



Cigna Medical Coverage Policy

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Subject **Oxygen for Home Use**

Table of Contents

Coverage Policy	1
General Background	3
Coding/Billing Information	7
References	8

Hyperlink to Related Coverage Policies

[Hyperbaric Oxygen Therapy, Systemic & Topical](#)
[Obstructive Sleep Apnea Diagnosis and Treatment Services](#)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna companies. Coverage Policies are intended to provide guidance in interpreting certain **standard** Cigna benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supersedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations. Proprietary information of Cigna. Copyright ©2013 Cigna

Coverage Policy

Many benefit plans provide coverage for oxygen and oxygen delivery systems under the core medical benefits of the plan.

Stationary Home Oxygen

Cigna covers a stationary home oxygen system and associated oxygen delivery equipment and accessories as medically necessary for hypoxemia as documented by the presence of ANY of the following combinations of clinical findings and oxygenation results (performed on room air unless medically contraindicated):

- arterial PaO₂ ≤ 55 mm Hg or arterial oxygen saturation ≤ 88% at rest
- arterial PaO₂ ≤ 55 mm Hg or arterial oxygen saturation ≤ 88% for at least five minutes taken during sleep for an individual who demonstrates an arterial PaO₂ ≥ 56 mm Hg or arterial oxygen saturation ≥ 89% while awake
- a decrease in arterial PaO₂ 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 ECG, documented pulmonary hypertension and erythrocytosis
- arterial PaO₂ ≤ 55 mm Hg or arterial oxygen saturation ≤ 88% during exercise for an individual who demonstrates arterial PaO₂ ≥ 56 mm Hg or arterial oxygen saturation ≥ 89% during the day at rest (when documented that oxygen improves hypoxemia during exercise)
- arterial PaO₂ 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%

Portable Oxygen Systems

Cigna covers a portable oxygen system as medically necessary when the medical necessity criteria listed above for stationary home oxygen are met with the qualifying blood gas or arterial oxygen saturation study performed while at rest (awake) or during exercise, and the individual is mobile within the home.

Oxygen Transfilling Systems (HCPCS codes E0433 and K0738)

Cigna covers oxygen transfilling systems as medically necessary when the medical necessity criteria listed above for portable oxygen systems are met and the individual is mobile within the home.

Portable Oxygen Concentrators and Combination Stationary/Portable Oxygen Systems

Cigna covers portable oxygen concentrators and combination stationary/portable oxygen systems as medically necessary when the medical necessity criteria listed above for home oxygen are met with the qualifying blood gas or arterial oxygen saturation study performed while at rest (awake) or during exercise, and the individual is active and mobile and frequently exceeds the time constrictions inherent in traditional ambulatory oxygen systems.

Cluster Headaches

Cigna covers home oxygen and associated oxygen delivery equipment and accessories as medically necessary for the treatment of cluster headaches.

Note: Pulse oximetry and arterial blood oxygen are not required for approval of home oxygen for cluster headaches.

Spare Tank

Cigna covers one spare oxygen tank for any individual who meets the above medical necessity criteria for home oxygen and who requires continuous oxygen and/or the use of an oxygen concentrator.

Air Travel

Cigna covers charges for oxygen furnished by an airline only when the airline flight itself is medically necessary and covered under the medical benefit plan. Cigna does not cover charges for oxygen furnished by an airline for any other travel reason because under those circumstances it is provided for an individual's convenience and is not medically necessary.

Note: An individual who will be traveling to another location should contact Cigna in advance to determine whether coverage for oxygen is available and can be arranged in the new location.

Proof of Continued Need

The medical necessity for ongoing oxygen in the home must be demonstrated via either blood gas results or pulse oximetry performed by the individual'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 or arterial blood gas results must be reported within 12 months of the initiation of oxygen and whenever there is an increase in the amount of oxygen or change in the type of oxygen equipment being requested.

Non-covered Equipment

Emergency/Stand-by Systems

Cigna does not cover emergency or standby oxygen systems because they are considered not medically necessary.

