Local Coverage Determination (LCD) for Oxygen and Oxygen Equipment (L11446)

Contractor Information

Contractor Name	Contractor Number	Contractor Type
CIGNA Government Services	18003	DME MAC

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LCD Information

Document Information

LCD ID Number
L11446

LCD Title
Oxygen and Oxygen Equipment

Contractor's Determination Number
OXY

AMA CPT/ADA CDT Copyright Statement

Primary Geographic Jurisdiction
Alabama
Arkansas
Colorado
Florida
Georgia
Louisiana
Mississippi
North Carolina
New Mexico
Oklahoma
Puerto Rico
South Carolina
Tennessee
Texas
Virginia
Virgin Islands
West Virginia

Oversight Region
Region IV

DME Region LCD Covers
Jurisdiction C

Original Determination Effective Date
For services performed on or after 10/01/1993

Original Determination Ending Date

Revision Effective Date
For services performed on or after 01/01/2011

Revision Ending Date

CMS National Coverage Policy
CMS Pub. 100-3, Medicare National Coverage Determinations Manual, Chapter 1, Sections 240.2, 240.2.1, 240.2.2

Indications and Limitations of Coverage and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following indications and limitations of coverage and/or medical necessity.

For an item to be covered by Medicare, a written signed and dated order must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed order, the item will be denied as not reasonable and necessary.

Home oxygen therapy is covered only if 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, and
2. The patient's blood gas study meets the criteria stated below, and
3. The qualifying blood gas study was performed by a physician or by a qualified provider or supplier of laboratory services, and
4. The qualifying blood gas study was obtained under the following conditions:
    - If the qualifying blood gas study is performed during an 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
    - If the qualifying blood gas study is not performed during an inpatient hospital stay, the reported test must be performed while the patient is in a chronic stable state – i.e., not during a period of acute illness or an exacerbation of their underlying disease, and
5. Alternative treatment measures have been tried or considered and deemed clinically ineffective.

In this policy, the term blood gas study includes both an oximetry test and an arterial blood gas test.

Group I criteria include any of the following:

1. An arterial PO_2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent taken at rest (awake), or
2. An arterial PO_2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, for at least 5 minutes taken during sleep for a patient who demonstrates an arterial PO_2 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_2more 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_2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent, taken during exercise for a patient who demonstrates an arterial PO_2 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 for during exercise if it is documented that the use of oxygen improves the hypoxemia that was demonstrated during exercise when the patient was breathing room air.

Initial coverage for patients meeting Group I criteria is limited to 12 months or the physician-specified length of need, whichever is shorter. (Refer to the Certification section for information on recertification).

Group II criteria include the presence of (a) an arterial PO_2 of 56-59 mm Hg or an arterial blood oxygen saturation of 89 percent at rest (awake), during sleep for at least 5 minutes, or during exercise (as described under Group I criteria) and (b) any of the following:

1. Dependent edema suggesting congestive heart failure, or
2. 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
3. Erythrocythemia with a hematocrit greater than 56 percent.

Initial coverage for patients 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 patients with arterial PO_2 levels at or above 60 mm Hg or arterial blood oxygen saturations at or above 90 percent. For these patients there is a rebuttable presumption of noncoverage.

If all of the coverage conditions specified above are not met, the oxygen therapy will be denied as not reasonable and necessary. Oxygen therapy will also be denied as not reasonable and necessary if any of the following conditions are present:

1. 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.
2. Dyspnea without cor pulmonale or evidence of hypoxemia.
3. 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_2 will improve the oxygenation of tissues with impaired circulation.
4. Terminal illnesses that do not affect the respiratory system.

Oxygen is covered for patients who are enrolled subjects in clinical trials approved by CMS and sponsored by the National Heart, Lung, and Blood Institute (NHLBI) and who have an arterial PO_2 from 56 to 65 mm Hg or an oxygen saturation at or above 89 percent. The additional Group 2 coverage criteria do not apply to these patients.

