

**Subject: Oxygen for Home Use**  
**Number: 0207**

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## **INSTRUCTIONS FOR USE**

*This Medical Necessity Guideline outlines the factors CareAllies considers in determining medical necessity for this indication. Please note, the terms of a participant's particular benefit plan document or summary plan description (SPD) may differ significantly from the standard upon which this Medical Necessity Guideline is based. For example, a participant's benefit plan document or SPD may contain a specific exclusion related to the topic addressed. In the event of a conflict, a participant's benefit plan document or SPD always supercedes the information in this Medical Necessity Guideline. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document or SPD. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable group benefit plan document or SPD in effect on the date of service; 2) any applicable laws/regulations, and; 3) the specific facts of the particular situation. Medical Necessity Guidelines are not recommendations for treatment and should never be used as treatment guidelines. ©2006 Intracorp/CareAllies*

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## **Stationary home oxygen and associated oxygen delivery equipment and accessories are considered medically necessary when BOTH of the following criteria are met:**

- presence of diagnosis that significantly impacts respiratory status, including but not limited to chronic obstructive pulmonary disease (COPD), diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, widespread pulmonary neoplasm, pulmonary hypertension, erythrocytosis, pneumonia, asthma, bronchitis, bronchiolitis or recurrent congestive heart failure due to chronic cor pulmonale
- presence of **ANY** of the following findings and laboratory results (performed on room air unless medically contraindicated):
  - arterial PaO<sub>2</sub> ≤ 55 mm Hg or arterial oxygen saturation ≤ 88% at rest
  - arterial PaO<sub>2</sub> ≤ 55 mm Hg or arterial oxygen saturation ≤ 88% for at least five minutes taken during sleep for a patient who demonstrates an arterial PaO<sub>2</sub> ≥ 56 mm Hg or arterial oxygen saturation ≥ 89% while awake
  - a decrease in arterial PaO<sub>2</sub> of more than 10 mm Hg, or a decrease in arterial oxygen saturation of more than 5% for at least five minutes taken during sleep, associated with symptoms or signs reasonably attributable to hypoxemia, including but not limited to cor pulmonale, "p" pulmonale on EKG, documented pulmonary hypertension and erythrocytosis
  - arterial PaO<sub>2</sub> ≤ 55 mm Hg or arterial oxygen saturation ≤ 88% during exercise for a patient who demonstrates arterial PaO<sub>2</sub> ≥ 56 mm Hg or arterial oxygen saturation ≥ 89% during the day at rest (when documented that oxygen improves hypoxemia during exercise)
  - arterial PaO<sub>2</sub> of 56-59 mm Hg or arterial blood oxygen saturation of ≤ 89% at rest, during sleep for at least five minutes, or during exercise (as described in preceding bullet) and **ONE** of the following:
    - dependent edema secondary to congestive heart failure
    - pulmonary hypertension, chronic cor pulmonale, or congestive heart failure with hypoxemia
    - erythrocythemia with hematocrit > 56%

**One spare oxygen tank is considered medically necessary for patients who require continuous oxygen and/or use oxygen concentrators.**

**Emergency or standby oxygen systems are considered not medically necessary.**

**Home oxygen is considered not medically necessary for the treatment or management of the following conditions (this list may not be all-inclusive):**

- angina pectoris in the absence of hypoxemia
- dyspnea without cor pulmonale or hypoxemia
- severe peripheral vascular disease with clinically evident desaturation in one or more extremities in the absence of hypoxemia
- terminal illnesses that have no impact on the respiratory system

**Stationary or portable home oxygen and associated oxygen delivery equipment and accessories are considered medically necessary for the treatment of cluster headaches.**

**Portable oxygen systems (weight 10 pounds or more) for indications other than cluster headaches are considered medically necessary when BOTH of the following criteria are met:**

