.

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

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

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.

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Treatment of cluster headache: clinical trials

Trigeminal Autonomic Cephalalgias (M Matharu, Section Editor)  
Current Pain and Headache Reports  
April 2012, Volume 16, Issue 2, pp 175-179

Cluster Headache—Acute and Prophylactic Therapy  
Avi Ashkenazi, MD; Todd Schwedt, MD  
Headache. 2011;51(2):272-286
“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
High-Flow Oxygen for Treatment of Cluster Headache: A Randomized Trial

Anna S. Cohen, PhD, MRCP; Brian Burns, MD, MRCP; Peter J. Goadsby, MD, PhD, DSc, FRACP, FRCP

Author Affiliations: Headache Group, Institute of Neurology, et. Al.


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, $\chi^2 = 66.7$, $P < .001$). There were no important adverse events.


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.)
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

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 CDC to reconsider its position on Medicare coverage for home high-flow oxygen for cluster headache.