

Local Coverage Determination (LCD) for Oxygen and Oxygen Equipment (L11457)

Contractor Information

Contractor Name

Noridian Administrative Services

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19003

Contractor Type

DME MAC

LCD Information

Document Information

LCD ID Number

L11457

LCD Title

Oxygen and Oxygen Equipment

Contractor's Determination Number

OXY

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Montana

North Dakota

Nebraska

Nevada

Oregon

South Dakota

Utah

Washington

Wyoming

Northern Mariana Islands

Oversight Region

Region X

DME Region LCD Covers

Jurisdiction D

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 10/01/2011

Revision Ending Date

CMS National Coverage Policy

CMS Manual System, 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 detailed written 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 is covered only when both the reasonable and necessary criteria discussed below and the statutory criteria discussed in the Policy Article are met. Refer to the Policy Article for additional information on statutory payment policy requirements.

Home oxygen therapy is reasonable and necessary 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 refers to either an oximetry test or an arterial blood gas test.

Group I criteria include any of the following:

1. An arterial PO₂ at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent taken at rest (awake), or
2. An arterial PO₂ 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 PO₂ at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent while awake, or
3. A decrease in arterial PO₂ 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 PO₂ 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 PO₂ 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 PO₂ 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 PO₂ 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.
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 PO₂ 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 PO₂ 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.

CLUSTER HEADACHES

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 HCPCS codes 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. These prohibitions do 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. 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 3 tests must be performed within the same testing session. Only the testing during exercise without oxygen is used for qualification and reported on the CMN. The other two 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 done at rest and awake is nonqualifying, but either an exercise or sleep oximetry test on the same day is qualifying, the exercise or sleep 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 which 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 case 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.

Polysomnography and Home Sleep Tests

Coverage of home oxygen therapy requires that the patient be tested in the "chronic stable state." Chronic stable state is a requirement of the National Coverage Determination (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." Based on this NCD definition, all co-existing diseases or conditions that can cause hypoxia must be treated and the patient be in a chronic stable state before oxygen therapy is considered eligible for payment. In the case of OSA, it is required that the OSA be appropriately and sufficiently treated such that the patient is in the chronic stable state before oxygen saturation results obtained during sleep testing are considered qualifying for 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) 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 the related Policy Article **Nonmedical Necessity Coverage and Payment Rules, OXYGEN EQUIPMENT**, Initial 36-Months section.

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))

REFILLS OF OXYGEN CONTENTS

For DMEPOS items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. For DMEPOS products that are supplied as refills to the original order, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary, existing supplies are approaching exhaustion, and to confirm any changes/modifications to the order. Contact with the beneficiary or designee regarding refills must take place no sooner than 14 calendar days prior to the delivery/shipping date. For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized. (CMS' Program Integrity Manual, Internet-Only Manual, CMS Pub. 100-8, Chapter 5, Section 5.2.6).

For all DMEPOS items that are provided on a recurring basis, suppliers are required to have contact with the beneficiary or caregiver/designee prior to dispensing a new supply of items. Suppliers must not deliver refills without a refill request from a beneficiary. Items delivered without a valid, documented refill request will be denied as not reasonable and necessary.

Suppliers must not dispense a quantity of supplies exceeding a beneficiary's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the ordering physicians that any changed or atypical utilization is warranted. Refer to the Policy Article for additional information about the billing of contents.

See the **Nonmedical Necessity Coverage and Payment Rules** section of the related Policy Article for additional information about coverage of oxygen contents.

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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

GroupName

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

Q0 (Q-zero) - Investigational clinical service provided in a clinical research study that is in an approved clinical research study

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

RA – Replacement of a DME item

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

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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.

GENERAL DOCUMENTATION REQUIREMENTS

Prescription (order) Requirements (PIM 5.1)

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 dispensed and/or billed that do not meet these prescription requirements and those below must be submitted with an EY modifier added to each affected HCPCS code.

Dispensing Orders (PIM 5.2.2)

Equipment and supplies may be delivered upon receipt of a dispensing order. A dispensing order may be verbal or written. It must contain:

- Description of the item
- Beneficiary name
- Physician name
- Start date of the order (if different than the order date)

The supplier must keep a record of the dispensing order on file which must be available upon request.

For items that are dispensed based on a dispensing order, the supplier must obtain a detailed written order (DWO) before submitting the claim.

