CLINICAL MEDICAL POLICY	
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Products:	Highmark Wholecare℠ Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 18

Policy History

Date	Activity
09/01/2024	Provider Effective date
07/17/2024	QI/UM Committee review
07/17/2024	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections.
09/01/2023	Provider Effective date
07/19/2023	QI/UM Committee review
07/19/2023	Annual Review: No changes to clinical criteria. Updated 'Summary of Literature' and 'Reference Sources' sections.
10/01/2022	Provider Effective date
07/20/2022	QI/UM Committee review
07/20/2022	Annual Review: No changes to clinical criteria. Reformatted 'Procedures' section numbering. Updated 'Summary of Literature' and 'Reference Sources' sections. Removed the following 'Unspecified' ICD-10 codes: C34.00, C34.10, C34.30, C34.80, C34.90, C39.0, C39.9, C78.00, C78.30, D02.20, D02.4, I27.20, I27.9, I50.9, J43.9, J44.9, & J84.9. Added the following ICD-10 code: J84.114.
09/20/2021	Provider effective date
07/21/2021	QI/UM Committee Review
07/21/2021	Annual Review: Updated Summary of Literature. Revised typographical error with HCPCS code E0445, was previously listed as E0455 in error. Removed deleted ICD-10

	code D53.4. Updated wording for the following ICD-10 codes: I27.22, I27.23, and P27.28. Updated Reference section.
09/07/2020	Provider Effective Date
07/15/2020	QI/UM Committee Review
07/15/2020	Annual Review: In the Adult Procedure section, specific cluster headache criteria was added; formatting changes; added Icd-10 Diagnosis code D53.4 as eligible; updated the Operational Guidelines and Reference sections.
09/20/2017	Initial policy developed

Disclaimer

Highmark Wholecare℠ medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark Wholecare℠ may provide coverage under the Durable Medical Equipment (DME) benefits of the Company's Medicaid products for medically necessary oxygen therapy in the home. This policy addresses documentation and clinical requirements necessary for use of oxygen gas cylinders, liquid oxygen, and oxygen concentrators.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Durable Medical Equipment (DME) – Any equipment that provides therapeutic benefits to a patient because of certain medical conditions and/or illnesses that can withstand repeated use, is primarily and customarily used to serve a medical purpose, and is appropriate for use in the home.

Reasonable Useful Lifetime (RUL) – A time period that starts on the initial date of service and runs for five years from that date. RUL is not based on the chronological age of the equipment and does not take into account exchanges of equipment, new suppliers, or changes of modality (concentrator, gaseous, liquid).

Arterial Blood Gas (ABG) – The direct measurement of the partial pressure of oxygen on a sample of arterial blood.

Oxygen Gas Cylinder – Oxygen gas is compressed under high pressure and stored in tanks or metal cylinders. Large H cylinders weigh approximately 200 pounds and provide continuous oxygen at two liters per minute for 2.5 days.

Liquid Oxygen – Oxygen is stored in a reservoir as a very cold liquid (-300° F) that converts to gas when released from the tank. Liquid oxygen takes up less space and can be more easily transferred to a portable tank than compressed gaseous oxygen.

Oxygen Concentrator – An oxygen delivery system that operates electrically to separate oxygen from the air, concentrates it, and stores it by using a molecular sieve and electricity. A concentrator does not require filling or refilling with gaseous or liquid oxygen.

Obstructive Sleep Apnea (OSA) – A sleep disorder marked by pauses in breathing of 10 seconds or more during sleep and causes unrestful sleep. The airway collapses or becomes blocked during sleep, which causes shallow breathing or breathing pauses.

Hypoxemia – Deficiency in the amount of oxygen in arterial blood. Expressed as PO2 below normal (PO2 = 80-100 mmHg). Hypoxemia can lead to hypoxia, which is the deficiency in the amount of oxygen that reaches the tissues.

Obstructive Lung Disease – A narrowing of the airways inside the lungs, which causes air to come out more slowly than normal during exhale. Common obstructive lung diseases include COPD, asthma, bronchiectasis, and cystic fibrosis.

Restrictive Lung Disease – The lungs are restricted from fully expanding, which does not allow them to fully fill with air. Restrictive lung conditions result in lung stiffness or a loss of elasticity in the lungs. Common restrictive lung diseases include interstitial lung disease (e.g., idiopathic pulmonary fibrosis) and sarcoidosis.

