HIGHMARK Delaware
HEALTH OPTIONS

CLINICAL MEDICAL POLICY	
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Products:	Highmark Health Options Medicaid
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Page Number(s):	1 of 17

DISCLAIMER

Highmark Health Options 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 Health Options 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.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

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 PaO2 below normal (PaO2 = 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

Adult Patients

Home long-term oxygen therapy (LTOT) (> 15 hours per day), including oxygen equipment and supplies, is considered eligible for adult patients experiencing severe lung disease or hypoxic-related symptoms caused by one of the following cardiopulmonary conditions:

1) Emphysema; OR
2) Chronic bronchitis; OR
3) Bronchiectasis; OR
4) Chronic interstitial pneumonia; OR
5) Chronic interstitial pulmonary infiltrate-type pulmonary disease, such as pulmonary fibrosis from extensive tuberculosis, eosinophilia, granuloma, idiopathic fibrosis, and pneumoconiosis; OR
6) Cystic fibrosis; OR
7) Pulmonary hypertension; OR
8) Secondary polycythemia; OR
9) Widespread pulmonary neoplasm; OR
10) COPD; OR
11) Obstructive Sleep Apnea (OSA) that is unresponsive to CPAP therapy in combination with a cardiopulmonary condition; OR
12) Patients with hypoxemia-related symptoms or findings that might be expected to improve with home oxygen therapy such as:
    a) Recurring congestive heart failure due to chronic cor pulmonale;
    b) Erythrocytosis;
    c) Impairment of cognitive process;
    d) Nocturnal restlessness;
    e) Morning headaches;
    f) Cluster headaches – the cluster headaches must meet the diagnostic criteria used by the International Headache Society;
    g) Hemoglobinopathies;
    h) Infants with bronchopulmonary dysplasia (BPD) who have variable oxygen needs will be considered on a case-by-case basis in the absence of documentation of otherwise qualifying oxygen values

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 specialist. Any of the following pulmonary conditions are considered medically necessary:

1) Bronchopulmonary dysplasia
2) Prolonged seizures
3) Congenital heart disease
4) Cystic fibrosis
5) Any condition that causes significant hypoxia in the pediatric patient

Portable oxygen systems will be considered medically appropriate for pediatric patients when:

1) The patient requires home oxygen therapy; and
2) The patient is mobile or requires mobility for transportation

Initial Certification for Adults

A treating physician must complete a face-to-face patient evaluation for oxygen therapy. This includes documentation regarding the medical necessity of oxygen therapy and blood gas study obtained within 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 eligible for initial certification when the patient has a condition specified above and meets one of the following blood gas values:

The patient had a blood gas study performed by a qualified provider or supplier of laboratory services, which meets Group I **OR** Group II criteria, as stated below:

1) **Group I blood gas** (oximetry test/arterial blood gas) criteria for patients with significant hypoxemia 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 minutes during sleep for a patient demonstrating an arterial PO2 at or above 56 mmHg, or an arterial oxygen saturation at or above 89% while awake; OR
    c) 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 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 a patient 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 patients meeting Group I is limited to twelve months or the physician-specified length of need, whichever is shorter.

2) **Group II blood gas (oximetry test/ arterial blood gas) criteria for patients with 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 minutes, or during exercise (as described under Group I criteria); AND
    b) One of the following:
        1. Dependent edema suggesting congestive heart failure; OR
        2. 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 3 mm in standard leads II, III, or AVF); OR
        3. Erythrocythemia with a hematocrit greater than 56%

Portable oxygen system is considered eligible for initial certification when ALL the criteria mentioned above in sections 1 and 2 are met, and the patient meets the following criteria:

1) Patient is active and mobile in the home and would benefit from a portable oxygen system in the home; AND
2) The patient's qualifying blood gas study was performed while at rest (awake) or during exercise; AND
    a) The liter flow is greater than 4 LPM, evidenced from the patient's blood gas study that shows blood gas levels in the Group I or Group II range while the patient was receiving oxygen at the rate of 4 LPM.
3) A patient is eligible to receive certification for ONE stationary oxygen concentrator and ONE portable oxygen concentrator for combined home oxygen therapy.

