



Clinical Review Criteria Related to Home Use of Oxygen

I. Criteria for Approval

- A. Oxygen is considered to be medically necessary for members/beneficiaries with a severe lung disease (for example, chronic bronchitis, emphysema, and interstitial lung disease) that causes hypoxemia and where oxygen therapy can reasonably be expected to correct the patient's hypoxemia.
1. Coverage is provided for members/beneficiaries with significant hypoxemia evidenced by any of the following:
 - a. An arterial PO₂ at or below 55 mmHg, or an arterial oxygen saturation at or below 88 percent, taken at rest, awake. OR
 - b. An arterial PO₂ at or below 55 mmHg, or an arterial oxygen saturation at or below 88 percent, for at least 5 minutes taken during sleep for a beneficiary who demonstrates an arterial PO₂ at or above 56 mmHg or an arterial oxygen saturation at or above 89 percent while awake. OR
 - c. A decrease in arterial PO₂ more than 10 mmHg, 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
 - d. An arterial PO₂ at or below 56 mmHg or an arterial oxygen saturation at or below 88 percent, taken during exercise for a beneficiary who demonstrates an arterial PO₂ at or above 56 mmHg or an arterial oxygen saturation at or above 89 percent 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. OR
 2. Coverage is available for members/beneficiaries whose arterial PO₂ is 56-59 mmHg or whose arterial blood oxygen saturation is 89 percent, (awake), during sleep for at least 5 minutes, or during exercise if there is evidence of:
 - a. Dependent edema suggesting congestive heart failure; OR

- b. 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 AVFL; OR
 - c. Erythrocythemia with a hematocrit greater than 56 percent.
3. Coverage for cluster headaches only when the member is enrolled in a clinical study for the purpose of gaining further evidence that the home use of oxygen for cluster headache will improve health outcomes. Home use of oxygen for cluster headaches will not be covered for any other reason. The member and trial must meet Medicare criteria to participate. Refer - clinical policy MA-UM004POL, Clinical Trial for Medicare Advantage Members. Clinical Trials are covered by Original Medicare and not MHI. Per Proposed Decision Memo - [Proposed Decision Memo for Home Use of Oxygen to Treat Cluster Headache \(CAG-00296R\)](#) - CMS proposes that the evidence does not demonstrate that the home use of oxygen to treat cluster headache improves health outcomes in Medicare beneficiaries with cluster headache (CH). Therefore, we propose that home use of oxygen to treat CH is not reasonable and necessary under §1862(a)(1)(A) of the Social Security Act (the Act). However, we believe the available evidence suggests that the home use of oxygen to treat CH is promising and supports further research under §1862(a)(1)(E) of the Act through the Coverage with Study Participation (CSP) form of Coverage with Evidence Development (CED).
- B. A portable oxygen system is covered if the patient is mobile within the home and the qualifying blood gas study was performed while at rest (awake) or during exercise. If the only qualifying blood gas study was performed during sleep, portable oxygen is not medically necessary.
 - C. Per CMS guidelines: If a portable oxygen system is covered, the supplier must provide whatever quantity of oxygen the patient uses; Medicare's reimbursement is the same, regardless of the quantity of oxygen dispensed.
 - D. Coverage is limited to one stationary system and one portable system at one time.

II. What is Not Covered

- A. Oxygen use is not medically necessary for patients with arterial PO₂ levels at or above 60 mmHg, or arterial blood oxygen saturation at or above 90 percent unless approved for medical necessity on physician review.
- B. Emergency or standby oxygen systems for patients who are not regularly using oxygen are not medically necessary since they are precautionary and not therapeutic in nature.
- C. Breathlessness without cor pulmonale or evidence of hypoxemia.
- D. Peripheral vascular disease resulting in desaturation in one or more extremities without evidence of central hypoxemia.
- E. Angina pectoris in the absence of hypoxemia.

- F. Terminal illnesses that do not affect the lungs.
- G. Topical oxygen delivery systems (E0446).
- H. Topical hyperbaric oxygen chambers (A4575).

References:

NCQA Standard, UM 2, Clinical Criteria for Utilization Management Decisions, Element A

Centers for Medicare & Medicaid Services, NCD for Home use of Oxygen (240.2)

http://www.cms.gov/mcd/viewncd.asp?ncd_id=240.2&ncd_version=1&basket=ncd%3A240%2E2%3A1%3AHome+Use+of+Oxygen

(Last Accessed 10/14/16)

Centers for Medicare & Medicaid Services, LCD for Oxygen and Oxygen Equipment

(L11468) <http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>

(Last Accessed 10/14/16)

Commonwealth of Massachusetts Medical Assistance Program Provider Manual Series, Oxygen and Respiratory Therapy Equipment Manual, Section 427.441: Clinical Requirements: Oxygen Therapy Equipment

<http://www.mass.gov/eohhs/docs/masshealth/regs-provider/regs-oxygen.pdf>

(Last Accessed 10/14/16)

CMS Manual System, pub 100-3 Medicare National Coverage Determinations, Home Oxygen Use to Treat Cluster Headache (CH) (240.22)

<http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx>

(Last Accessed 10/14/16)

CMS.gov Centers for Medicare & Medicaid Services, Proposed Decision Memo for Home Use of Oxygen to Treat Cluster Headache (CAG-

00296R)

<https://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=244&ver=15&NcaName=Home+Use+of+Oxygen+to+Treat+Cluster+Headache&bc=BEAAAAAIAAA&>

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Summary of Changes:

02/09/2017

- Under I., Criteria for Approval, A., 3.: Added proposed decision statement.
- Under Source/Citation section: Added new CMS resource.