Cluster Headaches – An episodic, or chronic unilateral headache syndrome that begins with one to three short-lived headaches per day over many weeks followed by a period of remission. There may be a regular recurrence in the vast majority of attacks

BPD (Bronchopulmonary Dysplasia) – A chronic lung condition that affects newborn babies who were either put on a breathing machine after birth or were born very early (prematurely). In some cases, BPD may follow other lung conditions of the newborn, such as pneumonia or bronchiolitis.

Procedures

1. Initial Certification for Adults
   A treating physician must complete a face-to-face patient evaluation for home-based oxygen therapy. This includes documentation regarding the medical necessity of oxygen therapy and blood gas study obtained within thirty (30) days prior to the date of the initial certification.

   The treating physician must provide clinical documentation that indicates that the patient has received necessary treatment for the underlying condition. Necessary treatment may include therapy

for pulmonary secretions (pulmonary toilet, bronchodilators, inhaled steroids, and antibiotics for current pulmonary infections).

Home oxygen therapy, including equipment and supplies, is considered medically necessary for initial certification when an individual has a condition specified below and meets ANY ONE of the following blood gas values:

A. The individual is active and mobile in the home and would benefit from a portable oxygen system in the home; AND
B. The individual has had a qualifying blood gas study was performed while at rest (awake) or during exercise and the liter flow is greater than 4 LPM, evidenced from a blood gas study that shows blood gas levels in the Group I or Group II range while the individual was receiving oxygen at the rate of 4 LPM; AND
C. The individual is eligible to receive certification for one (1) stationary oxygen concentrator and one (1) portable oxygen concentrator for combined home oxygen therapy; AND
D. The individual's blood gas study was performed by a qualified provider or supplier of laboratory services, which meets **Group I** OR **Group II Blood Gas** criteria, as stated below:
    1) **Group I Blood Gas** (oximetry test/arterial blood gas) for indidivuals with significant hypoxemia is evidenced by ANY of the following:
        a) At rest (awake), an arterial PO2 at or below 55 mmHg or arterial oxygen saturation at or below 88%; OR
        b) An arterial PO2 at or below 55 mmHg, or the arterial oxygen saturation at or below 88%, taken for at least five (5) minutes during sleep for an individualdemonstrating an arterial PO2 at or above 56 mmHg, or an arterial oxygen saturation at or above 89% while awake; OR
        c) a) A decrease in arterial PO2 more than 10 mmHg, or a decrease in arterial oxygen saturation more than 5% from baseline saturation, for at least five (5) minutes taken during sleep associated with symptoms (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia) or signs (e.g., cor pulmonale, "P" pulmonale on EKG, documented pulmonary hypertension and erythrocytosis) reasonably attributable to hypoxemia; OR
        d) An arterial PO2 at or below 55 mmHg or an arterial oxygen saturation at or below 88%, taken during exercise for an individual who demonstrates an arterial PO2 at or above 56 mmHg or an arterial oxygen saturation at or above 89% during the day while at rest. In this case, oxygen is provided during exercise if it is documented that the use of oxygen improves the hypoxemia that was demonstrated during exercise when the patient was breathing room air.

            Note: Initial certification and coverage for individuals meeting Group I criteria is limited to twelve (12) months or the physician-specified length of need, whichever is shorter.

    2) **Group II Blood Gas** (oximetry test/arterial blood gas) is evidenced by ALL of the following:
        a) An arterial PO2 of 56-59 mmHg, or an arterial blood oxygen saturation of 89% at rest (awake), taken during sleep for at least five (5) minutes or during exercise (as described under Group I criteria); AND
        b) An individual who has ANY ONE of the following:
            I. Dependent edema suggesting congestive heart failure; OR

II. Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3mm in standard leads II, III, or AVF); OR
III. Erythrocythemia with a hematocrit greater than 56%.