Recertification for Adults

Stationary and/or portable home oxygen therapy, including oxygen equipment and supplies, are considered eligible for **recertification** when the provider documentation contains the following:

1) The treating physician orders and issues a new prescription for recertification when one of the following indications take place:
    a) There is a change in the prescription for the accessory, supply, etc.; OR
    b) Prescription renewal is required at least every 6 months; OR
    c) Oxygen system is replaced; OR
    d) There is a change in the oxygen system supplier;

    AND
2) The treating physician must recertify the continuing medical necessity for home oxygen therapy every six months.

Supplies, Accessories, and Oxygen Content Guidelines

1) 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 are not billed separately. Supplies and accessories that are separately billed will be denied as unbundling. The supplier must provide any accessory ordered by the physician.
2) Accessories used with patient-owned oxygen equipment are not paid for separately.
3) 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.
4) 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.

Maintenance, Repairs, and Servicing Guidelines

Following the 36-month capped rental period, the maintenance, repairs, and servicing for stationary and/or portable oxygen equipment are considered eligible when the following requirements are met:

1) 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

2) Payment for a maintenance, repairs, or servicing visit will be issued no more than every six months, beginning no sooner than six 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 months following the end of the warranty.

Notes:

- 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.

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.

Conditions Not Covered for Home Oxygen Therapy

Home oxygen therapy is not covered for conditions other than those listed above because the scientific evidence has not been established:

1) 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; OR
2) Breathlessness without cor pulmonale or evidence of hypoxemia. Although intermittent oxygen use is sometimes prescribed to relieve this condition, it is potentially harmful and psychologically addicting; OR
3) 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; OR
4) Terminal illnesses that do not affect the lungs; OR
5) Treatment of headaches other than cluster headaches

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)

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

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

Length of Coverage

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

CODING REQUIREMENTS

Procedure Codes
Codes are subject to initial certification and recertification.

HCPCS Codes	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
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
E0443	Portable oxygen contents, gaseous, 1 month's supply = 1 unit
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 Codes	Description
A4575	Topical hyperbaric oxygen chamber, disposable
E0446	Topical oxygen delivery systems
E0455	Oximeter device
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	Mouth piece
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
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 Codes	Description
B59	Pneumocytosis
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus

C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
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
C34.30	Malignant neoplasm of lower lobe, unspecified 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
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus and 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
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or 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
C39.0	Malignant neoplasm of upper respiratory tract, part unspecified
C39.9	Malignant neoplasm of lower respiratory tract, part unspecified
C78.00	Secondary malignant neoplasm of unspecified lung
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
C78.30	Secondary malignant neoplasm of unspecified respiratory organs
C78.39	Secondary malignant neoplasm of other respiratory organs
D02.0	Carcinoma in situ of larynx
D02.1	Carcinoma in situ of trachea
D02.20	Carcinoma in situ of unspecified bronchus and lung
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
D02.4	Carcinoma in situ of respiratory system, unspecified
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
G44.00	Cluster headache syndrome, unspecified
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
I27.20	Pulmonary hypertension unspecified (Effective 10/01/2017)
I27.21	Secondary pulmonary arterial hypertension (Effective 10/01/2017)
I27.22	Pulmonary hypertension DT left heart DZ
I27.23	Pulmonary hypertension DT lung disorder & hypoxia
I27.24	Chronic Thromboembolic pulmonary hypertension
I27.29	Other secondary pulmonary hypertension (Effective 10/01/2017)
I27.81	Cor Pulmonale (chronic)
I27.82	Chronic pulmonary embolism
I27.83	Eisenmenger's syndrome (Effective 10/01/2017)
I27.89	Other specified pulmonary heart diseases
I27.9	Pulmonary heart disease, unspecified
I50.1	Left ventricular failure
I50.82	Biventricular heart failure (Effective 10/01/2017)
I50.9	Heart failure, unspecified
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
J43.9	Emphysema, unspecified
J44.0	Chronic obstructive pulmonary disease with acute lower respiratory infection
J44.1	Chronic obstructive pulmonary disease with (acute) exacerbation
J44.9	Chronic obstructive pulmonary disease, unspecified
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
J84.115	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
J84.9	Interstitial pulmonary disease, unspecified
P27.0	Wilson-Mikity syndrome
P27.1	Bronchopulmonary dysplasia originating in the perinatal period

