



## Medicare Part C Medical Coverage Policy

### Oxygen and Oxygen Supplements

**Origination:** April 10, 1992

**Review Date:** July 12, 2017

**Next Review:** July, 2019

#### **DESCRIPTION OF PROCEDURE OR SERVICE**

USP Oxygen is a gaseous element existing free in the air. The United States Pharmacopia (USP) determines the strength, quality and purity. It is administered by inhalation (breathing) with devices that provide controlled oxygen concentrations and flow rates to the member. Oxygen therapy should maintain adequate oxygen levels to the tissues and cells while avoiding oxygen toxicity (too much oxygen). The member's condition must be monitored to assure that the member is receiving the proper mixes of gases, mists and aerosols.

Examples of conditions for which oxygen and oxygen equipment would be eligible for coverage are:

1. Severe lung disease;
2. Hypoxemia related symptoms or findings that might be expected to improve with oxygen therapy.

#### **POLICY STATEMENT**

Coverage will be provided for oxygen when it is determined to be medically necessary when the medical criteria and guidelines shown below are met.

#### **BENEFIT APPLICATION**

Please refer to the member's individual Evidence of Coverage (E.O.C.) for benefit determination. Coverage will be approved according to the E.O.C. limitations if the criteria are met.

Coverage decisions will be made in accordance with:

- The Centers for Medicare & Medicaid Services (CMS) national coverage decisions;
- General coverage guidelines included in original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member's particular Evidence of Coverage (E.O.C.), the E.O.C. always governs the determination of benefits.

#### **INDICATIONS FOR COVERAGE**

**A. Preauthorization by the Plan is required.**

B. Home oxygen therapy is covered only if **ALL** of the following conditions are met:

1. The treating physician has determined that the member has a severe lung disease or hypoxia related symptoms that might be expected to improve with oxygen therapy,

**AND**

2. The member's blood gas study meets Group I or Group II criteria stated below,

**AND**

3. The qualifying blood gas study **on room air** was obtained under the following conditions:
  - If performed during an inpatient hospital stay, the blood gas must be the one obtained closest to, but no earlier than 2 days prior to the hospital discharge date; **OR**
  - If the blood gas is not performed during an inpatient hospital stay, it must be performed while the member is in a chronic stable state, i.e., not during a period of acute illness or an exacerbation of their underlying disease;

**AND**

4. Alternative treatment measures have been tried or considered and deemed clinically ineffective.

**Group I blood gas (oximetry test/arterial blood gas) criteria for members with significant hypoxemia evidenced by any of the following:**

1. An arterial PO<sub>2</sub> at or below 55 mm Hg or arterial oxygen saturation at or below 88 percent taken at rest (awake), **OR**
2. An arterial PO<sub>2</sub> at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, taken during sleep for a member who demonstrates an arterial PO<sub>2</sub> at or above 56 mm Hg, or an arterial oxygen saturation at or above 89 percent while awake, **OR**
3. A decrease in arterial PO<sub>2</sub> more than 10 mm Hg, or a decrease in arterial oxygen saturation more than 5 percent 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**
4. An arterial PO<sub>2</sub> at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent, taken during exercise for a member who demonstrates an arterial PO<sub>2</sub> at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent 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 member was breathing room air.

**Group II blood gas criteria include:**

1. An arterial PO<sub>2</sub> of 56-59 mm Hg or an arterial blood oxygen saturation of 89 percent at rest (awake), during sleep for at least 5 minutes (the 5 minutes does not have to be continuous), or during exercise (as described under Group I criteria) **AND**
2. Any of the following:
  - Dependent edema suggesting congestive heart failure, **or**
  - 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**
  - Erythrocythemia with a hematocrit greater than 56 percent.

Initial coverage for members meeting Group I and Group II criteria is 36 months or physician specified length of need, whichever is shorter.

**Group III blood gas criteria include:**

- An arterial PO<sub>2</sub> level at or above 60 mm Hg or arterial blood oxygen saturation at or above 90 percent.
- These are not covered.

**Cluster Headaches:**

- Effective for services on and after January 4, 2011, oxygen is covered for the treatment of cluster headaches for members enrolled in a clinical trial approved by CMS.