2. Home-based long-term oxygen therapy (LTOT) (use > 15 hours per day), including oxygen equipment and supplies, is considered medically necessary for adults experiencing severe lung disease or hypoxic-related symptoms caused by ANY ONE of the following cardiopulmonary conditions:
   - Emphysema
   - Chronic bronchitis
   - Bronchiectasis
   - Chronic interstitial pneumonia
   - Chronic interstitial pulmonary infiltrate-type pulmonary disease, such as pulmonary fibrosis from extensive tuberculosis, eosinophilia, granuloma, idiopathic fibrosis, and pneumoconiosis
   - Cystic fibrosis
   - Pulmonary hypertension
   - Secondary polycythemia
   - Widespread pulmonary neoplasm
   - COPD
   - Obstructive Sleep Apnea (OSA) that is unresponsive to CPAP therapy in combination with a cardiopulmonary condition
   - Individuals with hypoxemia-related symptoms or findings that might be expected to improve with home oxygen therapy such as:
     - Recurring congestive heart failure due to chronic cor pulmonale
     - Erythrocytosis
     - Impairment of cognitive process
     - Nocturnal restlessness
     - Morning headaches
     - Hemoglobinopathies
   - Cluster headaches (intermittent home oxygen) – the cluster headaches must meet the following diagnostic criteria used by the International Headache Society:
     - At least five (5) attacks; AND
     - Attacks are characterized by severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15-180 minutes (when untreated); AND
     - Headaches occur with a frequency between one (1) every other day and eight (8) per day; AND
     - A sense of restlessness/agitation, or at least one (1) of the following symptoms, ipsilateral to the headache:
       - Conjunctival injection and/or lacrimation
       - Nasal congestion and/or rhinorrhea
       - Eyelid edema
       - Forehead and facial sweating
       - Miosis and/or ptosis

3. Recertification for Adults
   Home oxygen therapy, including oxygen equipment and supplies, are considered eligible for recertification when ALL of the following criteria are met:
   A. The treating physician orders and issues a new prescription for recertification for ANY ONE of the following:
      1) There is a change in the prescription for the accessory, supply, etc; OR
      2) The oxygen system is replaced; OR
      3) There is a change in the oxygen system supplier; AND
   B. The treating physician must recertify the continuing medical necessity for home oxygen therapy every six (6) months.

4. Pediatric Patients
   Home oxygen therapy will be considered medically necessary in the treatment of pediatric patients with severe lung disease. The initial oxygen order must be written by an appropriate physician specialist. ANY ONE of the following pulmonary conditions are considered medically necessary:
   A. Bronchopulmonary dysplasia; OR
   B. Prolonged seizures; OR
   C. Congenital heart disease; OR
   D. Cystic fibrosis; OR
   E. Any condition that causes significant hypoxia in the pediatric patient.

   Note: Infants with bronchopulmonary dysplasia (BPD) who have variable oxygen needs will be considered by a Medical Director on a case-by-case basis in the absence of documentation of otherwise qualifying oxygen values.

5. Supplies, Accessories, and Oxygen Content Guidelines
   - Supplies and accessories (e.g., transtracheal catheters, cannulas, tubing, mouthpieces, face tent, masks, and oxygen conserving devices, oxygen tent, humidifiers, nebulizer for humidification, regulators, and stand/rack) are included in the allowance for rented oxygen systems as a bundled service and should not be billed separately. Supplies and accessories that are separately billed will be denied as unbundling. The supplier must provide any accessory ordered by the physician.
   - Accessories used with patient-owned oxygen equipment are not paid for separately.
   - Liquid oxygen systems and gaseous oxygen systems require oxygen content and are required on a recurring basis. The oxygen content needs to be refilled monthly and is the ONLY item billed separately using HCPCS codes E0441, E0442, E0443, or E0444.
   - Oxygen contents are reimbursed with a monthly refill allowance and cover all contents necessary for the given month.

   Note: Oxygen concentrators are the only type of home oxygen system that does not require oxygen contents.

6. Maintenance, Repairs, and Servicing Guidelines
   Following the 36-month capped rental period, the maintenance, repairs, and servicing for stationary and/or portable home oxygen therapy equipment will continue to be considered medically necessary when ALL of the following care met:
   A. Reasonable and necessary maintenance, repairs, and servicing for oxygen equipment may be reimbursed when not covered by a supplier or manufacturer warranty at the end of the 36-month

capped rental timeframe and until the item reaches the end of its reasonable useful lifespan (RUL); AND

B. Payment for a maintenance, repairs, or servicing visit will be issued no more than every six (6) months, beginning no sooner than six (6) months following the end of the 36-month capped rental period. If oxygen equipment is covered under a supplier or manufacturer warranty, payment for the first maintenance, repair, or service visit will be no sooner than six (6) months following the end of the warranty.

Note:

- During the 36-month capped rental period, maintenance, repair, and servicing fees are considered a bundled service with the monthly oxygen system reimbursement.
- At any time after the end of the 5-year reasonable useful lifetime for oxygen equipment, the patient may elect to receive new equipment, thus beginning a new 36-month rental period.