P27.8	Other chronic respiratory disease
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 Health Options contract.

SUMMARY OF LITERATURE

Home oxygen therapy (HOT) consists of supplemental oxygen administered at concentrations greater than in ambient air within the home setting (AARC, 2007). The most common way oxygen is administered to a patient is through a nasal cannula (AARC, 2017). Oxygen therapy should maintain adequate tissue and cell oxygenation while trying to avoid oxygen toxicity. The patient's condition is monitored to ensure that the patient is receiving the proper mixture of gases, mists, and aerosols. The major reason for HOT is due to hypoxia, which can lead to heart failure in patients with obstructive or restrictive chronic pulmonary diseases.

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 (American Thoracic Society [ATS], 2016). 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.

According to the U.S. Government Accountability Office (GAO) (2011), 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 (ATS, 2016):

- 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

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 (AARC, 2017). 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, 2017).

Oxygen concentrators are the most common and frequently used equipment in home oxygen therapy (Inogen, 2015). 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 (Inogen, 2015). 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 (Inogen, 2015). 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 (WHO, 2015). 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 HOT, 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.

Rationale

The clinical criteria is supported by societal recommendations, clinical studies, and the Centers for Medicare & Medicaid Services (CMS). 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 90% (NHOPA, 2013). An individual that has a S_aO_2 below 88% without oxygen is indicated for supplemental long term oxygen therapy (LTOT) to treat hypoxemia (NHOPA, 2013). The American College of Chest Physicians and the National Heart Lung and Blood Institute recommend instituting oxygen therapy in the following events (Fulmer, 1984):

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

The underlying pathology of the above recommendations are instituted in the clinical criteria of this policy. According to the American College of Physicians (ACP) (2011), the clinical guidelines state that supplemental long-term oxygen therapy (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” (Khatri, 2016). Most clinical trials and societal

recommendation indicate the first line of therapy for the treatment of OSA-associated cardiovascular episodes is Continuous Positive Airway Pressure (CPAP) (Khatri, 2016). 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 (Hadjiliadis, 2013). 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). Cluster headaches is another condition that can benefit from short-term 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 (Robbins, 2016). Oxygen inhalations may be repeated up to five times per day (Robbins, 2016).

CMS legislations on oxygen and oxygen equipment gained focus in the 1980s and have evolved through increased oxygen technologies, increased utilization of oxygen equipment, and increased patient need. Original CMS regulation authorized Medicare payment for home oxygen by implementing the reasonable charge methodology. The reasonable charge methodology governed DME reimbursement at that time (GAO, 2011). In 1986, fee schedule was implemented for home oxygen based on the average payment that Medicare made for each state (GAO, 2011).