**Relocation and Travel**

Months 1 through 36

If the member relocates outside the supplier's service area (either short-term travel, extended temporary relocation, or permanent relocation), then for the remainder of the rental month for which it billed, the home supplier is required to provide the equipment and related items/service itself or make arrangements with a different supplier to provide the equipment, items, and services. For subsequent rental months that the member is outside the service area, the home supplier is encouraged to either provide the equipment and related items/services itself or assist the member in finding another supplier in the new location. The home supplier may not bill for or be reimbursed by the Plan if it is not providing oxygen equipment or has not made arrangements with a different supplier to provide the equipment on the anniversary billing date. The Plan will pay only one supplier to provide oxygen during any one-rental month. Prior approval guidelines apply.

Months 37 through 60

If the member relocates outside the supplier's service area (i.e., short-term travel, extended temporary relocation, or permanent relocation), the home supplier is required to either provide the equipment and related items/services itself or make arrangements with a different supplier to provide the equipment and related items/services. Prior approval guidelines apply.

**Polysomnography and Home Sleep Tests**

Coverage of home oxygen therapy requires that the member be tested in the “chronic stable state.” Chronic stable state is a requirement of the National Coverage Determination [NCD] (CMS Internet-only Manual, Pub. 100-3, Section 240.2) and is one of the key criteria when determining coverage of home oxygen therapy. The NCD defines chronic stable state as “...not during a period of an acute illness or an exacerbation of their underlying disease.” In the case of obstructive sleep apnea (OSA), it is required that the OSA be appropriately and sufficiently treated such that the member is in the chronic stable state before oxygen saturation results obtained during sleep testing are considered qualifying for oxygen therapy.

The Plan will authorize coverage of oxygen therapy based on the results of a qualifying oxygen saturation level.

### **WHEN COVERAGE WILL NOT BE APPROVED**

1. If all of the coverage conditions specified above are not met, the oxygen therapy will be denied as not medically necessary. Oxygen therapy will also be denied as not medically necessary if any of the following conditions are present:
  - a. 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.
  - b. Dyspnea without cor pulmonale or evidence of hypoxemia.
  - c. Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities but in the absence of systemic hypoxemia. There is no evidence that increased PO<sub>2</sub> will improve the oxygenation of tissues with impaired circulation.
  - d. Terminal illnesses that do not affect the respiratory system.
2. Group III Medicare Criteria are not covered.
3. Cluster Headaches- after January 4, 2011, oxygen therapy for the treatment of cluster headaches for members **not** enrolled in a CMS approved clinical trial.
4. Prior to January 4, 2011, coverage of oxygen therapy for cluster headaches was authorized for coverage for three (3) months intervals when there was documentation of attempts and failure of other treatment modalities is required. Requests for continued coverage will not be covered if the member is not enrolled in a CMS approved clinical trial.
5. Purchased oxygen equipment is statutorily not covered.
6. Oxygen services furnished by an airline to a member.
7. Portable Oxygen will be denied if the blood gas study was performed only during sleep.
8. Topical hyperbaric oxygen (THO) in the treatment of wounds. Topical hyperbaric oxygen systems deliver oxygen directly to the site of the wound. THO is non-covered.
9. Oximeters (E0445) and replacement probes (A4606) are not covered for home use for patients who have oxygen.

10. Topical oxygen delivery systems (E0446) will be denied as not reasonable and necessary.

### **BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION**

This policy may apply to the following codes. Inclusion of a code in the section does not guarantee reimbursement.

*Applicable codes: E0424, E0430, E0431, E0433, E0434, E0439, E0441, E0442, E0443, E0444, E1390, E1391, E1392, E1405, E1406, K0738*

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

### **SPECIAL NOTES**

- For initial coverage, the blood gas study must be the most recent study obtained within 30 days prior to the date the physician signed the orders.
- For chronic use, initial authorization is given for 36 months.
- **For Newly enrolled members** with Blue Medicare HMO/ Blue Medicare PPO who have previously received oxygen approval from Original Medicare or another Medicare Advantage Plan for more than 3 months; the providers of the oxygen will not be required to submit a qualifying oxygen saturation if the member has one of the diagnoses that CMS identifies as meeting the guidelines for oxygen.
  - These include a severe lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, whether of known or unknown etiology; cystic fibrosis bronchiectasis; widespread pulmonary neoplasm; or hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy. Examples of these symptoms and findings are pulmonary hypertension, recurring congestive heart failure due to chronic cor pulmonale, erythrocytosis, impairment of the cognitive process, nocturnal restlessness, and morning headache.
- When both arterial blood gas (ABG) and oximetry tests are performed on the same day under the same conditions (i.e., at rest/awake, during exercise, or during sleep), the ABG result will be used to determine if the coverage criteria were met. If an ABG test at rest/awake is non-qualifying, but an exercise or sleep oximetry test on the same day is qualifying, the oximetry test result will determine coverage.
- Home Sleep Oximetry Studies:
  - Members may self-administer home based overnight oximetry tests under the direction of a Plan-enrolled Independent Diagnostic Testing Facility (IDTF). A DME supplier may deliver a pulse oximetry test unit and related technology to a member's home under the following circumstances:
    - a. The member's treating physician has ordered an overnight pulse oximetry test before the test is performed.