7. Oxygen and Water Vapor Enriching Systems
   The oxygen and water vapor enriching systems are available with or without heated delivery. These devices extract oxygen from the surrounding air (similar to an oxygen concentrator) and add humidification. These systems require substantially higher oxygen flow rates in order to deliver the same concentration of oxygen as that achieved by standard oxygen delivery systems. Due to this fact, modifiers QB, QF, QG, and QR are to be submitted to indicate oxygen flow rates greater than 4 liters/minute.

   Note: Coverage will begin on the day the device is delivered, set up, and ready for use by the patient at the location needed.

8. Conditions Not Considered Medically Necessary for Home Oxygen Therapy
   Home oxygen therapy is not considered medically necessary for conditions other than those listed above because the scientific evidence has not been established. These conditions include, but are not limited to ANY of the following:
   - Angina pectoris in the absence of hypoxemia. This condition is generally not the result of a low oxygen level in the blood, and there are other preferred treatments.
   - Breathlessness/dyspnea without cor pulmonale or evidence of hypoxemia
   - Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities. There is no evidence that increased PO2 improves the oxygenation of tissues with impaired circulation.
   - Terminal illnesses that do not affect the lungs
   - Treatment of headaches other than cluster headaches

9. Oxygen Equipment Items That Are Not Covered
   - Oxygen reimbursement is a bundled payment. All options, supplies and accessories are considered included in the monthly rental payment. Separately billed options, accessories, or supply items will be denied as unbundling.
   - Oximeters (E0445) and replacement probes (A4606)
   - Oxygen items or services furnished or used outside the United States and its territories
   - Oxygen services furnished by an airline
   - Respiratory therapist services
   - Topical hyperbaric oxygen chambers (A4575)

- Topical oxygen delivery systems (E0446)

10. Post-payment Audit Statement
    The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Wholecare℠ at any time pursuant to the terms of your provider agreement.

11. Place of Service
    The proper place of service for home oxygen therapy is in the home setting.

12. Length of Coverage
    - Reimbursement for oxygen concentrator equipment is limited to monthly capped rental payments for 36 months.
    - The reasonable useful lifetime (RUL) for oxygen concentrator equipment is five (5) years, which includes the 36-month capped rental period. Rental payments stop at 36 months and will not resume until the five (5) year RUL oxygen equipment replacement occurs.

Governing Bodies Approval

CMS
The Centers for Medicare and Medicaid Services (CMS) has published the following guidance on home oxygen therapy:

- National Coverage Determination (NCD) Home Use of Oxygen (240.2)

Summary of Literature

Home oxygen therapy is the administration of oxygen at concentrations greater than that in ambient air (20.9%) with the intent of treating or preventing the symptoms and manifestations of hypoxia. Oxygen is a medical gas and should only be dispensed in accordance with all federal, state, and local laws and regulations. Oxygen therapy has only limited benefit for the treatment of hypoxia due to anemia and benefit may be limited when circulatory disturbances are present. Oxygen therapy should not be used in lieu of but in addition to mechanical ventilation when ventilatory support is indicated (AARC, 2007).

Supplemental oxygen is provided for short-term oxygen therapy, intermittent use, long-term oxygen therapy (LTOT), and ambulatory oxygen therapy (portable). For a stable patient with a chronic condition causing dyspnea on optimal medical therapy, LTOT is a likely life-long commitment. Ambulatory oxygen therapy (portable oxygen therapy) provides LTOT patients who are mobile and need to leave the home on a regular basis with oxygen during exercise and activities of daily living (ADLs). Patient outcomes are determined by clinical and physiological assessment to establish adequacy of patient response to therapy (American Thoracic Society [ATS], 2016).

According to the U.S. Government Accountability Office (GAO), patients can obtain supplemental oxygen through three different types of oxygen therapy, which include oxygen concentrators, liquid oxygen systems, and compressed gaseous systems (i.e., oxygen cylinders). All three oxygen therapies can provide

a patient with oxygen using stationary or portable equipment (GAO, 2011). The appropriate oxygen system for a patient depends on the following:

- How much oxygen the patient needs (flow rate)
- When the patient needs the oxygen (day, evening, or both)
- The patient's living circumstances
- How the patient receives his or her electrical supply
- The patient's activity and mobility levels (ATS, 2016).