- patient is ambulatory within the home and occasionally goes beyond the limits of the stationary system tubing
- arterial PaO<sub>2</sub> or arterial oxygen saturation at rest or during exercise meets criteria for stationary oxygen as described above

**Ambulatory oxygen systems (weight less than 10 pounds) are considered medically necessary when BOTH of the following criteria are met:**

- patient ambulatory within the home and regularly goes beyond the limits of the stationary system tubing
- arterial PaO<sub>2</sub> or arterial oxygen saturation at rest or during exercise meets criteria for stationary oxygen as described above

**Portable oxygen concentrators and combination stationary/portable oxygen systems are considered medically necessary when ALL of the following criteria are met:**

- patient is active and mobile and frequently exceeds the time constrictions inherent in traditional ambulatory oxygen systems
- blood gas results demonstrate hypoxia at rest or during exercise
- for combination systems, patient's attending physician confirms that system is expected to meet the patient's stationary and portable oxygen requirements

**The medical necessity for ongoing oxygen in the home should be demonstrated via pulse oximetry performed by the patient's attending physician or an independent respiratory practitioner one month after initiation of therapy for conditions that may be expected to be short term, such as pneumonia, asthma, bronchitis or bronchiolitis, and three months after initiation of therapy for other conditions.**

**Following the three-month initial evaluation, pulse oximetry should be reported on an annual basis as long as the patient remains on home oxygen. (Note: Pulse oximetry requirement does not apply to oxygen for cluster headaches.)**

**Charges for oxygen furnished by an airline are considered medically necessary only when the airline flight itself is medically necessary. Charges for oxygen furnished by an airline for any other travel reason are considered not medically necessary because under those circumstances it is provided for the convenience of the individual.**

## **General Background**

Home oxygen therapy is used to treat and prevent symptoms and manifestations of hypoxemia. Home oxygen may be indicated for patients with severe lung disease such as chronic obstructive pulmonary disease (COPD), diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, or widespread pulmonary neoplasm. Oxygen therapy may also be indicated for patients with hypoxia-related symptoms, such as

pulmonary hypertension, erythrocytosis and recurrent congestive heart failure due to chronic cor pulmonale, which may be expected to improve with oxygen therapy. Short-term oxygen therapy may be indicated for conditions such as pneumonia, asthma, bronchitis or bronchiolitis. Hypoxemia must be demonstrated by a recent blood gas analysis, and alternative treatment methods should be considered and attempted prior to initiating home oxygen.

The presence of any of the following findings and laboratory results demonstrates the appropriateness of home oxygen therapy for the conditions described below:

- arterial PaO<sub>2</sub> ≤ 55 mm Hg or arterial oxygen saturation ≤ 88% at rest
- arterial PaO<sub>2</sub> ≤ 55 mm Hg or arterial oxygen saturation ≤ 88% for at least five minutes taken during sleep for a patient who demonstrates an arterial PaO<sub>2</sub> ≥ 56 mm Hg or arterial oxygen saturation ≥ 89% while awake
- a decrease in arterial PaO<sub>2</sub> of more than 10 mm Hg, or a decrease in arterial oxygen saturation of more than 5% for at least five minutes taken during sleep, associated with symptoms or signs reasonably attributable to hypoxemia, including but not limited to cor pulmonale, “p” pulmonale on electrocardiogram (ECG), documented pulmonary hypertension and erythrocytosis
- arterial PaO<sub>2</sub> ≤ 55 mm Hg or arterial oxygen saturation ≤ 88% during exercise for a patient who demonstrates arterial PaO<sub>2</sub> ≥ 56 mm Hg or arterial oxygen saturation ≥ 89% during the day at rest (when documented that oxygen improves hypoxemia during exercise)
- arterial PaO<sub>2</sub> of 56-59 mm Hg or arterial blood oxygen saturation of ≤ 89% at rest, during sleep for at least five minutes, or during exercise (as described in preceding bullet) and ONE of the following:
  - dependent edema secondary to congestive heart failure
  - pulmonary hypertension, chronic cor pulmonale, or congestive heart failure with hypoxemia
  - erythrocythemia with hematocrit > 56%