Duplicate Oxygen Systems

Cigna does not cover duplicate oxygen systems because they are considered a convenience item and not medically necessary, including but not limited to (this list may not be all-inclusive):

- provision of both a stationary (E1390) and portable (E1392) oxygen concentrator
- provision of both an oxygen refilling systems and a portable oxygen system (e.g., E0433 will not be covered with E0434; and, K0738 will not be covered with E0431)

Non-covered Conditions

Cigna does not cover home oxygen for the treatment or management of any of the following conditions because it is considered not medically necessary (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
- headaches other than cluster headaches, as noted above
- sleep apnea when the condition does not otherwise qualify for home oxygen

General Background

Home oxygen therapy is used in treatment of hypoxia in certain chronic pulmonary conditions, other conditions that may include hypoxia-related symptoms, as well as medical conditions that are known to clinically improve with oxygen. Home oxygen may be indicated for patients with severe lung disease that significantly impacts respiratory status and they develop hypoxemia, including but not limited to:

- chronic obstructive pulmonary disease (COPD)
- diffuse interstitial lung disease
- cystic fibrosis
- bronchiectasis
- widespread pulmonary neoplasm.

Oxygen therapy on intermittent basis may also be indicated for patients with hypoxia-related symptoms which may be expected to improve with oxygen therapy, including but not limited to:

- pulmonary hypertension
- erythrocytosis
- recurrent congestive heart failure due to chronic cor pulmonale

There are times when short-term oxygen therapy may be indicated for acute conditions that are expected to resolve with limited use of oxygen and there is the presence of hypoxemia. These conditions do not typically require oxygen, but when they develop hypoxemia, oxygen may be needed. They include but are not limited to:

- pneumonia

- asthma
- bronchitis
- bronchiolitis.

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

- arterial PaO₂ ≤ 55 mm Hg or arterial oxygen saturation ≤ 88% at rest
- arterial PaO₂ ≤ 55 mm Hg or arterial oxygen saturation ≤ 88% for at least five minutes taken during sleep for a patient who demonstrates an arterial PaO₂ ≥ 56 mm Hg or arterial oxygen saturation ≥ 89% while awake
- a decrease in arterial PaO₂ 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 PaO₂ ≤ 55 mm Hg or arterial oxygen saturation ≤ 88% during exercise for a patient who demonstrates arterial PaO₂ ≥ 56 mm Hg or arterial oxygen saturation ≥ 89% during the day at rest (when documented that oxygen improves hypoxemia during exercise)
- arterial PaO₂ 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%

Hypoxemia must be demonstrated by a recent blood gas analysis or pulse oximetry, and alternative treatment methods should be considered and attempted prior to initiating home oxygen. 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 within 12 months from the initiation of oxygen and whenever there is an increase in the amount of oxygen or change in the type of oxygen equipment being requested.

Cluster Headache

Home oxygen is also frequently used to treat cluster headache. Cluster headache is a distinct, treatable vascular headache syndrome. Episodic cluster headaches are the most common type, causing one to three brief attacks per day over a four- to eight-week period, followed by a pain-free interval of approximately one year. 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. Subcutaneous sumatriptan may also be used to shorten an attack. Oxygen inhalation at a rate of seven to ten liters per minute via a loose mask is the most effective treatment for the actual attack. Inhalation of 100% oxygen for 15 minutes is often necessary. Oxygen is not indicated for headaches other than cluster headaches, including migraines.

Sleep Apnea

The use of home oxygen therapy as the sole treatment for sleep apnea, including obstructive sleep apnea (OSA), is not considered medically appropriate. Positive airway pressure devices (e.g., CPAP and BiPAP) are generally considered for treatment of OSA. The inability to tolerate a positive airway device with nocturnal desaturations is not an indication for long-term use of oxygen as treatment for OSA. Oxygen may be needed if

the individual has hypoxemia not related to the sleep apnea and due to an underlying significant respiratory condition.

