Anthem

Clinical UM Guideline

Subject: Home Oxygen Therapy
Guideline #: CG-DME-18
Status: Reviewed

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Last Review Date: 08/10/2023

Description

This document addresses the clinical indications for use of home oxygen therapy.

Clinical Indications

Medically Necessary:

A. Short term supplemental home oxygen therapy is **medically necessary** for treatment of hypoxemia-related symptoms with qualifying laboratory values (see **Note** below) associated with acute conditions including, but not limited to **any** of the following:
   1. Bronchiolitis; **or**
   2. Chronic obstructive pulmonary disease exacerbation; **or**
   3. Pneumonia

B. Long term supplemental home oxygen therapy is **medically necessary** for treatment of hypoxemia-related symptoms with qualifying laboratory values (see **Note** below) from chronic lung conditions including, but not limited to **any** of the following:
   1. Bronchiectasis; **or**
   2. Chronic lung disease; **or**
   3. Chronic obstructive pulmonary disease; **or**
   4. Cystic fibrosis; **or**
   5. Diffuse interstitial lung disease; **or**
   6. Pulmonary hypertension; **or**
   7. Pulmonary neoplasm (primary or metastatic); **or**
   8. Recurring congestive heart failure due to chronic cor pulmonale.

C. Intermittent home oxygen therapy is considered **medically necessary** for the treatment of cluster headaches.

D. Supplemental home oxygen therapy is considered **medically necessary** during exercise when there is documentation of **both** of the following:
   1. Hypoxemia during exercise; **and**
   2. Improvement in hypoxemia and dyspnea or exercise capacity during exercise while using supplemental oxygen.

E. Supplemental home oxygen therapy is considered **medically necessary** during sleep in an individual with **any** of the following conditions:
   1. Unexplained pulmonary hypertension, cor pulmonale, edema secondary to right heart failure, **or** erythrocytosis **and** hematocrit is greater than 56%; **or**
   2. When obstructive sleep apnea, other nocturnal apnea, **or** a hypoventilation syndrome has been ruled out **and** there is documentation of desaturation during sleep to an SaO_2 of equal to or less than 88% for greater than 30% of the night; **or**
   3. When an individual with documented obstructive sleep apnea, other nocturnal apnea, **or** a hypoventilation syndrome experiences desaturation during sleep to a SaO_2 of equal to or less than 88% for greater than 30% of the night, which persists despite use of continuous positive airway pressure **or** non-invasive positive pressure ventilation devices.

Note: Hypoxemia is evidenced by **any** of the qualifying laboratory values obtained while breathing room (ambient) air unless contraindicated:

A. Adults:
   1. Arterial partial pressure of oxygen (PaO_2) equal to or less than 55 mm Hg **or** SaO_2 equal to or less than 88%; **or**
   2. Arterial PaO_2 of 56-59 mm Hg or SaO_2 equal to or less than 89% with **any** of the following conditions:
      a. Cor pulmonale; **or**
      b. Dependent edema secondary to right heart failure; **or**
      c. Erythrocytosis with hematocrit greater than 56%; **or**
      d. Pulmonary hypertension.

B. Infants and Children:
   1. PaO_2 of equal to or less than 60 mm Hg; **or**
   2. SaO_2 of equal to or less than 92%.

Not Medically Necessary:

Home oxygen therapy is considered **not medically necessary** for **any** of the following indications, including but not limited to:

1. Severe peripheral vascular disease with clinically evident desaturation in one or more extremities in the absence of hypoxemia; **or**
2. Terminal illness not affecting the respiratory system; **or**
3. Treatment of angina pectoris or dyspnea in the absence of documented associated cor pulmonale or hypoxemia; **or**
4. The use of preset regulators used with portable oxygen systems.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

HCPCS

	Equipment
E0424-E0425	Stationary compressed gaseous oxygen system
E0430-E0431	Portable gaseous oxygen system
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
E0434-E0435	Portable liquid oxygen system
E0439-E0440	Stationary liquid oxygen system
E0550	Humidifier, durable for extensive supplemental humidification during IPPB treatments or oxygen delivery
E0555	Humidifier, durable, glass or autoclavable plastic bottle type, for use with regulator or flowmeter
E0560	Humidifier, durable for supplemental humidification during IPPB treatment or oxygen delivery
E0580	Nebulizer, with compressor, durable, glass or autoclavable plastic, bottle type, for use with regulator or flowmeter
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 adaptor for portable concentrator, any type, replacement only, each
E1390-E1391	Oxygen concentrator single/dual delivery port
E1392	Portable oxygen concentrator, rental
E1405-E1406	Oxygen and water vapor enriching system
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
	Contents
E0441	Stationary oxygen contents, gaseous, 1 month’s supply = 1 unit
E0442	Stationary oxygen contents, liquid, 1 month’s supply = 1 unit
E0443	Portable oxygen contents, gaseous, 1 month’s supply = 1 unit
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)
S8120	Oxygen contents, gaseous, 1 unit equals 1 cubic foot
S8121	Oxygen contents, liquid, 1 unit equals 1 pound
	Supplies
A4615	Cannula, nasal
A4616	Tubing (oxygen), per foot
A4619	Face tent
A4620	Variable concentration mask