Blood gas values must be obtained on room air unless medically contraindicated. Home oxygen must be prescribed by a physician who has seen and examined the patient within one month of the request. The prescription must specify the diagnosis and the oxygen flow rate and estimate the frequency and duration of therapy. The need for ongoing oxygen should be assessed via pulse oximetry performed by the patient’s attending physician or an independent respiratory practitioner three months after initiation of home oxygen. Pulse oximetry should be repeated annually as long as the patient remains on home oxygen.

### **Cluster Headache**

Home oxygen is also frequently used to treat cluster headache. Cluster headache, also known as Raeder’s syndrome, histamine cephalgia, and sphenopalatine neuralgia, 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. 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.

Cluster headaches begin without warning with periorbital and sometimes temporal pain that peaks within five minutes. The pain is unilateral and may be excruciating, deep, and generally non-fluctuating, lasting from 30 minutes to two hours. Treatment includes the administration of medications to prevent cluster attacks until the bout ends. Prophylactic medications include prednisone, lithium, methysergide, ergotamine, sodium valproate, and verapamil. Oxygen inhalation at a rate of seen to nine 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. Subcutaneous sumatriptan usually shortens an attack to 10 or 15 minutes (Raskin and Peroutka, 2001).

## Oxygen Delivery Systems

**Stationary Systems:** Stationary oxygen systems include gaseous oxygen cylinders, liquid oxygen systems and oxygen concentrators.

- **Oxygen gas cylinders:** Oxygen gas is stored under pressure in tanks or 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 that converts to gas when released from the tank. Liquid oxygen is more expensive than compressed gas but takes up less space and can be more easily transferred to a portable tank. A typical liquid oxygen system weighs approximately 120 pounds and provides continuous oxygen at two liters per minute for 8.9 days. Certain liquid oxygen systems can provide oxygen at the same rate for 30 days or more.
- **Oxygen concentrator:** An oxygen concentrator is an electric device that extracts oxygen from ambient air and delivers oxygen at 85% or greater at concentrations of up to four liters per minute. A back-up oxygen cylinder is used in the event of a power failure for patients on continuous oxygen using concentrators.

**Portable Systems:** Portable oxygen systems may be appropriate for patients with stationary oxygen systems who are ambulatory within the home and occasionally go beyond the limits of the stationary system tubing. Portable oxygen systems are indicated for patients with blood gas results demonstrating hypoxia at rest or during exercise. Portable systems are not indicated for patients with hypoxia documented only during sleep. Smaller gas cylinders, such as the E cylinder, are available as portable systems. The E cylinder weighs 12.5 pounds alone, 22 pounds with a rolling cart. An E cylinder with an oxygen-conserving device (see below) provides oxygen at two liters per minute for 28.3 hours. Portable oxygen systems, while lighter in weight than stationary systems, are not designed for patients to carry.

**Ambulatory Systems:** Ambulatory systems are lightweight (less than ten pounds) oxygen systems that most patients can carry. Ambulatory oxygen systems may be indicated for patients who regularly go beyond the limits of a stationary system and have blood gas results demonstrating hypoxia at rest or during exercise. Ambulatory systems are not indicated for patients with hypoxia documented only during sleep. Small gas cylinders are available that weigh 4.5 pounds, including conserver, and provide oxygen at two liters per minute for 12 hours. Portable liquid-oxygen systems that can be filled from the liquid-oxygen reservoir are available in various weights. The smallest weighs 3.4 pounds with a conserver and provides oxygen at two liters per minute for 10 hours.

