Coverage Summary

Oxygen for Home Use


Approved by: UnitedHealthcare Medicare Benefit Interpretation Committee  Last Review Date: 02/14/2017

Related Medicare Advantage Policy Guidelines:
- Home Oxygen Use To Treat Cluster Headache (CH) (NCD 240.2.2)
- Home Use of Oxygen in Approved Clinical Trials (NCD 240.2.1)

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The benefit information in this Coverage Summary is based on existing national coverage policy, however, Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable.

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I. COVERAGE

Coverage Statement: Home use of oxygen is covered when Medicare coverage criteria are met.

DME Face to Face Requirement: Effective July 1, 2013, Section 6407 of the Affordable Care Act (ACA) established a face-to-face encounter requirement for certain items of DME (including home oxygen). For DME Face to Face Requirement information, refer to the Coverage Summary of Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid.
Guidelines/Notes:
The following guidelines (Guidelines 1 -7) are based on the NCD for Home Use of Oxygen (240.2) and the DME MAC LCDs for Oxygen and Oxygen Equipment (L33797). Compliance with these LCDs is required where applicable. (Accessed January 18, 2017)

1. Indications and Limitations of Coverage
Medicare coverage of home oxygen and oxygen equipment under the durable medical equipment (DME) benefit is considered reasonable and necessary only for patients with significant hypoxemia who meet the medical documentation, laboratory evidence, and health conditions specified below.

2. Medical Documentation, Laboratory Evidence and Covered Blood Gas Values
   a. The treating physician’s prescription or other medical documentation must indicate that other forms of treatment (e.g., medical and physical therapy directed at secretions, bronchospasm and infection) have been tried, have not been sufficiently successful, and oxygen therapy is still required. While there is no substitute for oxygen therapy, each patient must receive optimum therapy before long-term home oxygen therapy is ordered.

   b. A physician’s certification of medical necessity for oxygen equipment must include the results of specific testing before coverage can be determined.
   Claims for oxygen must also be supported by medical documentation in the patient’s record. Separate documentation is used with electronic billing. This documentation may be in the form of a prescription written by the patient’s attending physician who has recently examined the patient (normally within a month of the start of therapy) and must specify:
      - A diagnosis of the disease requiring home use of oxygen;
      - The oxygen flow rate; and
      - An estimate of the frequency, duration of use (e.g., 2 liters per minute, 10 minutes per hour, 12 hours per day), and duration of need (e.g., 6 months or lifetime)

     Note: A prescription for “Oxygen PRN” or “Oxygen as needed” does not meet this last requirement. Neither provides any basis for determining if the amount of oxygen is reasonable and necessary for the patient.

   c. Oxygen for home use and accompanying necessary accessories is recommended when ALL of the following conditions are met:
      1) The treating physician has determined that the patient has a severe lung disease or hypoxia-related symptoms that might be expected to improve with oxygen therapy
      2) The member’s blood gas study meets the criteria stated below
         (See GROUP I, II, III criteria below)
      3) The qualifying blood gas study was performed by a physician or by a qualified provider or supplier of laboratory services
      4) The qualifying blood gas study was obtained under the following conditions:
         a. Inpatient hospital stay: The reported test must be the one obtained closest to, but no earlier than 2 days prior to the hospital discharge date, or
b. **Non-Inpatient hospital stay:*** The reported test must be performed while the patient is in a chronic stable state

5) Alternative treatment measures (as described in 1-A above) have been tried and found or considered and deemed clinically ineffective

d. **Covered Blood Gas Values**
   
   *(Note: In this policy, the term blood gas study refers to either an oximetry test or an arterial blood gas test)*

**Group I criteria include any of the following**

1. Arterial PO2 at or below 55 mm Hg or arterial oxygen saturation at or below 88%, taken at rest, breathing room air
2. Arterial PO2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88%, for at least 5 minutes taken during sleep for a patient who demonstrates an arterial PO2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89% while awake
3. A decrease in arterial PO2 more than 10 mm Hg or a decrease in arterial oxygen saturation more than 5%, for at least 5 minutes taken during sleep with symptoms or signs reasonably attributable to hypoxemia
4. Arterial PO2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88%, taken during exercise for a member who demonstrates a PO2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89% during the day while at rest. In this case, oxygen is provided for during exercise if it is documented that the use of oxygen improves the hypoxemia that was demonstrated during exercise when the beneficiary was breathing room air.

