

Local Coverage Determination (LCD): OXYGEN and OXYGEN Equipment (L33797)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi North Carolina New Mexico Oklahoma Puerto Rico South Carolina Tennessee Texas Virginia Virgin Islands West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut District of Columbia Delaware Massachusetts Maryland Maine New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Iowa Idaho Kansas Missouri - Entire State Montana North Dakota Nebraska Nevada Oregon South Dakota Utah Washington Wyoming Northern Mariana Islands

LCD Information

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LCD Title

OXYGEN and OXYGEN Equipment

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Notice Period End Date

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Statement

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CMS National Coverage Policy

CMS Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 240.2, 240.2.1,240.2.2

Coverage Guidance

Coverage Indications, Limitations, 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.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding "reasonable and

“reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the “reasonable and necessary” criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the “reasonable and necessary” criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

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 beneficiary has a severe lung disease or hypoxia-related symptoms that might be expected to improve with oxygen therapy, and
2. The beneficiary'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 beneficiary 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 beneficiary 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 beneficiary 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 beneficiary was breathing room air.

Initial coverage for beneficiaries 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 beneficiaries meeting Group II criteria is limited to 3 months or the physician specified length of need, whichever is shorter. (Refer to the Certification section for information on recertification.) Group III includes beneficiaries with arterial PO₂ levels at or above 60 mm Hg or arterial blood oxygen saturations at or above 90 percent. For these beneficiaries there is a rebuttable presumption of non-coverage.

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 PO₂ will improve the oxygenation of tissues with impaired circulation.
4. Terminal illnesses that do not affect the respiratory system

LONG TERM OXYGEN THERAPY CLINICAL (LTOT) TRIALS

Oxygen and oxygen equipment is covered for beneficiaries 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 beneficiaries.

Refer to the APPENDICES section of this policy for additional information about approved clinical trials.

CLUSTER HEADACHES (CH):

Only a stationary gaseous oxygen system (E0424) and related contents (E0441) are covered for the treatment of cluster headaches for beneficiaries enrolled in a clinical trial approved by CMS which are in compliance with the requirements described in the CMS National Coverage Determination Manual (Internet Only Manual 100-03) §240.2.2 for dates of service on or after 01/04/2011. This section states, in part:

Only those beneficiaries diagnosed with the condition of cluster headache are eligible for participation in a clinical study. CMS adopts the diagnostic criteria used by the International Headache Society to form a definitive diagnosis of CH. Therefore, the home use of oxygen to treat CH is covered by Medicare only when furnished to Medicare beneficiaries who have had at least five severe to very severe unilateral headache attacks lasting 15-180 minutes when untreated. (Intensity of pain: Degree of pain usually expressed in terms of its functional consequence and scored on a verbal 5-point scale: 0=no pain; 1=mild pain, does not interfere with usual activities; 2=moderate pain, inhibits but does not wholly prevent usual activities; 3=severe pain, prevents all activities; 4=very severe pain. It may also be expressed on a visual analogue scale.)

The headaches must be accompanied by at least one of the following findings:

1. Ipsilateral conjunctival injection and/or lacrimation; or
2. Ipsilateral nasal congestion and/or rhinorrhea; or
3. Ipsilateral eyelid edema; or
4. Ipsilateral forehead and facial sweating; or
5. Ipsilateral miosis and/or ptosis; or
6. A sense of restlessness or agitation

Claims for oxygen equipment not meeting the criteria above will be denied as not reasonable and necessary.

Claims for stationary oxygen equipment other than E0424 and all portable oxygen equipment used for cluster headaches will be denied as not reasonable and necessary.

Claims for E0424 and E0441 used to treat cluster headaches follow the same payment rules for all other covered oxygen equipment. Refer to the related Policy Article for information on statutory payment rules and coding guidelines to be used for these claims.

Refer to the APPENDICES section of this policy for additional information about approved clinical trials.

Refer to the "**ICD-10 Codes that are Covered**" section in the LCD-related Policy Article for applicable diagnoses.

TESTING SPECIFICATIONS:

General

For purposes of this policy:

- "Blood gas study" shall refer to both arterial blood gas (ABG) studies and pulse oximetry
- "Oximetry" shall refer to routine or "spot" pulse oximetry
- "Overnight oximetry" shall refer to stand-alone pulse oximetry continuously recorded overnight. It does not include oximetry results done as part of other overnight testing such as polysomnography or home sleep testing.

Refer to the Positive Airway Pressure Devises used for the Treatment of Obstructive Sleep Apnea policy for information on sleep tests used for the diagnosis of sleep apnea.

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.

The qualifying blood gas study may be performed while the beneficiary 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 non-qualifying, but either an exercise or sleep oximetry test on the same day is qualifying, the exercise or oximetry test result will determine coverage.

All oxygen qualification testing must be performed in-person by a physician or other medical professional qualified to conduct oximetry testing. With the exception of overnight oximetry (see below), unsupervised or remotely supervised home testing does not qualify as a valid test for purposes of Medicare reimbursement of home oxygen and oxygen equipment.

Exercise testing:

When oxygen is covered based on an oximetry study obtained during exercise, there must be documentation of three (3) oximetry studies in the beneficiary's medical record. (1) Testing at rest without oxygen, (2) testing during exercise without oxygen, and (3) 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. Exercise testing must be performed in-person by a physician or other medical professional qualified to conduct exercise oximetry testing. Unsupervised or remotely supervised home exercise testing does not qualify as a valid test for purposes of Medicare reimbursement of home oxygen and oxygen equipment. 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.

