

<b>MEDICAL POLICY</b>	<b>Home Oxygen Therapy and Equipment for Cluster Headaches (All Lines of Business Except Medicare)</b>
<b>Effective Date: 4/1/2021</b>	Medical Policy Number: 87
 4/1/2021	Medical Policy Committee Approved Date: 1/16; 3/17; 3/18; 3/19; 2/2020; 3/2021
Medical Officer	Date

**See Policy HCPCS CODE section below for any prior authorization requirements**

**SCOPE:**

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

**APPLIES TO:**

All lines of business except Medicare

**BENEFIT APPLICATION**

Medicaid Members

*Oregon:* Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

<p><b>POLICY CRITERIA</b></p> <ol style="list-style-type: none"> <li>I. Home oxygen therapy for cluster headaches may be considered <b>medically necessary and covered</b> when <b>all</b> of the following criteria (A.-C.) are met: <ol style="list-style-type: none"> <li>A. Neurologist has evaluated patient and confirmed the diagnosis of cluster headache; <b>and</b></li> <li>B. Neurologist has prescribed oxygen in conjunction with both an acute and preventative medical treatment plan; <b>and</b></li> <li>C. The cluster headaches must be accompanied by <b>at least one</b> of the following findings: <ol style="list-style-type: none"> <li>1. Ipsilateral conjunctival injection and/or lacrimation; <b>or</b></li> <li>2. Ipsilateral nasal congestion and/or rhinorrhea; <b>or</b></li> <li>3. Ipsilateral eyelid edema; <b>or</b></li> <li>4. Ipsilateral forehead and facial sweating; <b>or</b></li> </ol> </li> </ol> </li> </ol>
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- 5. Ipsilateral miosis and/or ptosis; **or**
  - 6. A sense of restlessness or agitation
- II. Home oxygen therapy is considered **investigational and is not covered** as a treatment of cluster headaches when criterion I. above is not met.
- Link to [Policy Summary](#)

**HCPCS CODES**

All Lines of Business Except Medicare	
No Prior Authorization Required	
E0424	Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0425	Stationary compressed gas system, purchase; includes regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0430	Portable gaseous oxygen system, purchase; includes regulator, flowmeter, humidifier, cannula or mask, and tubing
E0431	Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing
E0433	Portable liquid oxygen system, rental; home liquefier used to fill portable liquid oxygen containers, includes portable containers, regulator, flowmeter, humidifier, cannula or mask and tubing, with or without supply reservoir and contents gauge
E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing
E0435	Portable liquid oxygen system, purchase; includes portable container, supply reservoir, flowmeter, humidifier, contents gauge, cannula or mask, tubing and refill adaptor
E0439	Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, & tubing
E0440	Stationary liquid oxygen system, purchase; includes use of reservoir, contents indicator, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0441	Stationary oxygen contents, gaseous, 1 month's supply = 1 unit
E0442	Stationary oxygen contents, liquid, 1 month's supply = 1 unit
E0443	Portable oxygen contents, gaseous, 1 month's supply = 1 unit
E0444	Portable oxygen contents, liquid, 1 month's supply = 1 unit
E1390	Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate
E1391	Oxygen concentrator, dual delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate, each
E1392	Portable oxygen concentrator, rental

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K0738	Portable gaseous oxygen system, rental; home compressor used to fill portable oxygen cylinders; includes portable containers, regulator, flowmeter, humidifier, cannula or mask, and tubing
Accessories: No Prior Authorization Required	
A4615	Cannula, nasal
A4616	Tubing (oxygen), per foot
E1352	Oxygen accessory, flow regulator capable of positive inspiratory pressure
E1353	Regulator
E1354	Oxygen accessory, wheeled cart for portable cylinder or portable concentrator, any type, replacement only, each
E1355	Stand/rack
E1356	Oxygen accessory, battery pack/cartridge for portable concentrator, any type, replacement only, each
E1357	Oxygen accessory, battery charger for portable concentrator, any type, replacement only, each
E1358	Oxygen accessory, dc power adapter for portable concentrator, any type, replacement only, each

## DESCRIPTION

A cluster headache is a distinct, treatable vascular headache syndrome. Episodic cluster headaches are the most common type, causing one to three brief attacks per day over a four- to eight-week period, followed by a pain-free interval of approximately one year.

Symptoms include:

- Headaches that come on suddenly without warning
- Pain that is severe, excruciating, piercing, burning, or sharp
- Pain that affects only one side of the face, head, and neck
- A drooping eyelid
- A watery, red eye and a smaller (contracted) pupil on the effected side
- A stuffy or runny nose on the effected side
- A warm and red (flushed) face or forehead on the affected side
- A sweaty forehead
- Headache that emerges 2 to 3 hours after falling asleep
- Pain that quickly intensifies, peaking within 5 to 10 minutes of onset
- Intense pain that can last from several minutes to 3 hours

By definition, chronic cluster headaches do not include sustained periods of remission. Chronic cluster headaches may develop several years after an episodic pattern has begun, or they may develop in patients who have never experienced cluster headaches. Treatment includes the administration of medications to prevent cluster attacks until the bout ends. Subcutaneous sumatriptan may also be used

to shorten an attack. Oxygen inhalation at a rate of seven to ten liters per minute via a loose mask is the most effective treatment for the actual attack. Inhalation of 100% oxygen for 15 minutes is often necessary.

## REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of oxygen therapy as a treatment for cluster headaches. Below is a summary of the available evidence identified through January 2021.

### *Systematic Reviews*

No recent systematic reviews were identified.

### *Nonrandomized Studies*

In 2017, Petersen and colleagues conducted a single-blinded, placebo-controlled crossover study that sought to evaluate pain at 15-minute follow up among 57 cluster head patients receiving either demand valve oxygen (DVO), O2ptimask, simple mask or placebo delivered by DVO.<sup>1</sup> Among the 57 patients, only 10 had multiple CH attacks and reached the point of placebo. No significant differences between masks were reported in the primary end-point of a 2-point decrease of pain on a 5-point rating scale. After 15 minutes 48% had a two-point decrease using the DVO compared to 45% with placebo (  $p = 0.867$ ). After 30 minutes 68% were pain free or had pain relief using DVO and 45% by placebo (  $p = 0.061$ ).

## CLINICAL PRACTICE GUIDELINES

### American Headache Society

In 2016, the American Headache Society published an evidence-based clinical practice guideline addressing the treatment of cluster headaches.<sup>2</sup> Authors listed high flow oxygen as a Level A recommended treatment (i.e. established as effective) for both episodic and chronic cluster headaches.

### Institute for Clinical Systems Improvement (ICSI)

In 2013, ICSI published evidence-based clinical practice guidelines regarding the diagnosis and treatment of headaches.<sup>3</sup> ICSI made the following recommendations regarding the classification and treatment of cluster headaches:

#### Cluster Headache Algorithm Annotations

There is no more severe pain than that sustained by a cluster headache sufferer. This headache is often termed "suicide headache." Cluster headache is characterized by repeated short-lasting but excruciating intense attacks of strictly unilateral peri-orbital pain associated with local autonomic symptoms or signs. The most striking feature of cluster headache is the unmistakable

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circadian and circannual periodicity. Many patients typically suffer daily (or nightly) from one or more attacks over a period of weeks or months.

*Acute Treatment Recommendations*

- Clinicians should utilize inhaled oxygen for the treatment of cluster headaches at a rate of 7-15 L/min.
- Clinicians should consider using subcutaneous sumatriptan or intranasal zolmitriptan as a first line option for the treatment of cluster headaches.

Oxygen inhalation is highly effective when delivered at the beginning of an attack with a non-rebreathing facial mask (7-15 L/min). Most patients will obtain relief within 15 minutes. Acute drugs may be difficult to obtain in adequate quantity.

National Institute for Health and Clinical Excellence (NICE)

The 2015 NICE guidelines regarding the diagnosis and management of headaches in young people and adults issued the following practice guidelines regarding the use of oxygen therapy as a treatment of cluster headaches:<sup>4</sup>

*Acute Treatment*

- Offer oxygen and/or a subcutaneous or nasal triptan for the acute treatment of cluster headache.

When using oxygen for the acute treatment of cluster headache:

- Use 100% oxygen at a flow rate of at least 12 litres per minute with a non-rebreathing mask and a reservoir bag; and
- Arrange provision of home and ambulatory oxygen.

**POLICY SUMMARY**

Despite a lack of recent clinical evidence suggesting efficacy, oxygen therapy is supported by 3 prominent clinical practice organizations for the treatment of chronic and episodic cluster headaches.

**INSTRUCTIONS FOR USE**

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days’ notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and PHP and PHA Medical Policy will be resolved in favor of the coverage agreement.

## **REGULATORY STATUS**

### Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

## **REFERENCES**

1. Petersen AS, Barloese MC, Lund NL, Jensen RH. Oxygen therapy for cluster headache. A mask comparison trial. A single-blinded, placebo-controlled, crossover study. *Cephalalgia : an international journal of headache*. 2017;37(3):214-224.
2. Robbins MS, Starling AJ, Pringsheim TM, Becker WJ, Schwedt TJ. Treatment of Cluster Headache: The American Headache Society Evidence-Based Guidelines. *Headache*. 2016;56(7):1093-1106.
3. Beithon J, Gallenberg M, Johnson K, et al. Diagnosis and treatment of headache. *Bloomington (MN): Institute for Clinical Systems Improvement (ICSI)*. 2013.
4. National Institute for Health and Care Excellence. Headaches in over 12s: diagnosis and management. <https://www.nice.org.uk/guidance/cg150>. Published 2012. Accessed 1/8/2019.