Oxygen is covered for the treatment of cluster headaches (ICD-9 339.00, 339.01, 339.02) for patients enrolled in a clinical trial approved by CMS and are in compliance with the requirements at IOM 100-3 240.2.2 for dates of service on or after 01/04/2011. Refer to the CODING GUIDELINES section of the related Policy Article for information on the coding to be used for these claims.

TESTING SPECIFICATIONS:

The qualifying blood gas study must be one that complies with the Fiscal Intermediary, Local Carrier, or A/B Medicare Administrative Contractor (MAC) policy on the standards for conducting the test and is covered under Medicare Part A or Part B. This includes a requirement that the test be performed by a provider who is qualified to bill Medicare for the test – i.e., a Part A provider, a laboratory, an Independent Diagnostic Testing Facility (IDTF), or a physician. A supplier is not considered a qualified provider or a qualified laboratory for purposes of this policy. Blood gas studies performed by a supplier are not acceptable. In addition, the qualifying blood gas study may not be paid for by any supplier. This prohibition does not extend to blood gas studies performed by a hospital certified to do such tests.

For sleep oximetry studies, the oximeter provided to the patient must be tamper-proof and must have the capability to download data that allows documentation of the duration of oxygen desaturation below a specified value.

For all the sleep oximetry criteria described above, the 5 minutes does not have to be continuous. Baseline saturation is defined as the mean saturation level during the duration of the test. For purposes of meeting criterion 3 described in Group I above there must be a minimum of 2 hours test time recorded for sleep oximetry. The result must reach a qualifying test value otherwise the Group III presumption of noncoverage applies.

When oxygen is covered based on an oxygen study obtained during exercise, there must be documentation of three (3) oxygen studies in the patient's medical record – i.e., testing at rest without oxygen, testing during exercise without oxygen, and testing during exercise with oxygen applied (to demonstrate the improvement of the hypoxemia). All 3 tests must be performed within the same testing session. Only the qualifying test value (i.e., testing during exercise without oxygen) is reported on the CMN. The other results do not have to be routinely submitted but must be available on request.

The qualifying blood gas study may be performed while the patient is on oxygen as long as the reported blood gas values meet the Group I or Group II criteria.

When both arterial blood gas (ABG) and oximetry tests have been 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 nonqualifying, but an exercise or sleep oximetry test on the same day is qualifying, the oximetry test result will determine coverage.

Home Sleep Oximetry Studies:

Beneficiaries 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 beneficiary's home under the following circumstances:

1. The beneficiary's treating physician has contacted the IDTF to order an overnight pulse oximetry test before the test is performed.
2. The test is performed under the direction and/or instruction of a Medicare-approved IDTF. Because it is the beneficiary who self-administers this test, the IDTF must provide clear written instructions to the beneficiary on proper operation of the test equipment and must include access to the IDTF in order to address other concerns that may arise. The DME supplier may not create this written instruction, provide verbal instructions, answer questions from the beneficiary, apply or demonstrate the application of the testing equipment to the beneficiary, or otherwise participate in the conduct of the test.
3. 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. The DME supplier may use related technology to download test results from the testing unit and transmit those results to the IDTF. In no cases may the DME supplier access or manipulate the test results in any form.

The 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 test results obtained through a similar process while the beneficiary is awake, either at rest or with exercise, may not be used for purposes of qualifying the beneficiary for home oxygen therapy.

CERTIFICATION:

An Initial, Recertification, or Revised CMN must be obtained and submitted in the situations described below. The Initial Date, Recertification Date, and Revised Date specified below refer to the dates reported in Section A of the CMN.

Initial CMN is Required:

1. With the first claim for home oxygen, (even if the patient was on oxygen prior to Medicare eligibility or oxygen was initially covered by a Medicare HMO).
2. During the first 36 months of the rental period, when there has been a change in the patient's condition that has caused a break in medical necessity of at least 60 days plus whatever days remain in the rental month during which the need for oxygen ended. Refer to the Policy Article NONMEDICAL NECESSITY COVERAGE AND PAYMENT RULES for additional information
3. When the equipment is replaced because the reasonable useful lifetime of prior equipment has been reached.
4. When the equipment is replaced because of irreparable damage, theft, or loss of the originally dispensed equipment.
    a. Irreparable damage refers to a specific accident or to a natural disaster [e.g., fire, flood].
    b. Irreparable damage does not refer to wear and tear over time.