**Portable Oxygen Concentrators:** Portable oxygen concentrators have recently been introduced as an alternative for highly mobile patients. The AirSep LifeStyle™ Portable Oxygen Concentrator (AirSep Corp., Buffalo, NY) received U.S. Food and Drug Administration (FDA) approval through the 510(k) process in March 2002. The unit weighs 9.75 pounds, operates continuously on AC current and may also be operated using a DC outlet, available in an automobile, or using a rechargeable battery. The unit operates for 50 minutes on battery power.

The OxyTec™ 900 Personal Ambulatory Oxygen System (Respironics, Inc., Murrysville, PA) received FDA approval through the 510(k) process in February 2005 and will become available in the U.S. in 2006. According to the FDA Summary of Safety and Effectiveness, there is no significant difference between the OxyTec System and its predicate device, the AirSep LifeStyle Portable Oxygen Concentrator.

A portable oxygen concentrator may be indicated for active, mobile patients who frequently exceed the time constrictions inherent in traditional ambulatory oxygen systems. Although this unit is comparable in weight to portable oxygen systems, it allows greater flexibility and increased mobility, since patients need not worry about running out of oxygen.

The Inogen One Oxygen Concentrator (Inogen, Inc., Goleta, CA) received FDA approval through the 510(k) process in May 2004 and became available in October 2004. The Inogen One is marketed as an apparatus that will serve as both a stationary and portable device. It delivers oxygen to the patient using a proprietary demand flow system during the inspiratory cycle. This conserver technology eliminates waste of unused oxygen at other times in the breathing cycle. The device senses the beginning of the inhalation

cycle and releases a specified amount of oxygen-enriched gas from the accumulation reservoir through a final filter into the nasal cannula. The Inogen One device weighs 9.7 pounds, including the battery. Battery duration is three hours, and battery charging takes approximately three hours with AC or DC power. The device includes nine flow settings from 1-5 in increments of 0.5.

Combination stationary/portable oxygen concentrators such as the Inogen One may be indicated for active, mobile patients who frequently exceed the time constrictions inherent in traditional ambulatory oxygen systems. The patient's attending physician must confirm that the device is expected to meet the patient's stationary and portable oxygen requirements.

**Oxygen-Conserving Devices**

Oxygen-conserving devices increase cylinder duration, allowing a patient to use a stationary oxygen system for longer periods of time, especially when a high flow rate is needed. These devices also facilitate the use of smaller, lighter portable and ambulatory systems. Oxygen-conserving devices target oxygen delivery to early inhalation, reducing the liter flow. There are three types of oxygen-conserving devices: reservoir cannulas, demand-pulsing oxygen delivery devices and transtracheal catheters.

**Oxygen Accessories**

Oxygen accessories include cannulas, humidifiers, masks, mouthpieces, nebulizers for humidification, regulators, stands/racks, and tubing, as well as the oxygen-conserving devices described above: reservoir cannulas, demand-pulsing oxygen delivery devices and transtracheal catheters.

**Summary**

Home oxygen may be indicated for patients with severe lung disease such as chronic obstructive pulmonary disease (COPD), diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, or widespread pulmonary neoplasm. Oxygen therapy may also be indicated for patients with hypoxia-related symptoms, such as pulmonary hypertension, erythrocytosis and recurrent congestive heart failure due to chronic cor pulmonale. Short-term oxygen therapy may be indicated for conditions such as pneumonia, asthma, bronchitis or bronchiolitis. Hypoxemia must be demonstrated by a recent blood gas analysis, and alternative treatment methods should be considered and attempted prior to initiating home oxygen. Home oxygen is also frequently used to treat cluster headache and does not require evidence of hypoxia. Portable or ambulatory oxygen systems, portable oxygen concentrators, or combination stationary/portable oxygen systems may be appropriate for certain patients based on mobility, activity, laboratory results and oxygen requirements.