Clinical guidelines from the American Academy of Sleep Medicine for the evaluation, management and long-term care of OSA in adults (Epstein, et. al., 2009) note that oxygen supplementation is not recommended as a primary treatment for OSA. The guidelines note that supplemental oxygen used alone may reduce nocturnal hypoxemia but may also prolong apneas and may potentially worsen nocturnal hypercapnia in patients with comorbid respiratory disease.

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 and Ambulatory 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 are portable oxygen systems that are lightweight (less than ten pounds) 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 and Combination Stationary/Oxygen Concentrators: These devices are an alternative for highly mobile patients. 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 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 became 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.

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 Transfilling Systems (HCPCS codes E0433 and K0738)

Oxygen transfilling systems, which may also be referred to as oxygen cylinder filling systems, are devices that accompany oxygen concentrators and allow an individual to fill their own portable oxygen cylinders in their home. They may be integrated into the stationary concentrator or be a separate component. There are both gaseous and liquid transfilling systems. They may be provided to individuals instead of another portable gaseous (E0431) or liquid (E0434) oxygen system. It would be considered duplicate equipment to provide an individual with both an oxygen transfilling system and a portable oxygen system.

Oxygen transfilling systems include but are not limited to these devices:

- Invacare HomeFill[®] (Invacare Corporation, Elyria, OH): this device serves as the patient's stationary concentrator and will also fill cylinders.
- DeVilbiss iFill Personal Oxygen Station (DeVilbiss Healthcare, Somerset, PA): this is a standalone filling station and can be used with any concentrator.
- VIAspire[™] Liquefier/Personal Oxygen System (Inspired Technologies, North Huntingdon, PA): this system includes a liquefier that takes room air, concentrates the oxygen, then creates liquid oxygen—and a system that will then transfill cylinders from the liquefier.

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. Types of oxygen-conserving devices include: 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.

Use Outside of the US

The European Federation of Neurological Societies (EFNS) guidelines for cluster headache and other trigemino-autonomic cephalgias includes in the recommendations that as a first choice, acute attacks of cluster headache should be treated with the inhalation of 100% oxygen with at least 7 l/min over 15 min (Level A: A denotes effective) (Gilhus, et al., 2010).

The National Institute for Health and Clinical Excellence (NICE) published guidelines for the diagnosis and management of headaches in young people and adults (NICE, 2012). The guidelines include recommendation for acute treatment of cluster headaches:

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

- when using oxygen for the acute treatment of cluster headache: use 100% oxygen at a flow rate of at least 12 litres per minute with a non-rebreathing mask and a reservoir bag and arrange provision of home and ambulatory oxygen

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: 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

Stationary Home Oxygen

Covered when medically necessary:

HCPCS Codes	Description
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
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	Stationary oxygen contents, gaseous, 1 month's supply = 1 unit
E0442	Stationary oxygen contents, liquid, 1 month's supply = 1 unit
E1353	Regulator
E1355	Stand/Rack
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
E1405	Oxygen and water vapor enriching system; with heated delivery
E1406	Oxygen and water vapor enriching system; without heated delivery
S8120	Oxygen contents, gaseous, 1 unit equals 1 cubic foot
S8121	Oxygen contents, liquid, 1 unit equals 1 pound

Portable Oxygen Systems

Covered when medically necessary:

HCPCS Codes	Description
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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
E0443	Portable oxygen contents, gaseous, 1 month's supply = 1 unit
E0444	Portable oxygen contents, liquid, 1 month's supply = 1 unit
E1354	Oxygen accessory, wheeled cart for portable cylinder or portable concentrator, any type, replacement only, each
E1392	Portable oxygen concentrator, rental

Oxygen Transfilling Systems

Covered when medically necessary

HCPSC Codes	Description
E0433	Portable liquid oxygen system, rental; home liquefier used to fill portable liquid oxygen containers, includes portable containers, regulator, flowmeter, humidifier, cannula or mask and tubing, with or without supply reservoir and contents gauge
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

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