*Note: In cases 1-4 above, initial coverage is limited to 12 months or the physician specified length of need, whichever is shorter.*

**Group II criteria include the following:**

Members with arterial PO2 at 56-59 mm Hg or an arterial blood oxygen saturation of 89% at rest (awake), during sleep for a continuous period of at least 5 minutes, or during exercise (as described under Group I criteria), **AND** any of the following:

1. Dependent edema suggesting congestive heart failure (CHF)
2. Cor Pulmonale (pulmonary hypertension), 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)
3. Erythrocythemia with a hematocrit greater than 56%

*Note: Initial coverage for patient meeting Group II criteria is limited to 3 months or the physician specified length of need, whichever is shorter. (Refer to the Certification section for information on recertification.)*

**Group III includes beneficiaries:**

Patients with arterial PO2 levels at or above 60mm Hg or arterial blood oxygen saturations at or above 90 %. For these patients there is a presumption of non-coverage which must be
refuted.

3. **Overnight Oximetry Studies**

Members may self-administer home based overnight oximetry tests under the direction of a Medicare-enrolled Independent Diagnostic Testing Facility (IDTF). A DME supplier or another shipping entity may deliver a pulse oximetry test unit and related technology, to a member’s home. Home oximetry testing for determining home oxygen use is covered when the following criteria are met:

a. The patient’s treating physician has contracted the independent diagnostic testing facility (IDTF) to order the overnight pulse oximetry test before it is performed.

b. The test is performed under the direction and/or instruction of a Medicare-approved IDTF. Because it is patient who self-administers this test, the IDTF must provide clear written instructions on the proper operation of test equipment and must include access to the IDTF in order to address other concerns that might arise. The DME provider may not provide the instructions, answer questions or participate in the test in any way.

c. Test must be sealed and tamper proof such that the test results cannot be accessed by anyone other than the IDTF who is responsible for transmitting a test report to the treating physician.

*Notes:*

- DME providers may use technology to download the test to the IDTF. In no case may a DME supplier access or manipulate test results in any form.
- IDTF must send the test results to the physician. The IDTF may send the test results to the supplier if the supplier is currently providing or has an order to provide oxygen or other respiratory services to the beneficiary or if the beneficiary has signed a release permitting the supplier to receive the report.
- Oximetry results obtained through a similar process while the patient is awake, either at rest or exercise, cannot be used to qualify a patient for home oxygen.

4. **Flow Liters**

Liter flow greater > 4 LPM for home use is covered when Group I or Group II criteria for oxygen are met and the blood gas study is performed while the patient is on 4 LPM.

5. **Home oxygen usage is not covered for the following:**

a. Angina pectoris in the absence of hypoxemia
b. Breathlessness or 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 hypoxia
d. Terminal illnesses that do not affect the respiratory system

6. **Portable Oxygen System**

Portable Oxygen system may be purchased for chronic use when patient is mobile within the home and the qualified blood gas study was performed while rest (awake) or during exercise. If patient meets the above requirement, the portable oxygen system is usually paid for separately in addition to the stationary system.
Notes:
- If a patient qualifies for additional payment for greater than 4 LPM of oxygen and also meets the requirements for portable oxygen, payment will be made for either the stationary system of oxygen (at higher allowance) or the portable system (at the standard fee schedule allowance for portable system), but not both.
- When a portable system is added to a stationary system or vise versa a need for blood gas study is not required.
- If a portable oxygen system is covered, the supplier must provide whatever quantity of oxygen the beneficiary uses; Medicare’s reimbursement is the same, regardless of the quantity of oxygen dispensed.

7. Emergency or Standby Oxygen
Emergency or stand-by oxygen tanks, concentrators and other oxygen systems for patients who are not regularly using oxygen are not covered and will be denied as not reasonable and necessary since they are precautionary and not therapeutic in nature.

8. Home Oxygen for COPD
The home use of oxygen is covered for those members with arterial oxygen partial pressure measurements from 56 to 65 mmHg or oxygen saturation at or above 89% who are enrolled subjects in clinical trials approved by CMS and sponsored by the National Heart, Lung, and Blood Institute [(NHLBI); CMS, 2006] The additional Group II criteria do not apply to these patients.

See the NCD for Home Use of Oxygen in Approved Clinical Trials (240.2.1). (Accessed January 18, 2017)


For payment rules for NCDs requiring CED, see the Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials.