- b. The test is performed under the direction and/or instruction of a Plan-approved IDTF. (Because it is the member who self-administers the test, the IDTF must provide clear written instructions to the member on proper operation of the test equipment and must include access to the IDTF in order to address other concerns that may arise.)
  - c. The test unit is sealed and tamper-proof such that test results cannot be accessed by anyone other than the IDTF who is responsible for transmitting a test report to the treating physician.
- Oxygen is covered for members enrolled in clinical trials approved by CMS and sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and who have an arterial PO<sub>2</sub> from 56-65 mmHg or oxygen saturation at or above 89%. The additional Group II criteria do not apply to these members.
- The reasonable useful lifetime (RUL) for oxygen equipment is five (5) years. The RUL is not based on the chronological age of the equipment. It starts on the initial date of service and runs for 5 years from that date. The Plan follows Medicare guidelines in determining the RUL.
- When oxygen is covered based on an oxygen study obtained during exercise, there must be documentation of three (3) oxygen studies in the member's medical record; Testing at rest without oxygen, testing during exercise without oxygen, and testing during exercise with oxygen applied (to demonstrate the improvement of the hypoxemia) are required. All three (3) tests must be performed within the same testing session. Only the testing during exercise without oxygen is used for qualification. The other two results do not have to be routinely submitted but must be available on request.
- The Plan will cover one (1) maintenance visit no more than every six (6) months, beginning no sooner than the sixth month following the end of the rental period which would be the 36<sup>th</sup> month. Maintenance service will not apply to member-owned oxygen equipment or if the oxygen equipment is covered under a warranty.

**NOTE:** Authorization for maintenance will be applicable from months 42-60.

References:

1. Medicare Local Coverage Determination for Oxygen and Oxygen Equipment – CGS Administrator (L33797); Effective date: 10/01/2015; accessed via [www.cms.gov](http://www.cms.gov) 7/12/17.
2. Medicare National Coverage Determination for Home Oxygen Use to Treat Cluster Headache (NCD 240.2.2). Effective date: 1/4/11. Accessed via Internet site [www.cms.gov](http://www.cms.gov); Viewed 7/12/17.
3. Medicare National Coverage Determination for Home Use of Oxygen (NCD 240.2). Effective date: 10/27/93. Assessed via Internet site at [www.cms.gov](http://www.cms.gov). Viewed on 7/12/17.

4. MLNMatters Article – MM6990 Clarification of the Date of Service for Maintenance and Servicing Payments for Certain Oxygen Equipment after July 1, 2010; Effective date: 07/01/2010. Accessed via Internet site <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM6990.pdf> 06/30/2015.

**Policy Implementation/Update Information:**

**Revision Date:** May 29, 2001; August 24, 2001; October 11, 2001; May 20, 2004; September 8, 2004; June 28, 2006;

**Revision Date:** February 18, 2009: Clarified newly enrolled section

June 17, 2009: Removed 3-month initial trial period for chronic conditions

September 2009: Code review only

February 15, 2012: Criteria updated to be consistent with Medicare coverage.

**Revision Date:** August 21, 2013; Added non-coverage for Topical hyperbaric oxygen (THO) and Oximeters are non-covered.

Codes updated, K0671 Deleted.

**Revision Date:** July 15, 2015; Annual Review, updated Group I and II length of coverage per current process; added Maintenance criteria to Special Notes section-last bullet; reference section updated. October 29, 2015 updated LCD due to ICD-10 update only.

**Revision Date:** July 12, 2017; Annual Review. No CMS Updates. Minor Revisions Only.

**Approval Dates:**

Medical Coverage Policy Committee: July 12, 2017

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