A compressed gaseous oxygen system is the oldest method of home oxygen therapy and is not a current common practice due to the frequency of required tank replacement. Liquid oxygen systems are similar to compressed gaseous oxygen systems in use. Two important advantages to using the liquid oxygen system over the gaseous system are (1) the patient has the ability to transfer liquid oxygen into a smaller, portable vessel, enabling the patient to leave home with the device, and (2) oxygen refills are less frequent (AARC, 2007).

Oxygen concentrators are the most common and frequently used equipment in home oxygen therapy. An oxygen concentrator requires minimal servicing, and no oxygen refill is required because the device is designed to concentrate oxygen from ambient air (World Health Organization [WHO], 2015). Oxygen concentrators were first invented for home use in the late 1970s. Patients began to receive oxygen prescriptions earlier in their disease than in prior decades, which required an advancement to portable oxygen concentrator technology to meet younger, more active patients. The portable oxygen concentrator is intended for use everywhere, with many being approved by the FAA for use on airplanes (Inogen, 2015). Many patients need stationary oxygen concentrators for night use and portable oxygen concentrators during the day. The advantages of oxygen concentrators include high reliability and low cost compared to liquid oxygen systems and compressed gaseous systems. There is minimal, regular maintenance on the oxygen concentrators, and reliable power supply seems to be the only outstanding issue, which has been addressed with effective device management and training (WHO, 2015).

It is important that treating physicians are involved in the process of prescribing patients with home oxygen therapy, because it is a key factor in appropriate physician documentation for DME devices. A prescription with incorrect oxygen levels can be very dangerous to a patient with a chronic condition, which supports the importance of accurate physician documentation. Appropriate physician documentation also protects the physicians from adverse legal issues and allows the physician to set up the most economical and tailored oxygen therapy for patients (AARC, 2007).

Some patients who are hypoxemic during the day spend 30% of sleep time with oxygen saturation levels less than 90%, even while on CPAP; therefore, home oxygen therapy may be considered for second-line therapy in patients that have a co-existing chronic pulmonary condition and experience nocturnal hypoxemia (Khatri, 2016). Although home oxygen therapy (i.e., LTOT) is considered as second-line therapy, the treatment may prolong the duration of apnea episodes, worsen hypercapnia, and significantly reduce blood pressure (Gottlieb, 2014).

There are conditions that benefit from short-term oxygen therapy and intermittent oxygen therapy. Short-term oxygen therapy can be used in the treatment of some infants with BPD due to low blood oxygen levels from conditions such as congenital heart disease, prematurity, or severe respiratory infections. BPD patients may require supplemental oxygen to decrease respiratory symptoms (e.g., pulmonary hypertension, abnormal vascular development) in the acute phase, after leaving the hospital (Hadjiliadis, 2013).

The American Thoracic Society (ATS) published the clinical practice guideline (CPG) Home Oxygen Therapy for Adults with Chronic Lung Disease. This CPG is a comprehensive review and analysis of the available evidence surrounding the clinical indications, appropriate prescribing, and effective use of home oxygen therapy in adults with chronic lung disease, specifically chronic obstructive pulmonary disease (COPD) or interstitial lung disease (ILD). The CPG provides for the following major recommendations based on a range of moderate to very low-quality evidence:

- **Chronic Obstructive Pulmonary Disease**
    - In adults with COPD who have severe chronic resting room air hypoxemia,* it is recommended to prescribe LTOT for at least 15 h/d (*strong recommendation, moderate-quality evidence*). *Severe hypoxemia is defined as meeting either of the following criteria: 1) PaO2 ≤ 55 mm Hg (7.3 kPa) or oxygen saturation as measured by pulse oximetry (SpO2) ≤ 88%; 2) PaO2 = 56–59 mm Hg (7.5–7.9 kPa) or SpO2 = 89% plus one of the following: edema, hematocrit ≥ 55%, or P pulmonale on an ECG.)
    - In adults with COPD who have moderate chronic resting room air hypoxemia,* it is suggested to not prescribe LTOT (*conditional recommendation, low-quality evidence*). *Moderate hypoxemia is defined as an SpO2 of 89–93%.
- **Interstitial Lung Disease**
    - For adults with ILD who have severe chronic resting room air hypoxemia, it is recommended prescribing LTOT for at least 15 h/d (*strong recommendation, very-low-quality evidence*).
    - For adults with ILD who have severe exertional room air hypoxemia, it is suggested to prescribe ambulatory oxygen (*conditional recommendation, low-quality evidence*).
- **Liquid Oxygen**
    - In patients with chronic lung disease who are mobile outside of the home and require continuous oxygen flow rates of >3 L/min during exertion, it is suggested prescribing portable liquid oxygen (LOX) (*conditional recommendation, very-low-quality evidence*).
- **Education and Safety**
    - For patients prescribed home oxygen therapy, we recommend that the patient and their caregivers receive instruction and training on the use and maintenance of all oxygen equipment and education on oxygen safety, including smoking cessation, fire prevention, and tripping hazards (*best-practice statement*).