ICD-10 Diagnosis

	All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

Home oxygen therapy administered at concentrations greater than air external to a building or device (ambient or room air) is intended to treat or prevent symptoms and manifestations of hypoxemic or non-hypoxemic medical conditions that are known to clinically improve with oxygen.

Arterial oxygen saturation of hemoglobin (SaO_2) can be measured by arterial blood gas (ABG) sampling or pulse oximetry. The healthcare practitioner orders the testing type and frequency. In adults and children (excluding premature infants), normal values of SaO_2 are 94% to 100% (NIH, 2018).

For the diagnosis of cluster headache, oxygen inhalation (100%) delivered at a rate of 7 to 10L/min. for 15 minutes through a loose-fitting facemask is considered a safe and effective, first-line treatment for acute attacks. High-flow oxygen has been shown to abort the headache within several minutes.

Oxygen equipment alternatives include three types of systems to provide home oxygen:

- Compressed oxygen (tanks);
- Liquid oxygen;
- Oxygen concentrators.

With all of these systems, oxygen is inhaled through a mask or more commonly, a nasal cannula. Oxygen conserving devices can be used with compressed or liquid oxygen. The most popular oxygen conserving devices are demand inspiratory flow systems. These devices use a sensor to detect when inspiration begins and deliver oxygen only during inspiration, thus conserving oxygen during exhalation.

There has been recent interest in multiple factors, including skin pigmentation, that can impact the accuracy of pulse oximeter readings potentially resulting in overreliance on pulse oximeter levels and suboptimal treatment management of individuals whose oxygen levels are below normal. The Australian Government Department of Health and Aged Care Therapeutic Goods Administration produced a Medical Device Safety Update regarding the limitations of pulse oximeters and the effect of skin pigmentation in 2022.

Pulse oximeter devices work by shining light through the skin. Oxygen transporters in blood reflect light differently depending on how much oxygen they contain. The accuracy of the measurement has been known to be affected by many factors, including skin pigmentation. Other factors include correct fitting of the device, peripheral blood flow, nail coatings, tattoos and dyes, and maintenance and cleaning of the devices.

The Australian safety update noted recent cohort studies and systematic reviews indicating the potential for pulse oximeter readings that may over-estimate oxygen saturation levels in people with darker skin pigmentation (Bickler, 2005; Cabanas, 2022; Feiner, 2007; Sjoding, 2020; Valbuena, 2022). These inaccuracies are greater at lower levels of oxygenation and are more frequently reported in persons with darker skin pigmentation. They also occur at saturation levels where key decisions are often made around supplemental home oxygen therapy (at SaO_2 levels of 88-94%) with measures that are 3-4 percentage points above the actual oxygen saturation determined by arterial blood gas analysis. The authors propose that the effect in persons with intermediate skin tones may be in between that of darker and fairer skin tones. Investigators also acknowledged disparities in the accuracy of different pulse oximeter devices. The safety report concluded that home use of pulse oximeters is safer and more effective when done as part of coordinated medical management of the individual's total condition with consideration of all clinical factors when recommending treatment. Clinicians are reminded that pulse oximeter devices may not accurately detect hypoxemia in persons with darker skin tones where oxygen saturations levels may be overestimated. At the present time, there is insufficient available evidence to make recommendations about any specific pulse oximeter devices (Australian Therapeutic Goods Administration, 2022).

On June 21, 2022 the U.S. Food and Drug Administration (FDA) issued an FDA Safety Communication about Pulse Oximeter Accuracy and Limitations, in which the following was noted:

> The FDA continues to evaluate all available information pertaining to factors that may affect pulse oximeter accuracy and performance. Because of ongoing concerns that these products may be less accurate in individuals with darker skin pigmentations, the FDA is planning to convene a public meeting of the Medical Devices Advisory Committee later this year to discuss the available evidence about the accuracy of pulse oximeters, recommendations for patients and health care providers, the amount and type of data that should be provided by manufacturers to assess pulse oximeter accuracy, and to guide other regulatory actions as needed. Further details concerning the agenda, timing, and location of the Advisory Committee meeting will be announced in the coming weeks.
>
> The FDA recommendations provided below have not changed. The FDA will continue to keep the public informed as significant new information or recommendations become available.
>
> - Follow your health care provider's recommendations about when and how often to check your oxygen levels.
> - Be aware that multiple factors can affect the accuracy of a pulse oximeter reading, such as poor circulation, skin pigmentation, skin thickness, skin temperature, current tobacco use, and use of fingernail polish. To get the best reading from a pulse oximeter:
>   - Follow the manufacturer's instructions for use;
>   - When placing the oximeter on your finger, make sure your hand is warm, relaxed, and held below the level of the heart. Remove any fingernail polish on that finger;
>   - Sit still and do not move the part of your body where the pulse oximeter is located;
>   - Wait a few seconds until the reading stops changing and displays one steady number.
> - Write down your oxygen levels with the date and time of the reading so you can easily track changes and report these to your health care provider (FDA, 2022).