Detailed Written Orders (PIM 5.2.3)

A DWO is required before billing. Someone other than the ordering physician may produce the DWO, but the ordering physician must review the content and sign and date the document.

A prescription is not considered as part of the medical record. Medical information intended to demonstrate compliance with coverage criteria may be included on the prescription but must be corroborated by information contained in the medical record.

Medical Record Information (PIM 5.7 -5.9)

The *Indications and Limitations of Coverage and/or Medical Necessity* section of this LCD and the *Nonmedical Necessity Coverage and Payment Rules* section of the Policy Article contain numerous reasonable and necessary (R&N) and statutory requirements that must be met in order for payment to be justified. Suppliers are reminded that:

- Supplier produced records, even if signed by the ordering physician, and attestation letters (e.g. letters of medical necessity) are deemed to not be part of a medical record for Medicare payment purposes.

- Templates and forms, including CMS Certificates of Medical Necessity are subject to corroboration with information in the medical record.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS (NCD 240.2)

Initial claims for oxygen must be supported by medical information that specifies:

- A diagnosis of the disease requiring home use of oxygen,
- The oxygen flow rate,
- An estimate of the frequency or duration of use, and
- Duration of need.

"Oxygen PRN" or "Oxygen as needed" does not meet the frequency/duration of use requirement. Neither provides any basis for determining if the amount of oxygen is reasonable and necessary for the patient.

If no frequency or duration of use is specified "continuous use" is assumed. Duration of need may be specified on the CMN in the "Length of Need" field.

Documentation for initial coverage requires:

- Evidence of qualifying test results done within 30 days before the initial date of service
- Evidence of an in-person visit with a treating physician done within 30 days before the initial date of service

Information contained directly in the medical record is the source required to justify payment except as noted elsewhere for prescriptions and CMNs. The medical record is not limited to physician's office records but may include records from hospitals, nursing facilities, home health agencies, other healthcare professionals, etc. (not all-inclusive) (PIM 5.8).

CONTINUED USE

Continued use describes the ongoing utilization of an item or service by a beneficiary.

Suppliers are responsible for monitoring utilization of DMEPOS items and must discontinue billing Medicare when an item is no longer being used by the beneficiary. Ongoing use must be periodically documented. Either beneficiary medical records or supplier records are sufficient to confirm that a DMEPOS item continues to be used by the beneficiary.

CONTINUED MEDICAL NEED

For all DMEPOS items, the initial medical need or justification is established at the time the item(s) is first ordered; therefore, beneficiary medical records demonstrating that the item is reasonable and necessary are formed prior to the creation of the initial order. For a purchased item, the initial months of a rental item or for ongoing supplies or drugs, information justifying reimbursement will come from this initial time period. Information from the beneficiary's medical record must have been created prior to the initial DOS to establish whether reimbursement was justified based upon the applicable coverage policy.

For DMEPOS items for which there is on-going use, in addition to information described above that justifies the initial provision of the item(s) and/or supplies, there must be information in the beneficiary's medical record to support that the item continues to remain reasonable and necessary. Information used to justify this continued need must be timely for the DOS under review.

REFILL DOCUMENTATION

A routine refill prescription is not needed. A new prescription is needed when:

- There is a change of supplier
- There is a change in treating physician

- There is a change in the item(s), frequency of use, or amount prescribed
- There is a change in the length of need or a previously established length of need expires
- State law requires a renewal.

For items that the patient obtains in person at a retail store, the signed delivery slip or copy of itemized sales receipt is sufficient documentation of a request for refill.

For items that are delivered to the beneficiary, documentation of a request for refill must be either a written document received from the beneficiary or a contemporaneous written record of a phone conversation/contact between the supplier and beneficiary. The refill request must occur and be documented before shipment. A retrospective attestation statement by the supplier or beneficiary is not sufficient. The refill record must include:

- Beneficiary's name or authorized representative if different than the beneficiary
- A description of each item that is being requested
- Date of refill request
- Quantity of each item that the beneficiary still has remaining

This information must be kept on file and be available upon request.

CERTIFICATE OF MEDICAL NECESSITY

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 the detailed written order if it contains the same information as required in a detailed written order. 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 PO₂ 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.

CLUSTER HEADACHES

A CMN is not required for claims for cluster headaches.