**Coding/Billing Information**

**Note:** This list of codes may not be all-inclusive.

**When medically necessary:**

<b>CPT®*</b> <b>Codes</b>	<b>Description</b>
82803	Gases, blood, any combination of pH, pCO2, pO2, CO2, HCO3 (including calculated O2 saturation)
82805	Gases, blood, any combination of pH, pCO2, pO2, CO2, HCO3 (including calculated O2 saturation); with O2 saturation by direct measurement, except pulse oximetry
82810	Gases, blood O2 saturation only, by direct measurement, except pulse oximetry
94760	Noninvasive ear or pulse oximetry for oxygen saturation; single determination
94761	Noninvasive ear or pulse oximetry for oxygen saturation; multiple determinations (eg, during exercise)
94762	Noninvasive ear or pulse oximetry for oxygen saturation; by continuous overnight monitoring (separate procedure)

<b>HCPCS</b>	<b>Description</b>
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<b>Codes</b>	
A4615	Cannula, nasal
A4616	Tubing (oxygen), per foot
A4617	Mouth piece
A4618	Breathing circuits
A4619	Face tent
A4620	Variable concentration mask
E0424	Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizers, cannula or mask, and tubing
E0425	Stationary compressed gas system, purchase; includes regulator, flowmeter, humidifier, nebulizers, cannula or mask, and tubing
E0430	Portable gaseous oxygen system, purchase; includes regulator, flowmeter, humidifier, cannula or mask, and tubing
E0431	Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing
E0434	Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing
E0435	Portable liquid oxygen system, purchase; includes portable container, supply reservoir, flowmeter, humidifier, contents gauge, cannula or masks, tubing and refill adaptor
E0439	Stationary liquid oxygen system; rental, includes container, contents, regulator, flowmeter, humidifier, nebulizers, cannula or mask, and tubing
E0440	Stationary liquid oxygen system; purchase, includes use of reservoir, contents indicator, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing
E0441	Oxygen contents, gaseous (for use with owned gaseous stationary systems or when both a stationary and portable gaseous system are owned), 1 month's supply = 1 unit
E0442	Oxygen contents, liquid (for use with owned liquid stationary systems or when both a stationary and portable liquid system are owned), 1 month's supply = 1 unit
E0443	Portable oxygen contents, gaseous (for use only with portable gaseous systems when no stationary gas or liquid system is used), 1 month's supply = 1 unit
E0444	Portable oxygen contents, liquid (for use only with portable liquid systems when no stationary gas or liquid system is used), 1 month's supply = 1 unit
E0445	Oximeter device for measuring blood oxygen levels non invasively
E1353	Regulator
E1355	Stand/Rack
E1372	Immersion external heater for nebulizer
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
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

<b>ICD-9-CM Diagnosis Codes</b>	<b>Description</b>
162.0-162.9	Malignant neoplasm of trachea, bronchus, and lung
165.0-165.9	Malignant neoplasm of other and ill-defined sites within the respiratory system and intrathoracic organs
239.1	Neoplasms of unspecified nature, respiratory system
277.00-	Cystic fibrosis

277.09	
282.1	Hereditary elliptocytosis
289.0	Polycythemia, secondary
289.6	Familial polycythemia
346.2	Variants of migraine (cluster headache)
416.0-416.9	Chronic pulmonary heart disease
428.0-428.9	Heart failure
466.0-466.19	Acute bronchitis and bronchiolitis
480.0-480.9	Viral pneumonia
481	Pneumococcal pneumonia
482.0-482.9	Other bacterial pneumonia
483.0-483.8	Pneumonia due to other specified organisms
484.1-484.8	Pneumonia in infectious diseases classified elsewhere
485	Bronchopneumonia, organism unspecified
486	Pneumonia, organism unspecified
490	Bronchitis, not specified as acute or chronic
491.1-491.9	Chronic bronchitis
492.0-492.8	Emphysema
493.00-493.9	Asthma
494.0-494.1	Bronchiectasis
515	Postinflammatory pulmonary fibrosis
748.61	Congenital bronchiectasis

**\*Current Procedural Terminology (CPT®) ©2005 American Medical Association: Chicago, IL.**

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