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

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.

POLICY CRITERIA

All Lines of Business Except Medicare

I. For all lines of business except Medicare, home oxygen therapy for cluster headaches may be considered medically necessary and covered when all of the following criteria (A.-C.) are met:

   A. Neurologist has evaluated patient and confirmed the diagnosis of cluster headache; and
   B. Neurologist has prescribed oxygen in conjunction with both an acute and preventative medical treatment plan; and
   C. The cluster headaches must be accompanied by at least one of the following findings:
      1. Ipsilateral conjunctival injection and/or lacrimation; or
      2. Ipsilateral nasal congestion and/or rhinorrhea; or
3. Ipsilateral eyelid edema; or
4. Ipsilateral forehead and facial sweating; or
5. Ipsilateral miosis and/or ptosis; or
6. A sense of restlessness or agitation

II. For non-Medicare members, home oxygen therapy is considered investigational and is not covered as a treatment of cluster headaches when criterion I. above is not met.

**Medicare Only**

**Note:** Criteria in this section are based on the following Centers for Medicare & Medicaid Services guidances:

- National Coverage Determination (NCD) for Home Oxygen Use to Treat Cluster Headache (CH) (240.2.2)¹
- Local Coverage Determination (LCD): Oxygen and Oxygen Equipment (L33797)²

III. For Medicare members stationary gaseous oxygen system (E0424) and related contents (E0441) are covered for the treatment of cluster headaches for beneficiaries enrolled in a clinical trial approved by CMS which are in compliance with the requirements described in the CMS National Coverage Determination Manual (Internet Only Manual 100-03) §240.2.2 for dates of service on or after 01/04/2011. This section states, in part:

Only those beneficiaries diagnosed with the condition of cluster headache are eligible for participation in a clinical study. CMS adopts the diagnostic criteria used by the International Headache Society to form a definitive diagnosis of CH. Therefore, the home use of oxygen to treat CH is covered by Medicare only when furnished to Medicare beneficiaries who have had at least five severe to very severe unilateral headache attacks lasting 15-180 minutes when untreated. (Intensity of pain: Degree of pain usually expressed in terms of its functional consequence and scored on a verbal 5-point scale: 0=no pain; 1=mild pain, does not interfere with usual activities; 2=moderate pain, inhibits but does not wholly prevent usual activities; 3=severe pain, prevents all activities; 4=very severe pain. It may also be expressed on a visual analogue scale.)

The headaches must be accompanied by at least one of the following findings (A.-F.):

A. Ipsilateral conjunctival injection and/or lacrimation; or
B. Ipsilateral nasal congestion and/or rhinorrhea; or
C. Ipsilateral eyelid edema; or
D. Ipsilateral forehead and facial sweating; or
E. Ipsilateral miosis and/or ptosis; or
F. A sense of restlessness or agitation.
IV. Oxygen equipment not meeting the criteria above will be denied as not reasonable and necessary.

V. Claims for stationary oxygen equipment other than E0424 and all portable oxygen equipment used for cluster headaches will be denied as not reasonable and necessary.

Link to Policy Summary

### HCPCS CODES

<table>
<thead>
<tr>
<th>All Lines of Business</th>
<th>No Prior Authorization Required</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>E0424</strong></td>
<td>Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing</td>
</tr>
<tr>
<td><strong>E0425</strong></td>
<td>Stationary compressed gas system, purchase; includes regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing</td>
</tr>
<tr>
<td><strong>E0430</strong></td>
<td>Portable gaseous oxygen system, purchase; includes regulator, flowmeter, humidifier, cannula or mask, and tubing</td>
</tr>
<tr>
<td><strong>E0431</strong></td>
<td>Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing</td>
</tr>
<tr>
<td><strong>E0433</strong></td>
<td>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</td>
</tr>
<tr>
<td><strong>E0434</strong></td>
<td>Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing</td>
</tr>
<tr>
<td><strong>E0435</strong></td>
<td>Portable liquid oxygen system, purchase; includes portable container, supply reservoir, flowmeter, humidifier, contents gauge, cannula or mask, tubing and refill adaptor</td>
</tr>
<tr>
<td><strong>E0439</strong></td>
<td>Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing</td>
</tr>
<tr>
<td><strong>E0440</strong></td>
<td>Stationary liquid oxygen system, purchase; includes use of reservoir, contents indicator, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing</td>
</tr>
<tr>
<td><strong>E0441</strong></td>
<td>Stationary oxygen contents, gaseous, 1 month’s supply = 1 unit</td>
</tr>
<tr>
<td><strong>E0442</strong></td>
<td>Stationary oxygen contents, liquid, 1 month’s supply = 1 unit</td>
</tr>
<tr>
<td><strong>E0443</strong></td>
<td>Portable oxygen contents, gaseous, 1 month’s supply = 1 unit</td>
</tr>
<tr>
<td><strong>E0444</strong></td>
<td>Portable oxygen contents, liquid, 1 month’s supply = 1 unit</td>
</tr>
<tr>
<td><strong>E1390</strong></td>
<td>Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate</td>
</tr>
<tr>
<td><strong>E1391</strong></td>
<td>Oxygen concentrator, dual delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate, each</td>
</tr>
<tr>
<td><strong>E1392</strong></td>
<td>Portable oxygen concentrator, rental</td>
</tr>
</tbody>
</table>
MEDICAL POLICY

Home Oxygen Therapy and Equipment for Cluster Headaches

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>K0738</td>
<td>Portable gaseous oxygen system, rental; home compressor used to fill portable oxygen cylinders; includes portable containers, regulator, flowmeter, humidifier, cannula or mask, and tubing</td>
</tr>
</tbody>
</table>

Accessories: No Prior Authorization Required

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4615</td>
<td>Cannula, nasal</td>
</tr>
<tr>
<td>A4616</td>
<td>Tubing (oxygen), per foot</td>
</tr>
<tr>
<td>E1352</td>
<td>Oxygen accessory, flow regulator capable of positive inspiratory pressure</td>
</tr>
<tr>
<td>E1353</td>
<td>Regulator</td>
</tr>
<tr>
<td>E1354</td>
<td>Oxygen accessory, wheeled cart for portable cylinder or portable concentrator, any type, replacement only, each</td>
</tr>
<tr>
<td>E1355</td>
<td>Stand/rack</td>
</tr>
<tr>
<td>E1356</td>
<td>Oxygen accessory, battery pack/cartridge for portable concentrator, any type, replacement only, each</td>
</tr>
<tr>
<td>E1357</td>
<td>Oxygen accessory, battery charger for portable concentrator, any type, replacement only, each</td>
</tr>
<tr>
<td>E1358</td>
<td>Oxygen accessory, dc power adapter for portable concentrator, any type, replacement only, each</td>
</tr>
</tbody>
</table>

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 December 2019.

*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 headache patients receiving either demand valve oxygen (DVO), O2ptimask, simple mask or placebo delivered by DVO. 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. 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. 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 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 2012 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:

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.

REFERENCES