9. Home Oxygen Use to Treat Cluster Headaches (CH)
Effective for claims with dates of services on or after January 4, 2011, the home use of oxygen to treat CH is covered by Medicare only for beneficiaries with CH participating in an approved prospective clinical study comparing normobaric 100% oxygen (NBOT) with at least one clinically appropriate comparator for the treatment of CH.

See the NCD for Home Oxygen Use to Treat Cluster Headache (CH) (240.2.2) for specific coverage information. (Accessed January 18, 2017)


For payment rules for NCDs requiring CED, see the Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials.

II. DEFINITIONS
III. REFERENCES

See above

IV. REVISION HISTORY

02/14/2017  Annual review with the following updates:

Guideline 1 - Moved the following language: “The following guidelines (Guidelines 1 - 7) are based on the NCD for Home Use of Oxygen (240.2) and the DME MAC LCDs for Oxygen and Oxygen Equipment (L33797). Compliance with these LCDs is required where applicable.” from the end of guideline 1 to before Guideline 1.

Guideline 5 (Home oxygen usage is not covered for the following) – Added “or dyspnea” to guideline 5.b. to reflect language from DME MAC LCD for Oxygen and Oxygen Equipment (L33797)

02/16/2016  Annual review with the following updates:

- Guideline 2.d (Covered Blood Gas Values; Group I Criteria) -Moved the following language from “Notes” section to item #4: “In this case, oxygen is provided for during exercise if it is documented that the use of oxygen improves the hypoxemia that was demonstrated during exercise when the beneficiary was breathing room air.”

- Guideline 2.d (Covered Blood Gas Values; Group II Criteria)
  - Added the following language to item #2: “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 “
  - Removed the following under “Notes” section: “of the physician specified length of need, whichever is shorter.”

- Guideline 5 (Home Oxygen) - Deleted the following language: “Patients with arterial PO2 levels at or above 60mm Hg or arterial blood oxygen saturations at or above 90 %, except if there is substantial documentation by the physician of need”

- Guideline 6 (Portable Oxygen System) - Added the following language under “Notes” section: “If a portable oxygen system is covered, the supplier must provide whatever quantity of oxygen the beneficiary uses; Medicare’s reimbursement is the same, regardless of the quantity of oxygen dispensed.”

04/21/2015  Guideline #8 (Home Oxygen for COPD)

- Changed title from “Medicare Clinical Trial Coverage” to “Home Oxygen for COPD”

- Added reference link to the list of Medicare approved clinical trials.

- Updated payment info; added reference link to the Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials for payment rules for NCDs requiring CED.
Guideline # 9 (Home Oxygen Use to Treat Cluster Headaches)
- Added reference link to the list of Medicare approved clinical trials.
- Updated payment info; added reference link to the Coverage Summary for Experimental Procedures and Items, Investigational Devices and Clinical Trials for payment rules for NCDs requiring CED.

03/24/2015 Annual review with following updates:
- Guideline # 3 (Overnight Oximetry Studies)
  - Updated title from” Home Sleep Overnight Oximetry Studies/Testing” to “Overnight Oximetry Studies”
  - Removed reference to “Test results obtained under these circumstances will be accepted for the purpose of qualifying for home oxygen therapy. See the DME MAC Local Articles for Overnight Oximetry Testing – Policy Clarification (A36044; A47120; A35433)””. These articles are retired.
- Definitions:
  - Oxygen Concentrator- deleted not in body of CS.
  - Oximetry Device – deleted not in body of CS.

10/21/2014 Removed detailed DME Face-to-Face Requirement information and replaced with a reference link to the DME, Prosthetics, Corrective Appliances/Orthotic and Medical Supplies Grid.

02/18/2014 Annual review; no updates

08/20/2013 Added a note pertaining to the DME Face-to-Face Requirement in accordance with Section 6407 of the Affordable Care Act as defined in the 42 CFR 410.38(g)

02/19/2013 Annual review; no updates

02/27/2012 Annual review; updated to include additional benefit coverage clarification to the following:
  - Guidelines #2.d Covered Blood Gas Values;
  - Guidelines #3-Home Sleep Oximetry Studies/Testing; and
  - Guidelines #7-Emergency or Standby Oxygen

06/30/2011 Annual review; no updates

02/21/2011 Updated to include
Guidelines #3 Home Oxygen Use to Treat Cluster Headaches based on the new NCD for Home Oxygen Use to Treat Cluster Headaches (CH) (240.2.2)

12/21/2010 Corrected/updated the link to the NCD for Home Use of Oxygen (240.2); could not open NCD link