Testing and Visit Requirements:
Initial CMN for situations 1 and 2

- The blood gas study must be the most recent study obtained within 30 days prior to the Initial Date.
    - For situation 1, there is an exception to the 30-day test requirement for patients who were started on oxygen while enrolled in a Medicare HMO and transition to fee-for-service Medicare. For those patients, the blood gas study does not have to be obtained 30 days prior to the Initial Date, but must be the most recent qualifying test obtained while in the HMO.
- The patient must be seen and evaluated by the treating physician within 30 days prior to the date of Initial Certification.

Initial CMN for scenarios 3 and 4 (replacement equipment)

- Repeat blood gas testing is not required. Enter the most recent qualifying value and test date. This test does not have to be within 30 days prior to the Initial Date. It could be the test result reported on the most recent prior CMN.
- There is no requirement for a physician visit that is specifically related to the completion of the CMN for replacement equipment.

Recertification CMN is Required:

5. 12 months after Initial Certification (i.e., with the thirteenth month's claim) for Group I.
6. 3 months after Initial Certification (i.e., with the fourth month's claim) for Group II.

Testing and Visit Requirements:
Recertification following initial certification situations 1 and 2

- For patients initially meeting Group I criteria, the most recent qualifying blood gas study prior to the thirteenth month of therapy must be reported on the Recertification CMN.
- For patients initially meeting Group II criteria, the most recent blood gas study that was performed between the 61st and 90th day following Initial Certification must be reported on the Recertification CMN. If a qualifying test is not obtained between the 61st and 90th day of home oxygen therapy but the patient continues to use oxygen and a test is obtained at a later date, if that test meets Group I or II criteria, coverage would resume beginning with the date of that test.
- For patients initially meeting group I or II criteria, the patient must be seen and re-evaluated by the treating physician within 90 days prior to the date of any Recertification. If the physician visit is not obtained within the 90-day window but the patient continues to use oxygen and the visit is obtained at a later date, coverage would resume beginning with the date of that visit.

Recertification following initial situations 3 and 4 (replacement equipment)

- Repeat testing is not required. Enter the most recent qualifying value and test date. This test does not have to be within 30 days prior to the Initial Date. It could be the test result reported on the most recent prior CMN.
- There is no requirement for a physician visit that is specifically related to the completion of the CMN for replacement equipment.

Revised CMN is Required:

7. When the prescribed maximum flow rate changes from one of the following categories to another:
   a. less than 1 LPM,
   b. 1-4 LPM,
   c. greater than 4 LPM

   If the change is from category (a) or (b) to category (c), a repeat blood gas study with the patient on 4 LPM must be performed
8. When the length of need expires – if the physician specified less than lifetime length of need on the most recent CMN.
9. When a portable oxygen system is added subsequent to Initial Certification of a stationary system.
10. When a stationary system is added subsequent to Initial Certification of a portable system
11. When there is a new treating physician but the oxygen order is the same.
12. If there is a new supplier and that supplier does not have the prior CMN.

Submission of a Revised CMN does not change the Recertification schedule specified above.

If the indications for a Revised CMN are met at the same time that a Recertification CMN is due, file the CMN as a Recertification CMN.

Testing and Visit Requirements:
None of the Revised Certification situations (7-12, above) require a physician visit.

Revised Certification situations 7 and 8

- The blood gas study must be the most recent study obtained within 30 days prior to the Initial Date.

Revised Certification situation 9

- There is no requirement for a repeat blood gas study unless the initial qualifying study was performed during sleep, in which case a repeat blood gas study must be performed while the patient is at rest (awake) or during exercise within 30 days prior to the Revised Date.

Revised Certifications situations 10-12

- No blood gas study is required
- For situations 11 and 12, the revised certification does NOT have to be submitted with the claim

A completed and signed Certificate of Medical Necessity (CMN) is required to receive payment for oxygen. Claims submitted without a valid CMN will be denied as not reasonable and necessary.

PORTABLE OXYGEN SYSTEMS:

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 will be denied as not reasonable and necessary.