Cluster Headaches

Cluster headaches is another condition that can benefit from short-term home oxygen therapy. There is no cure for cluster headaches, and the goal of treatment is to decrease the severity of pain, shorten the headache period, and prevent the attacks (Mayo Clinic Staff, 2017). The inhalation of 100% oxygen via a tight-fitting mask at a flow rate of 8-10 liters per minute for 10-15 minutes at the beginning of a cluster headache is effective in 80% of patients; oxygen is particularly effective for nocturnal attacks. Oxygen inhalations may be repeated up to five times per day. Cluster headaches are classified as one of the trigeminal autonomic cephalalgias (TACs). The age of onset of this condition is usually between 20 to 40 years of age and, for unknown reasons, men are afflicted three time more often than women. Cluster headaches can be considered episodic or chronic (Robbins, 2016).

In the episodic form, the cluster headache attacks can last from seven days to one year, separated by pain-free periods lasting at least three months. The headaches occur in bouts and there are at least two cluster periods lasting from seven days to one year (when untreated) and are separated by pain-free

remission periods ≥ 3 months. Typically, the cluster periods range between two weeks and three months. The chronic cluster headache attacks occur for one year or longer without remission, or with remission periods lasting less than three months. The attacks include the symptoms of episodic headaches, and the attacks occur without a remission period, or with remission lasting < 3 months, for a least one year (Robbins, 2016).

The International Classification of Headache Disorders (ICHD-3) has provided the following diagnostic criteria for cluster headaches:

- At least five attacks fulling the following criteria B-D
- Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15-180 minutes (when untreated);
- Either or both of the following:
    - At least one of the following symptoms or signs, ipsilateral to the headache
        - conjunctival injection and/or lacrimation
        - nasal congestion and/or rhinorrhea
        - eyelid edema
        - forehead and facial sweating
        - forehead and facial flushing
        - sensation of fullness in the ear
        - miosis and/or ptosis
    - A sense of restlessness or agitation
- Occurring with a frequency between one every day and eight per day
- Not better accounted for by another ICHD-3 diagnosis

During part, but less than half of the active time, cluster headache attacks may be less severe and/or of shorter or longer duration. During part, but less than half of the active time, cluster headache attacks may be less frequent (ICHD, 2018).

There is no known cure for cluster headaches, however, existing treatments are known to decrease pain, prevent an attack and shorten the duration. Common treatments prescribed for this condition include oxygen delivered by mask, injectable sumatriptan (Imitrex), calcium channel blockers, benzodiazepines, alkali metal, intranasal lidocaine, intravenous magnesium sulfate, and steroids. There are many home treatments which may include Vitamin B-2, Kudzu extract, melatonin, capsaicin cream, essential oils, and ginger tea. In addition, surgical procedures for the chronic form have been utilized such as hypothalamic deep brain stimulation (ICHD, 2018).

UpToDate (2019) recommends initial treatment for acute cluster headache attacks with either 100% oxygen or a triptan, which is in alignment with national guidelines and expert consensus. Specifically, it is recommended that oxygen should be tried first, if available, since it is without side effects. Otherwise, subcutaneous sumatriptan 6 mg can be used as initial therapy.

