Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 9/1/24**
(See policy history boxes for previous effective dates)

Title: Oxygen Therapy for the Treatment of Cluster Headaches

Description/Background

Cluster headaches, also known as migrainous neuralgia, are defined as primary headaches characterized by spontaneous attacks of excruciating unilateral pain that usually occurs in the eye, periorbital region and temple with associated cranial autonomic symptoms such as conjunctival injection, lacrimation, nasal blockage, rhinorrhea, ptosis and eyelid edema. Pain often radiates to the upper teeth, jaw and neck. Symptoms during attacks include aggravation, restlessness or both. There are 2 types of cluster headaches, episodic and chronic. The more common type, episodic, is characterized as an attack that can last from 7 days up to a year with breaks of 1 month or more between episodes. Chronic cluster headaches are defined as occurring for more than a year without remission or with remissions lasting less than a month. When untreated, attacks have a time frame ranging from 15 to 180 minutes, with a frequency of 1 episode every other day, for up to 8 attacks per day. An estimated 0.3 percent of the general population suffers from cluster headaches, with more men than women being affected.

In cases refractory to conservative measures, treatment of cluster headaches may include surgical options such as radiofrequency rhizotomy and microvascular decompression of the trigeminal nerve. To acutely treat an attack, sumatriptan and dihydroergotamine are highly effective pharmacological treatments. Triptan agents are contraindicated in patients with a vascular risk, such as ischemic heart disease or hypertension.

Oxygen therapy has been evaluated as a treatment for acute cluster headaches. The inhalation of high-dose, high-flowing oxygen has no adverse effects, can be combined with other treatments and can be utilized daily. Although the mechanism of action is not clearly understood, inhaled oxygen at a level of 100 percent for 15 minutes has been observed to be effective in relieving acute episodes of cluster headaches.

Pulse oximetry and arterial blood gas values are not required for the use of home oxygen for cluster headaches.

Regulatory Status:

N/A

Medical Policy Statement

The safety and effectiveness of oxygen therapy for cluster headaches have been established. It may be considered a useful therapeutic option when indicated.

Inclusionary and Exclusionary Guidelines

Patient selection criteria for the treatment of cluster headaches with oxygen therapy may include:

Cluster headache
A. At least 5 attacks fulfilling B through D

B. Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15 to 180 minutes if untreated

C. Headache is accompanied by at least 1 of the following:
1. Ipsilateral conjunctival injection and/or lacrimation
2. Ipsilateral nasal congestion and/or rhinorrhea
3. Ipsilateral eyelid edema
4. Ipsilateral forehead and facial sweating
5. Ipsilateral miosis and/or ptosis
6. A sense of restlessness or agitation

D. Attacks have a frequency from 1 every other day to 8 per day

E. Not attributed to another disorder

Episodic cluster headache
- All fulfilling criteria A through E from above
- At least 2 cluster periods lasting from 7 to 365 days and separated by pain free remissions of > 1 month.

Chronic cluster headache
- All fulfilling criteria A through E from above
- Attacks recur for > 1 year without remission periods or with remission periods lasting < 1 month.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure)*

Established codes:

E0424	E0425	E0430	E0431	E0434	E0435
E0439	E0440	E0441	E0442	E0443	E0444
E0447	E1353	E1390			

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

Medrea et al (2022) conducted a network meta-analysis regarding therapies for cluster headaches. Thirteen randomized control trials evaluating treatments (high flow oxygen, injectable sumatriptan, low flow oxygen, nasal spray zolmitriptan, octreotide and non-invasive vagal nerve stimulation) in adults (>18 years old) with cluster headaches were identified. Most treatments were compared against placebos in clinical trials, few head-to-head comparisons of treatments are available. High flow oxygen was found to be the most effective therapy for headache response at 15 and 30 min (OR 9.0, 95% CrI 5.3 to 15.9 vs. placebo), followed by injectable sumatriptan. High flow oxygen was also more effective than low flow oxygen (OR 2.55, 95% CrI 1.13 to 5.8), nasal spray zolmitriptan (OR 3.75, 95% CrI 1.72 to 8.4), octreotide (OR 4.5, 95% CrI 1.64 to 12.5), and non-invasive vagal nerve stimulation (nVNS; OR 5.2, 95% CrI 2.29 to 11.9). Authors concluded that when low flow oxygen fails in individuals who can tolerate oxygen, increased flow rates should be tried. Additionally, high flow oxygen is likely more effective than zolmitriptan nasal spray, nVNS, and octreotide.