If coverage criteria are met, a portable oxygen system is usually separately payable in addition to the stationary system. (See exception in Liter Flow Greater Than 4 LPM.)

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.

LITER FLOW GREATER THAN 4 LPM:

If basic oxygen coverage criteria have been met, a higher allowance for a stationary system for a flow rate of greater than 4 liters per minute (LPM) will be paid only if a blood gas study performed while the patient is on 4 LPM meets Group I or II criteria. If a flow rate greater than 4 LPM is billed and the coverage criterion for the higher allowance is not met, payment will be limited to the standard fee schedule allowance. (Refer to related Policy Article for additional information on payment for greater than 4 LPM oxygen.)

MISCELLANEOUS:

Emergency or stand-by oxygen systems for patients who are not regularly using oxygen will be denied as not reasonable and necessary since they are precautionary and not therapeutic in nature.

Topical hyperbaric oxygen chambers (A4575) will be denied as not reasonable and necessary. (IOM 100-3 20.29(B) & (C))

Topical oxygen delivery systems (E0446) will be denied as not reasonable and necessary. (IOM 100-3 20.29(C))

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Coding Information

Bill Type Codes:
Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

Revenue Codes:
Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

CPT/HCPCS Codes
The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS:

EY – No physician or other licensed health care provider order for this item or service
RA – Replacement of a DME item
QE - Prescribed amount of oxygen is less than 1 liter per minute (LPM)
QF - Prescribed amount of oxygen is greater than 4 liter per minute (LPM) and portable oxygen is also prescribed
QG - Prescribed amount of oxygen is greater than 4 liters per minute (LPM) and portable oxygen is not prescribed
QH - Oxygen conserving device is being used with an oxygen delivery system

HCPCS CODES:

EQUIPMENT:

E0424	STATIONARY COMPRESSED GASEOUS OXYGEN SYSTEM, RENTAL; INCLUDES CONTAINER, CONTENTS, REGULATOR, FLOWMETER, HUMIDIFIER, NEBULIZER, CANNULA OR MASK, AND TUBING
E0425	STATIONARY COMPRESSED GAS SYSTEM, PURCHASE; INCLUDES REGULATOR, FLOWMETER, HUMIDIFIER, NEBULIZER, CANNULA OR MASK, AND TUBING
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
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	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 MASK, TUBING AND REFILL ADAPTOR
E0439	STATIONARY LIQUID OXYGEN SYSTEM, RENTAL; INCLUDES CONTAINER, CONTENTS, REGULATOR, FLOWMETER, HUMIDIFIER, NEBULIZER, CANNULA OR MASK, & 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

E0443	PORTABLE OXYGEN CONTENTS, GASEOUS, 1 MONTH'S SUPPLY = 1 UNIT
E0444	PORTABLE OXYGEN CONTENTS, LIQUID, 1 MONTH'S SUPPLY = 1 UNIT
E0445	OXIMETER DEVICE FOR MEASURING BLOOD OXYGEN LEVELS NON-INVASIVELY
E0446	TOPICAL OXYGEN DELIVERY SYSTEM, NOT OTHERWISE SPECIFIED, INCLUDES ALL SUPPLIES AND ACCESSORIES
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, EACH
E1392	PORTABLE OXYGEN CONCENTRATOR, RENTAL
E1405	OXYGEN AND WATER VAPOR ENRICHING SYSTEM WITH HEATED DELIVERY
E1406	OXYGEN AND WATER VAPOR ENRICHING SYSTEM WITHOUT HEATED DELIVERY
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

ACCESSORIES:

A4575	TOPICAL HYPERBARIC OXYGEN CHAMBER, DISPOSABLE
A4606	OXYGEN PROBE FOR USE WITH OXIMETER DEVICE, REPLACEMENT
A4608	TRANSTRACHEAL OXYGEN CATHETER, EACH
A4615	CANNULA, NASAL
A4616	TUBING (OXYGEN), PER FOOT
A4617	MOUTH PIECE
A4619	FACE TENT
A4620	VARIABLE CONCENTRATION MASK
A7525	TRACHEOSTOMY MASK, EACH
A9900	MISCELLANEOUS DME SUPPLY, ACCESSORY, AND/OR SERVICE COMPONENT OF ANOTHER HCPCS CODE
E0455	OXYGEN TENT, EXCLUDING CROUP OR PEDIATRIC TENTS
E0555	HUMIDIFIER, DURABLE, GLASS OR AUTOCLAVABLE PLASTIC BOTTLE TYPE, FOR USE WITH REGULATOR OR FLOWMETER
E0580	NEBULIZER, 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 ADAPTER FOR PORTABLE CONCENTRATOR, ANY TYPE, REPLACEMENT ONLY, EACH

ICD-9 Codes that Support Medical Necessity
Not specified
AsteriskNoteText

Diagnoses that Support Medical Necessity
Not specified.
ICD-9 Codes that DO NOT Support Medical Necessity
Not specified.

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity
Not specified
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General Information

Documentations Requirements
Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider". It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Items billed before a signed and dated order has been received by the supplier must be submitted with an EY modifier added to each affected HCPCS code.

A Certificate of Medical Necessity (CMN) which has been completed, signed, and dated by the treating physician must be kept on file by the supplier and made available upon request. The CMN may act as a substitute for a written order if it is sufficiently detailed. The CMN for home oxygen is CMS Form 484(DME form 484.03). In addition to the order information that the physician enters in Section B, the supplier can use the space in Section C for a written confirmation of other details of the oxygen order or the physician can enter the other details directly–e.g., the means of oxygen delivery (cannula, mask, etc.) and the specifics of varying oxygen flow rates and/or noncontinuous use of oxygen.

For patients who qualify for oxygen coverage based only on a sleep oximetry study, the oxygen saturation value reported in question 1b of the Oxygen CMN must be the lowest value (not related to artifact) during the 5 minute qualifying period reported on the sleep oximetry study. A report of the sleep study documenting the qualifying desaturation must be available upon request.

If both an arterial blood gas and oximetry test have been performed on the same day under the condition reported on the CMN (i.e., at rest/awake, during exercise, or during sleep), the ABG PO_2 must be reported on the CMN.

REPLACEMENT EQUIPMENT:

For situations 3 and 4 described in the CERTIFICATION section of the "Indications and Limitations of Coverage", the following special instructions apply:

- Initial Date should be the date that the replacement equipment is initially needed. This is generally understood to be the date of delivery of the oxygen equipment.
- The Recertification Date should be 12 months following the Initial Date when the value on the Initial CMN (for the replacement equipment) meets Group I criteria or 3 months following the Initial Date when the qualifying blood gas value on the Initial CMN meets the Group II criteria. (**Note:** The Initial Date [for the replacement equipment] should also be entered on the Recertification CMN.)
- Claims for the initial rental month (and only the initial rental month) must have the RA modifier (Replacement of DME item) added to the HCPCS code for the equipment when there is replacement due to reasonable useful lifetime or replacement due to damage, theft, or loss.
- Claims for the initial rental month must include a narrative explanation of the reason why the equipment was replaced and supporting documentation must be maintained in the supplier's files.

MISCELLANEOUS:

In the following situations, a new order must be obtained and kept on file by the supplier, but neither a new CMN nor a repeat blood gas study are required:

- Prescribed maximum flow rate changes but remains within one of the following categories: (a) less than 1 LPM, (b) 1-4 LPM, (c) greater than 4 LPM.
- Change from one type of stationary system to another (i.e., concentrator, liquid, gaseous).
- Change from one type of portable system to another (i.e., gaseous or liquid tanks, portable concentrator, transfilling system).

A new CMN is not required just because a patient changes from Medicare secondary to Medicare primary.

A new CMN is not required just because the supplier changes assignment status on the submitted claim.

Suppliers are reminded that in an audit they may be asked to provide a copy of the actual test report and/or information from the medical record to verify that coverage criteria have been met.

Refer to the Supplier Manual for more information on documentation requirements.