Home oxygen therapy is deemed a standard of care for patients with hypoxia. The symptoms of hypoxia are dependent on the rapidity and severity of the decrease of arterial PO2. The causes of hypoxia vary and could be due to arterial hypoxemia or failure of the oxygen hemoglobin transport system. An individual has a normal oxygen level if the oxygen saturation in the blood (S_aO_2) is above 95%. An individual that has a S_aO_2 below 85% without oxygen is indicated for supplemental long term oxygen therapy (LTOT) to treat hypoxemia (NHOPA, 2020). The American College of Chest Physicians and the National Heart Lung and Blood Institute recommend instituting oxygen therapy in the following events:

- Cardiac and respiratory arrest
- Hypoxemia
- Hypotension (Systolic BP < 100 mmHg)
- Low Cardiac Output and metabolic acidosis
- Respiratory distress (RR > 24/min) (Fulmer, 1984)

The American College of Physicians (ACP) clinical guidelines has advised that supplemental LTOT is strongly recommended in patients with COPD that causes severe resting hypoxemia *(PO2 ≤ 55 mmHg or SpO2 ≤ 88%)*. There are four well-established randomized, controlled trials that have evaluated the effect of LTOT on mortality in patients with COPD. Two of the trials, the Nocturnal Oxygen Therapy Trial (NOTT) and the Medical Research Council (MRC), demonstrated improved survival among patients that received LTOT (Croxton, 2006).

Most LTOT studies focus on COPD, but many patients with other chronic hypoxemia causes benefit from the use of LTOT (Petty, 2006). Hypoxemia can be caused by pulmonary hypertension, interstitial lung disease, cystic fibrosis, and other restrictive pulmonary diseases, which can all be improved by LTOT (Hopkins, 2017). LTOT should be considered for the second line of therapy in Obstructive Sleep Apnea (OSA) patients. OSA has a similar connection to specific cardiopulmonary conditions including COPD, asthma, and pulmonary hypertension, also referred to as "overlap syndrome." Most clinical trials and societal recommendations indicate the first line of therapy for the treatment of OSA-associated cardiovascular episodes is Continuous Positive Airway Pressure (CPAP) (Khatri, 2016).

High-flow oxygen has been found to be effective and safe for the treatment of cluster headaches. Typically, oxygen is 100% high-flow, 12-15 LPM flow rate, and supplied with a non-rebreather mask. A randomized trial was published comparing high-flow inhaled oxygen to placebo in the acute treatment of cluster headache. The authors reported that 78% of patients using the high-flow oxygen (12 LPM) were able to abort 71-85% of 150 cluster headache attacks compared to 20% of patients using room air. The greatest advantage with oxygen inhalation was that there were no adverse effects that are of concern with other treatments. The conclusion was the treatment of patients with cluster headache at symptom onset using inhaled high-flow oxygen compared to placebo resulted in patients being pain-free at 15 minutes (Goadsby, Cohen and Burns, 2009).

Coding Requirements

Procedure Codes
Codes are subject to initial certification and recertification.

HCPCS Code	Description
Stationary Gaseous Oxygen System	
E0424	Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0441	Stationary oxygen contents, gaseous, 1 month's supply = 1 unit
Portable Gaseous Oxygen System	
E0431	Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing
E0443	Portable oxygen contents, gaseous, 1 month's supply = 1 unit

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
Stationary Liquid Oxygen System	
E0439	Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0442	Stationary oxygen contents, liquid, 1 month's supply = 1 unit
Portable Liquid Oxygen System	
E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing
E0444	Portable oxygen contents, liquid, 1 month's supply = 1 unit
E0447	Portable oxygen contents, liquid, 1 month's supply = 1 unit, prescribed amount at rest or nighttime exceeds 4 liters per minute (LPM)
Stationary Oxygen Concentrators	
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
Portable Oxygen Concentrators	
E1392	Portable oxygen concentrator, rental
E1405	Oxygen and water vapor enriching system with heated delivery
E1406	Oxygen and water vapor enriching system without heated delivery
Maintenance	
K0740	Repair or non-routine service for oxygen equipment requiring the skill of a technician, labor component, per 15 minutes

Noncovered Accessories

HCPCS Code	Description
A4575	Topical hyperbaric oxygen chamber, disposable
E0445	Oximeter device for measuring blood oxygen levels noninvasively
E0446	Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories
A4606	Oxygen probe for use with oximeter device, replacement
Accessories included in the allowance for rented oxygen equipment	
A4608	Transtracheal oxygen catheter, each
A4615	Cannula, nasal
A4616	Tubing (oxygen), per foot
A4617	Mouthpiece
A4619	Face tent
A4620	Variable concentration mask
A7525	Tracheostomy mask, each
A9900	Miscellaneous DME supply, accessory, and/or service component of another HCPCS code
E0455	Oxygen tent, excluding croup or pediatric tents
E0555	Humidifier, durable, glass or autoclavable plastic bottle type, for use with regular or flowmeter

E0580	Nebulizer, durable, glass or autoclavable plastic, bottle type, for use with regulator or flowmeter
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