Guo et al (2019) discussed the history and the effectiveness of oxygen for cluster headaches back to 1940. An attempt was made to explore the factors that can predict the response to oxygen treatment and to compare the effects between different flow rates. After review, it was still unclear why oxygen exhibits such good efficacy in the treatment of cluster headaches and no significant differences in effects between oxygen flow rates were noted. Authors concluded that high-flow oxygen is recommended as a more effective treatment for cluster headaches that has few complications, but the choice of suitable cases and oxygen flow rate or tools, as well as the appropriate time for oxygen inhalation, require more exploration in the future.

Cochrane review (2015) examined normobaric oxygen therapy (NBOT) for cluster headaches. The analysis found NBOT was effective in terminating cluster headache compared to sham in a single small study; however, it was not superior to ergotamine administration as another small study found. A third study found a statistically significant difference in the proportion of attacks treated with oxygen [117 of 150 attacks were successfully treated with NBOT (78%) versus 30 of 148 attacks treated with NBOT (20%)]. The proportion of responders was consistent across the studies, suggesting more than 75% of headaches were likely to respond to NBOT

Peterson et al (2014) reviewed the existing literature documenting the therapeutic effect of oxygen on cluster headache. After a review of 11 relevant studies, the authors concluded that there is a positive effect of low-flow oxygen and found a positive response in 56%-82% of the individuals. One study investigated high-flow oxygen, 12 l/min, and found efficacy in 78% of attacks. The authors noted that "despite the fact that only a few high-quality RCT studies are available, oxygen treatment is close to an ideal treatment because it is effective and safe."

Cohen et al (2009) investigated whether high-flow inhaled oxygen was superior to placebo in the acute treatment of cluster headache in a double-blind, randomized, placebo-controlled crossover trial of 109 adults (aged 18-70 years) that met the cluster headache criteria as defined by the International Headache Society. Subjects were excluded from the study if they had chronic migraines, were pregnant and/or lactating, had moderate to severe chronic obstructive pulmonary disease, could not tolerate the oxygen mask, or had previously tried oxygen at doses of 4 L/min and higher. Subjects treated 4 headache episodes with high-flow inhaled oxygen or placebo, alternately. Subjects were randomized to the order in which they received the active treatment or placebo: Inhaled oxygen at 100 percent, 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. The primary end point was to render the subject pain free, or in the absence of a diary to have adequate relief, at 15 minutes. Secondary end points included rendering the subject 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. Treatment of subjects with cluster headache at symptom onset using inhaled high-flow oxygen compared with placebo was more likely to result in being pain-free at 15 minutes. 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 percent (95 percent confidence interval, 71-85 percent for 150 attacks) and air, 20 percent (95 percent confidence interval, 14-26 percent; for 148 attacks) was significant (Wald test, chi (5) (2) = 66.7, P < .001). There were no significant adverse events. Investigators concluded treatment of subjects with cluster headache at symptom onset using inhaled high-flow oxygen compared with placebo was more likely to result in being pain-free at 15 minutes.

Supplemental Information

European Federation of Neurological Societies
The European Federation of Neurological Societies (EFNS) issued clinical guidelines on the treatment of cluster headache and other trigeminal-autonomic cephalalgias. The EFNS recommended the use of 100% oxygen with a flow of at least 7 L/min over 15 min and 6 mg subcutaneous sumatriptan as a first choice modality for the acute treatment of cluster headache attacks. According to these guidelines, the level of evidence for the use of oxygen for the treatment of cluster headaches is denoted as a Level A rating (established as effective) requiring at least one convincing class I study or at least two consistent, convincing class II studies.

European Academy of Neurology
For the acute treatment of cluster headache attacks, there is a strong recommendation for oxygen (100%) with a flow of at least 12 L/min over 15 min and 6 mg subcutaneous sumatriptan. Prophylaxis of cluster headache attacks with verapamil at a daily dose of at least

240 mg (maximum dose depends on efficacy and tolerability) is recommended. Corticosteroids are efficacious in cluster headache. To reach an effect, the use of at least 100 mg prednisone (or equivalent corticosteroid) given orally or at up to 500 mg iv per day over 5 days is recommended. Lithium, topiramate, and galcanezumab (only for episodic cluster headache) are recommended as alternative treatments. Noninvasive vagus nerve stimulation is efficacious in episodic but not chronic cluster headache. Greater occipital nerve block is recommended, but electrical stimulation of the greater occipital nerve is not recommended due to the side effect profile.