Appendices The term blood gas study in this policy refers to either an arterial blood gas (ABG) test or an oximetry test. An ABG is the direct measurement of the partial pressure of oxygen (PO_2) on a sample of arterial blood. The PO_2 is reported as mm Hg. An oximetry test is the indirect measurement of arterial oxygen saturation using a sensor on the ear or finger. The saturation is reported as a percent.

Utilization Guidelines Refer to Indications and Limitations of Coverage and/or Medical Necessity.

Sources of Information and Basis for Decision
CR7235 for cluster headache trial **Advisory Committee Meeting Notes**

Start Date of Comment Period 07/20/2001

End Date of Comment Period 09/14/2001

Start Date of Notice Period 09/01/2003

Revision History Number 010

Revision History Explanation Revision Effective Date: 01/01/2011
INDICATIONS AND LIMITATIONS OF COVERAGE:
Added: Noncoverage statement for E0446
Added: Clinical trial coverage for cluster headaches (CR7235)
Revised: Clarified sleep testing qualification using results that drop from baseline.
HCPCS CODES AND MODIFIERS:
Added:E0446

Revision Effective Date: 01/01/2010
HCPCS CODES AND MODIFIERS:
Added: E0433
Revised: E0441-E0444

11/15/2009 - The description for CPT/HCPCS code E0441 was changed in group 1
The description for CPT/HCPCS code E0442 was changed in group 1
The description for CPT/HCPCS code E0443 was changed in group 1
The description for CPT/HCPCS code E0444 was changed in group 1

Revision Effective Date: 01/01/2009(June Revision)
INDICATIONS AND LIMITATIONS OF COVERAGE:
Clarified: Conditions for blood gas studies
Clarified: Testing requirements when exercise test results are use to qualify

Revised: Certification section to address new payment policy.
Moved: Information on payment of greater than 4 LPM oxygen to the Policy Article, Non-Medical Necessity Coverage and Payment Rules section
HCPCS CODES AND MODIFIERS:
Added: RA modifier
DOCUMENTATION REQUIREMENTS:
Moved: CMN instructions to Indications and Limitations of Coverage section.
Added: Instructions for replacement equipment.

Revision Effective Date: 01/01/2009
HCPCS CODES AND MODIFIERS:
Added HCPCS Codes E1354, E1356, E1357, and E1358

03/01/2008 - In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC CIGNA Government Services (18003) LCD L11517 from DME PSC TrustSolutions (77012) LCD L11517.

Revision Effective Date: 01/01/2008
CMS NATIONAL COVERAGE POLICY:
Added: NCD 240.2.1
HCPCS CODES AND MODIFIERS:
Deleted: QR modifier
DOCUMENTATION REQUIREMENTS:
Deleted: Instructions for use of QR modifier

06/01/2007 - In accordance with Section 911 of the Medicare Modernization Act of 2003, Virginia and West Virginia were transitioned from DME PSC TriCenturion (77011) to DME PSC TrustSolutions (77012).

Revision Effective Date: 01/01/2007
INDICATIONS AND LIMITATIONS OF COVERAGE:
Added: Statement about coverage of oxygen used in approved clinical trials. Added: Requirements for supplier involvement with home oximetry studies. HCPCS CODES AND MODIFIERS:
Added: QR modifier
DOCUMENTATION REQUIREMENTS:
Noted the form number of the new CMN.
Added: Use of QR modifier for patients in an approved clinical trial.
Added: Clarification about the need for a CMN or order when switching to K0738.
LCD ATTACHMENTS:
Attached the new CMN.

03/01/2006 - In accordance with Section 911 of the Medicare Modernization Act of 2003, this policy was transitioned to DME PSC TrustSolutions (77012) from DMERC Palmetto GBA (00885).

Revision Effective Date: 01/01/2006
HCPCS CODES:
Added: E1392
Deleted: K0671

Revision Effective Date: 07/01/2005
LMRP converted to LCD and Policy Article
HCPCS CODES:
Added: E1405, E1406, K0671
INDICATIONS AND LIMITATIONS OF COVERAGE:
Clarified what oxygen studies are required when coverage is based on testing during exercise.