Diagnosis Codes

ICD-10 Code	**Description**
B59	Pneumocytosis
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C38.1	Malignant neoplasm of anterior mediastinum
C38.2	Malignant neoplasm of posterior mediastinum
C38.4	Malignant neoplasm of pleura
C38.8	Malignant neoplasm of overlapping sites of heart, mediastinum and pleura
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.1	Secondary malignant neoplasm of mediastinum
C78.2	Secondary malignant neoplasm of pleura
C78.39	Secondary malignant neoplasm of other respiratory organs
D02.0	Carcinoma in situ of larynx
D02.1	Carcinoma in situ of trachea
D02.21	Carcinoma in situ of right bronchus and lung
D02.22	Carcinoma in situ of left bronchus and lung
D02.3	Carcinoma in situ of other parts of respiratory system

D58.2	Other hemoglobinopathies
D75.1	Secondary polycythemia
D86.0	Sarcoidosis of lung
D86.1	Sarcoidosis of lymph nodes
D86.2	Sarcoidosis of lung with sarcoidosis of lymph nodes
D86.3	Sarcoidosis of skin
E84.0	Cystic fibrosis with pulmonary manifestations
G44.001	Cluster headache syndrome, unspecified, intractable
G44.009	Cluster headache syndrome, unspecified, not intractable
G44.011	Episodic cluster headache, intractable
G44.019	Episodic cluster headache, not tractable
G44.021	Chronic cluster headache, intractable
G44.029	Chronic cluster headache, not tractable
*G47.33	Obstructive sleep apnea (adult) (pediatric)
Cardiopulmonary Conditions	
I27.0	Primary pulmonary hypertension
I27.1	Kyphoscoliotic heart disease
I27.21	Secondary pulmonary arterial hypertension
I27.22	Pulmonary hypertension due to left heart disease
I27.23	Pulmonary hypertension due to lung disorder & hypoxia
I27.24	Chronic thromboembolic pulmonary hypertension
I27.29	Other secondary pulmonary hypertension
I27.81	Cor Pulmonale (chronic)
I27.82	Chronic pulmonary embolism
I27.83	Eisenmenger's syndrome
I27.89	Other specified pulmonary heart diseases
I50.1	Left ventricular failure, unspecified
I50.82	Biventricular heart failure
J41.1	Mucopurulent chronic bronchitis
J41.8	Mixed simple and mucopurulent chronic bronchitis
J43.0	Unilateral pulmonary emphysema [MacLeod's syndrome]
J43.1	Panlobular emphysema
J43.2	Centrilobular emphysema
J43.8	Other emphysema
J44.0	Chronic obstructive pulmonary disease with (acute) lower respiratory infection
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
J47.0	Bronchiectasis with acute lower respiratory infection
J47.1	Bronchiectasis with (acute) exacerbation
J47.9	Bronchiectasis, uncomplicated
J84.10	Pulmonary fibrosis, unspecified
J84.111	Idiopathic interstitial pneumonia, not otherwise specified

J84.112	Idiopathic pulmonary fibrosis
J84.113	Idiopathic non-specific interstitial pneumonitis
J84.114	Acute interstitial pneumonitis
J84.115	Respiratory bronchiolitis interstitial lung disease
J84.81	Lymphangioleiomyomatosis
J84.82	Adult pulmonary Langerhans cell histiocytosis
J84.83	Surfactant mutations of the lung
J84.841	Neuroendocrine cell hyperplasia of infancy
J84.842	Pulmonary interstitial glycogenosis
J84.843	Alveolar capillary dysplasia with vein misalignment
J84.848	Other interstitial lung diseases of childhood
J84.89	Other specified interstitial pulmonary diseases
P27.0	Wilson-Mikity syndrome
P27.1	Bronchopulmonary dysplasia originating in the perinatal period
P27.8	Other chronic respiratory diseases originating in the perinatal period
P29.0	Neonatal cardiac failure
P29.30	Pulmonary hypertension of newborn
P29.38	Other persistent fetal circulation
R09.02	Hypoxemia
Q33.4	Congenital bronchiectasis

***** *To code for Obstructive sleep apnea (OSA), an underlying cardiopulmonary condition must be coded in combination (e.g. Obstructive Sleep Apnea with chronic lung disease and/or pulmonary hypertension).*

Reimbursement

Participating facilities will be reimbursed per their Highmark Wholecare℠ contract.

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