British Thoracic Society
The British Thoracic Society published guidelines in 2015 for home oxygen use in adults. The following information was provided regarding short burst oxygen therapy (SBOT) for cluster headache:

- Use of SBOT in cluster headache
  - SBOT delivering high flow oxygen therapy (12 L/min via a non-rebreather mask) should be offered to treat acute attacks of cluster headache (CH). (Grade A)

- Good practice point
  - Appropriate equipment will need to be provided in order to ensure delivery of high flow rate oxygen at 12 L/min for CH using a non-rebreather mask. Individuals will usually have warning of a CH attack, and so provision should be made for urgent 4 h installation of home oxygen, if available, rather than a permanent home supply being provided.

American Headache Society
The American Headache Society Guideline (2016) gives an A recommendation to sumatriptan subcutaneous, zolmitriptan nasal spray, and high flow oxygen as treatment for acute cluster headache treatment.

Government Regulations

National:

National Coverage Determination (NCD): Home Oxygen Use to Treat Cluster Headache (CH): (240.2.2) 100-3, Version 2. Effective 4/10/23; Implementation Date 4/10/23; RETIRED

Effective September 27, 2021, the Centers for Medicare & Medicaid Services removed the national coverage determination (NCD) for home oxygen use to treat CLUSTER HEADACHEs. In the absence of an NCD, coverage determinations will be made by the Medicare Administrative Contractors under section 1862(a)(1)(A) of the Social Security Act, as allowed and described in Chapter 1, Section 240.2 (Home Use of Oxygen), Subsection D, of Publication 100-03 of the NCD Manual.

Local:

LCD: Oxygen and Oxygen Equipment (L33797):
Effective on or after 10/1/15; Revision date: 4/1/23
NOTE: LCD contains more information; only pieces referring to Cluster Headaches are mentioned below.

Initial coverage of home oxygen therapy and oxygen equipment is reasonable and necessary for beneficiaries…if all of the following conditions are met:

1. Absence of hypoxemia defined in Group I and Group II above; and,
2. A medical condition with distinct physiologic, cognitive, and/or functional symptoms documented in high-quality, peer-reviewed literature to be improved by oxygen therapy, such as cluster headaches (not all inclusive).

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

N/A

References

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3. Centers for Medicare and Medicaid Services (CMS). Medicare National Coverage Determinations Manual; publication number 100-3, manual section 240.2.2, "National Coverage Determination (NCD): Home Oxygen Use to Treat Cluster Headache (CH) - RETIRED"; Effective date: 4/10/23; https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=343&ncdver=3&keyword=cluster&keywordType=starts&areaId=s27&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1. Accessed April 24, 2023.
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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 4/8/24, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
3/1/12	12/13/11	12/21/11	Joint policy established
3/1/14	12/10/13	1/6/14	Routine maintenance Code update – Procedure codes K0741 and K0742 are deleted as of 1/1/13. Added procedure codes E0424 and E0441.
5/1/15	2/17/15	2/27/15	Routine maintenance
9/1/15	6/19/15	7/16/15	Routine maintenance; added codes for portable oxygen
9/1/16	6/21/16	6/21/16	Routine maintenance
9/1/17	6/20/17	6/20/17	• Routine maintenance • Retirement held r/t rare cases coming through
9/1/18	6/19/18	6/19/18	• Routine maintenance
9/1/19	6/18/19		• Routine maintenance • E0447 added per code update
9/1/20	6/16/20		Routine maintenance
9/1/21	6/15/21		Routine maintenance
9/1/22	6/21/22		• Routine maintenance • NCD updated
9/1/23	6/13/23		• Routine maintenance (slp) • Vendor managed: N/A
9/1/24	6/11/24		• Routine maintenance (slp) • Vendor managed: Northwood

Next Review Date: 2nd Qtr, 2025

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: N/A	Revised: N/A
BCBSM: N/A	Revised: N/A

BLUE CARE NETWORK BENEFIT COVERAGE POLICY: OXYGEN THERAPY FOR THE TREATMENT OF CLUSTER HEADACHES

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered, criteria apply
BCNA (Medicare Advantage)	Refer to Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.