For a patient to qualify for oxygen therapy, there must be (1) an existing breathing condition, such as COPD; (2) clinical tests documenting reduced levels of oxygen in the blood; (3) a certificate of medical necessity, signed by a physician; and (4) physician documentation on whether the patient should receive a portable unit in addition to a home-based stationary unit (GAO, 2011). The home oxygen payment rates to suppliers raised concerns due to high rates, which affected federal government spending and increased costs for the patient (GAO, 2011). Medicare's concerns resulted in Congress taking several actions in reducing and/or limiting the rates to suppliers (GAO, 2011). After several changes, Congress enacted new legislation, which is used today. The legislation includes the Deficit Reduction Act of 2005 (DRA) and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) (GAO, 2011). The two Medicare rulings focus on limiting rental payments to 36 months for suppliers of home oxygen equipment (CMS, 2008). After the 36-month maturity of the rental cap, the supplier must continue to maintain the home oxygen equipment at any period during the remainder of the reasonable useful lifetime (RUL) (CMS, 2008). The supplier will retain ownership after the rental payments stop, therefore the maintenance, repairs, and servicing of the equipment is the supplier's responsibility. According to Medicare law, once the five-year RUL has ended, the supplier's obligation to maintaining the oxygen equipment ends (CMS, 2008). Once the RUL ends, the patient may elect to obtain replacement equipment from any supplier, and a new 36-month capped rental will begin along with a new RUL supplier obligation period (CMS, 2008).

Cluster Headaches

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.

In the episodic form, the attacks 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.

According to the International Classification of Headache Disorders (ICHD-3) (2018), the diagnostic criteria for cluster headaches include:

A. At least five attacks fulling the following criteria B-D
B. Severe or very severe unilateral orbital, supraorbital and/or temporal pain lasting 15-180 minutes (when untreated);
C. Either or both of the following:
    1. 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
    2. A sense of restlessness or agitation
D. Occurring with a frequency between one every day and eight per day
E. Not better accounted for by another ICHD-3 diagnosis

Note: 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.

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.

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. Drs. Goadsby, Cohen and Burns (2009) reported on a randomized trial 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.

The Centers for Medicaid and Medicare Services published an NCD on the use of home oxygen to treat cluster headaches in January 2011. While CMS concluded that the currently available evidence does not demonstrate improvement in health outcomes, CMS concluded that additional clinical research is appropriate under Coverage with Evidence Development (CED). The NCD specifies the home use to treat cluster headaches is covered in a clinical trial setting with 100% oxygen and at least one clinically appropriate comparator.

UpToDate (2019) recommends initial treatment for acute 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.

POLICY SOURCE(S)

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Policy History

Date	Activity
9/20/2017	Initial policy developed
12/12/2017	QI/UM Committee approval
02/15/2018	Provider effective date
05/22/2018	Revisions and Updates: Revised recertification requirements in Section #5, letter B removing the face-to-face requirement every 6 months and replaced with the requirement of recertification of medical necessity every 6 months. This change is retroactive to 2/15/2018; removed the word 'Covered' from the procedure and diagnosis code tables in Attachments B & C.
06/19/2018	QI/UM Committee Review Approval (Retroactive changes)
06/28/2018	Urgent Revision: Added a note under section 5 to give direction over rental guidelines. This change is retroactive to 2/15/2018.
07/12/2018	Deleted code: P29.3 code invalid, requires 5th character and ADDED new codes P29.30 and P29.38.
06/19/2018	QI/UM Committee Review Approval – CONSENT AGENDA FYI
02/15/2018	Retroactive Provider Effective Date
12/11/2018	Annual Review: No clinical guideline changes; under Group 1 Initial Certification: updated limit of six months to 12 months and under Group 2 updated initial certification limit from six months to 3 months
12/11/2018	QI/UM Committee Review Approval
02/18/2019	Provider effective date
09/10/2019	Annual Review: Reformatted entire Procedure section; updated definitions; under Procedure Section added diagnostic criteria for cluster headaches, added new criteria for pediatric patients (#5) and oxygen and water vapor enriching systems; added list of oxygen equipment documenting noncoverage; updated summary of literature on cluster headaches; added procedure codes E0447, E1405, E1406; added table of noncovered HCPCS codes under Attachment B and updated References.
09/10/2019	QI/UM Committee Review Approval
11/04/2019	Provider effective date