Revision Effective Date: 04/01/2004
HCPCS CODES:
Added: A4608, A7525, E1391
Discontinued: A4621
INDICATIONS AND LIMITATIONS OF COVERAGE:

Substitutes A7525 for A4621, corrects code for transtracheal oxygen catheters (A4608), and adds E1355 in Oxygen Accessories section.
Adds E1391 in the Miscellaneous section.
NONCOVERED DIAGNOSES:
Added: E1391NU and E1391UE
CODING GUIDELINES:
Adds billing instructions for E1391.

Revision Effective Date: 01/01/2004
INDICATIONS AND LIMITATIONS OF COVERAGE:
Revises Group I and Group II coverage criteria for sleep oximetry testing to require at least 5 minutes of desaturation. Revises statements concerning who can perform qualifying blood gas tests.
Adds specifications for oximeters used in sleep oximetry studies. Adds statements of retesting requirements for patients who are on oxygen when they transfer from a Medicare HMO to Medicare fee-for-service.

Revises statement concerning which blood gas study will be used to determine coverage if an ABG and oximetry study are performed on the same day. Adds statement concerning coverage of oxygen if the patient is not re-evaluated by the physician within 90 days prior to recertification.
Adds statement regarding supplier's responsibility when providing portable oxygen contents.
Adds statement concerning the noncoverage of topical hyperbaric oxygen chambers.
HCPCS CODES:
Adds A4575
DOCUMENTATION REQUIREMENTS:
Adds a statement specifying the value that must be entered on the CMN if the qualifying test is a sleep oximetry study.
Adds a statement concerning what test result to report when an ABG and oximetry study are performed on the same day.
Adds several additional scenarios concerning the requirement for an Initial, Recertification, or Revised CMN.
SOURCES OF INFOMATION:
Adds a list of articles related to the revised sleep oximetry criteria.

Revision Effective Date: 04/01/2003
HCPCS CODES AND MODIFIERS:
Added: A4606, E0445, EY
INDICATIONS AND LIMITATIONS OF COVERAGE:
Adds standard language concerning coverage of items without an order.
Adds noncoverage statement concerning E0445 and A4606.
CODING GUIDELINES:
Removes statements concerning E1405 and E1406. This policy change had been previously published.
Removes mention of codes ZZ010 and E1377-E1385 which have been discontinued.
DOCUMENTATION REQUIREMENTS:
Adds standard language concerning use of EY modifier for items without an order.
Revises standard language concerning use of a CMN.
OTHER COMMENTS:
Moves Definitions section to this section.
The revision dates listed below are the dates the revisions were published and not necessarily the effective dates for the revisions.

07/01/2000 - This revision incorporates changes previously published in the DMERC Dialogue. Suppliers should be aware that this is the first revision of the Oxygen policy since 1993 and numerous changes will be found in all sections of the policy. The Documentation Section has been reorganized for easier determination of when initial, revised, and recertification Certificates of Medical Necessity (CMNs) are needed.

Effective for claims with dates of service on or after July 1, 2000, codes E1405 and E1406 (oxygen and water vapor enriching system) are invalid for claim submission to the DMERC. The DMERCs have determined that the devices for which these codes were established are no longer in production. Oxygen concentrators which are capable of delivering 85% or greater oxygen concentration at the prescribed flow rate and are used with a humidifier are correctly billed using code E1390. (There is no separate billing or payment for a humidifier used in conjunction with rented oxygen equipment.) If a manufacturer or supplier has an oxygen concentrator that they thought should be coded as E1405 or E1406, they should contact the SADMERC for a coding determination.
Code ZZ010 (transtracheal oxygen catheter for patient-owned equipment) is invalid for claim submission to the DMERC. As noted in the policy, accessories are separately payable only when they are used with a patient-owned system that was purchased prior to June 1, 1989. Accessories used with a patient-owned system that was purchased on or after June 1, 1989 are noncovered.

12/01/1993 – Corrected HAO to HA0 in the Documentation section.

Reason for Change HCPCS Addition/Deletion

Last Reviewed On Date

Related Documents
Article(s)
A33750 - Oxygen and Oxygen Equipment - Policy Article - Effective January 2011

LCD Attachments
Oxygen CMN (PDF - 43,295 bytes)

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