Definitions

Bronchiectasis: A condition characterized by the loss of smooth muscle and elasticity of segments of the bronchial tubes.

Bronchiolitis: An inflammation of the bronchioles, the smallest air passages of the lungs, usually caused by a virus.

Cor pulmonale: Abnormal enlargement of the right side of the heart as a result of disease of the lungs or the pulmonary blood vessels.

Hypoxemic: An oxygen deficiency in arterial blood.

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Peer Reviewed Publications:

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History

Status	Date	Action
Reviewed	08/10/2023	Medical Policy & Technology Assessment Committee (MPTAC) review. Updated References section.
Revised	08/11/2022	MPTAC review. The MN criterion D-1. for supplemental home oxygen therapy during exercise was revised to remove the SaO_2 level and clarify with presence of hypoxemia during exercise. Information was added to the Discussion section about disparities of SaO_2 levels sometimes seen in individuals with darkly pigmented skin. References were updated.
Reviewed	08/12/2021	MPTAC review. References were updated.
Reviewed	08/13/2020	MPTAC review. References were updated. Reformatted Coding section.
Reviewed	08/22/2019	MPTAC review. References were updated.
	12/27/2018	Updated Coding section with 01/01/2019 HCPCS changes; added E0447.
Revised	09/13/2018	MPTAC review. Updated formatting in the Clinical Indications section. Updated References section.
Reviewed	11/02/2017	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated Discussion and References sections.
Reviewed	11/03/2016	MPTAC review. Updated formatting in the Clinical Indications section. Added Definitions section. Updated Discussion/General Information and References sections.
Reviewed	11/05/2015	MPTAC review. Updated References. Removed ICD-9 codes from Coding section.
Revised	11/13/2014	MPTAC review. Format changes and clarifications throughout Clinical Indications section. Updated Description, Discussion and References sections.
Reviewed	11/14/2013	MPTAC review. Format change to Coding section. Updated References section.
Reviewed	11/08/2012	MPTAC review. Updated Discussion and References. Removed/deleted Index. Updated Coding section with 01/01/2013 HCPCS changes; removed K0741, K0742 deleted 12/31/2012.
Reviewed	11/17/2011	MPTAC review. Clarified acronyms in Clinical Indications. Updated Coding and References.
	07/01/2011	Updated Coding section with 07/01/2011 HCPCS changes.
Reviewed	11/18/2010	MPTAC review. Updated References.

Revised	11/19/2009	MPTAC review. Clarified and reformatted medically necessary Clinical Indication statements. Revised criteria addressing “erythrocytosis with hematocrit” from greater than 55% to greater than 56%. Removed Place of Service/Duration table. Updated References. Updated Coding section with 01/01/2010 HCPCS changes.
Revised	11/20/2008	MPTAC review. Addition of the following not medically necessary statements for the use of home oxygen therapy: severe peripheral vascular disease with clinically evident desaturation in one or more extremities in the absence of hypoxia; terminal illness not affecting the respiratory system; and, cor pulmonale was added to the “treatment of angina pectoris or dyspnea in the absence of documented associated cor pulmonale or hypoxia” statement. References updated. Updated Coding section with 01/01/2009 HCPCS changes.
	10/01/2008	Updated Coding section with 10/01/2008 ICD-9 changes.
Revised	11/29/2007	MPTAC review. Clarified and reformatted medically necessary Clinical Indications. Deleted medically necessary criteria for portable systems. Coding updated. References reformatted and updated.
Revised	12/07/2006	MPTAC review. Inclusion of medically necessary criteria for non-continuous oxygen during exercise and sleep. Revised hypoxemia criteria for children. Coding updated; removed HCPCS K0671 deleted 12/31/2005.
Revised	12/01/2005	MPTAC review. Revision based on Pre-merger Anthem and Pre-merger WellPoint Harmonization.

Pre-Merger Organizations	**Last Review Date**	**Document Number**	**Title**
Anthem, Inc.			No document
Anthem ME		Benefit Detail	Oxygen
WellPoint Health Networks, Inc.	12/02/2004	Clinical Document	Home Oxygen Therapy

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