Claims for oxygen used for the treatment of cluster headaches that meet the approved clinical trial and diagnosis requirements described in the **Indications and Limitations of Coverage and/or Medical Necessity** section of this policy must be submitted with the Q0 (Q-zero) modifier. Claims for oxygen used for cluster headaches that do not meet these criteria must not use this modifier.

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 (PO₂) on a sample of arterial blood. The PO₂ 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 OXY008

Revision History Explanation Revision Effective Date: 10/01/2011

INDICATIONS AND LIMITATIONS OF COVERAGE:

Added: PSG and HST testing guidance

Added: CR7452 refill requirements (effective 08/02/2011)

HCPCS CODES AND MODIFIERS:

Added: Q0 modifier

DOCUMENTATION REQUIREMENTS:

Revised: Prescription requirements

Clarified: Documentation requirements from NCD 240.2 and PIM Ch. 5

Added: CR7452 refill requirements effective (08/02/2011)

Added: Cluster Headache section

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

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

INDICATIONS AND LIMITATIONS OF COVERAGE:

Corrected: Requirements for supplier involvement with home oximetry studies. An incorrect statement was added with the 01/01/2007 revision.

Removed: Statement addressing respiratory therapist services to be consistent with other jurisdictions. Statement remains in the policy article.

HCPCS CODES AND MODIFIERS:

Added: E1354, E1356, E1357, and E1358

3/1/2008 - In accordance with Section 911 of the Medicare Modernization Act, this policy was transitioned to DME MAC Noridian Administrative Services (19003) LCD L11457 from DME PSC Electronic Data Systems Corp. (77006) LCD L11457.

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

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, K0738

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 Electronic Data Systems Corp. (77006) from DMERC CIGNA Government Services (05655).

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:

Substituted A7525 for A4621, corrected code for transtracheal oxygen catheters (A4608), and added E1355 in Oxygen Accessories section.

Added E1391 in the Miscellaneous section.

NONCOVERED DIAGNOSES:

Added E1391NU and E1391UE

CODING GUIDELINES:

Added billing instructions for E1391

Revision Effective Date: 01/01/2004

INDICATIONS AND LIMITATIONS OF COVERAGE:

Revised Group I and Group II coverage criteria for sleep oximetry testing to require at least 5 minutes of desaturation.

Revised statements concerning who can perform qualifying blood gas tests.

Added specifications for oximeters used in sleep oximetry studies.

Added statements of retesting requirements for patients who are on oxygen when they transfer from a Medicare HMO to Medicare fee-for-service.

Revised statement concerning which blood gas study will be used to determine coverage if an ABG and oximetry study are performed on the same day.

Added statement concerning coverage of oxygen if the patient is not re-evaluated by the physician within 90 days prior to recertification.

Added statement regarding supplier's responsibility when providing portable oxygen contents.

Added statement concerning the noncoverage of topical hyperbaric oxygen chambers.

HCPCS CODES:

Added: A4575

DOCUMENTATION REQUIREMENTS:

Added a statement specifying the value that must be entered on the CMN if the qualifying test is a sleep oximetry study.

Added a statement concerning what test result to report when an ABG and oximetry study are performed on the same day.

Added several additional scenarios concerning the requirement for an Initial, Recertification, or Revised CMN.

SOURCES OF INFORMATION:

Added 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:

Added standard language concerning coverage of items without an order.

Added noncoverage statement concerning E0445 and A4606.

CODING GUIDELINES:

Removed statements concerning E1405 and E1406. (This policy change had been previously published).
Removed mention of codes ZZ010 and E1377-E1385 which have been discontinued.

DOCUMENTATION REQUIREMENTS:

Added standard language concerning use of EY modifier for items without an order.
Revised standard language concerning use of a CMN.

OTHER COMMENTS:

Moved 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

Related Documents

Article(s)

[A33677 - Oxygen and Oxygen Equipment - Policy Article - Effective October 2011](#)

LCD Attachments

There are no attachments for this LCD.

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All Versions

Updated on 08/21/2011 with effective dates 10/01/2011 - N/A

Updated on 02/27/2011 with effective dates 01/01/2011 - 09/30/2011

Updated on 02/21/2010 with effective dates 01/01/2010 - 12/31/2010

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Updated on 06/14/2009 with effective dates 01/01/2009 - N/A

Updated on 06/14/2009 with effective dates 01/01/2009 - N/A

Updated on 11/30/2008 with effective dates 01/01/2009 - N/A

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