Oximetry obtained after exercise while resting, sometimes referred to as "recovery" testing, is not part of the three required test elements and is not valid for determining eligibility for oxygen coverage.

Overnight Oximetry Studies:

Overnight sleep oximetry may be performed in a facility or at home. For home overnight oximetry studies, the oximeter provided to the beneficiary 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 overnight 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 non-coverage applies.

Home overnight oximetry is limited solely to stand-alone overnight pulse oximetry performed in the beneficiary's home under the conditions specified below. Overnight oximetry performed as part of home sleep testing or as part of any other home testing is not considered to be eligible under this provision to be used for qualification for reimbursement of home oxygen and oxygen equipment even if the testing was performed in compliance with the requirements of this section.

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 as described for home overnight oximetry (see above) 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.

Overnight oximetry does not include oximetry obtained during polysomnography or other sleep testing for sleep apnea, regardless of the location the testing was performed. See below for information on sleep testing that may be used to qualify for oxygen coverage.

Obstructive Sleep Apnea (OSA), Polysomnography and Home Sleep Tests:

Some beneficiaries may require the simultaneous use of home oxygen therapy with a PAP device. To be considered for simultaneous coverage, all requirements in the Coverage Indications, Limitations and/or Medical Necessity for both the Oxygen and Oxygen Equipment and Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea LCDs must be met. Consequently, in addition to this Oxygen LCD, suppliers should refer to the Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea LCD and related Policy Article for additional coverage, coding and documentation requirements.

Coverage of home oxygen therapy requires that the beneficiary be tested in the "chronic stable state", and not during a period of acute illness or an exacerbation of their underlying disease. Thus, all co-existing diseases or

conditions that can cause hypoxia must be treated and the beneficiary must be in a chronic stable state before oxygen therapy is considered eligible for payment. In addition, the beneficiary must have a severe lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, widespread pulmonary neoplasm, or hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy. In the case of OSA, it is required that the OSA be appropriately and sufficiently treated such that the beneficiary is in the chronic stable state before oxygen saturation results obtained during sleep testing are considered qualifying for oxygen therapy (see PAP LCD for additional information).

For beneficiaries with OSA, this means that the OSA must be sufficiently treated such that the underlying severe lung disease is unmasked. This must be demonstrated before oxygen saturation results obtained during polysomnography are considered qualifying for oxygen therapy.

For beneficiaries with OSA, a qualifying oxygen saturation test may only occur during a titration polysomnographic study (either split night or stand-alone). The titration PSG is one in which all of the following criteria are met:

1. The titration is conducted over a minimum of two (2) hours; and
2. During titration:
 - A. The AHI/RDI is reduced to less than or equal to an average of ten (10) events per hour; or
 - B. If the initial AHI/RDI was less than an average of ten (10) events per hour, the titration demonstrates further reduction in the AHI/RDI; and
3. Nocturnal oximetry conducted for the purpose for oxygen reimbursement qualification may only be performed after optimal PAP settings have been determined and the beneficiary is using the PAP device at those settings; and
4. The nocturnal oximetry conducted during the PSG demonstrates an oxygen saturation \leq 88% for 5 minutes total (which need not be continuous)

If all of the above criteria are met, for the purposes of a qualifying oxygen saturation test, the beneficiary is considered to be in the "chronic stable state." To be eligible for Medicare coverage and payment for home oxygen therapy for concurrent use with PAP therapy, in addition to being in the chronic stable state, the beneficiary must meet all other coverage requirements for oxygen therapy. Beneficiaries that qualify for oxygen therapy based on testing conducted only during the course of a sleep test are eligible only for reimbursement of stationary equipment.

Overnight oximetry performed as part of home sleep testing or as part of any other home testing is not considered as eligible to be used for qualification for reimbursement of home oxygen and oxygen equipment (see overnight oximetry section above for additional information).

Claims for oxygen equipment and supplies for beneficiaries who do not meet the coverage requirements for home oxygen therapy will be denied as not reasonable and necessary.

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 beneficiary 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 beneficiary'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 NON-MEDICAL 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 beneficiaries who were started on oxygen while enrolled in a Medicare HMO and transition to fee-for-service Medicare. For those beneficiaries, 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 beneficiary 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 beneficiaries 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 beneficiaries 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 beneficiary 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 beneficiaries initially meeting group I or II criteria, the beneficiary 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 beneficiary 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 beneficiary 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 beneficiary 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.

General:

Beneficiaries do not change group classification going from an initial certification to a recertification based upon changes in blood oxygen testing results. For example: A beneficiary initially qualifies for group II with an 89% oximetry value. At the 3-month retest a result of 87% is obtained. Despite the group I retesting value, the beneficiary remains in group II. There is no reclassification to group I. Further recertification is not required unless:

- A non-qualifying test result is obtained at the time of recertification but the beneficiary later obtains a qualifying test result; or,
- The specified length of need (LON) is reached.

Generally, only one recertification is required regardless of group classification unless the LON specified on the recertification CMN is some value other than 99 (indicating lifetime). If other than lifetime is specified the certification will expire when the specified LON time period elapses. A recertification will be required to continue coverage.

Recertification is required to be completed on or prior to the end of the initial certification period. If timely recertification is not completed by the end of the initial certification period, reimbursement ends until the recertification is completed. At such time that the recertification requirements are met, payment will resume at the month in the rental cycle where the rental was stopped due to the expiration of the initial certification. A new, initial rental cycle does not begin when the recertification requirements are met.

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.

PORABLE OXYGEN SYSTEMS:

A portable oxygen system is covered if the beneficiary 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 Non-Medical 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 beneficiary 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 beneficiary is on 4 or more

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:

Oxygen reimbursement is a bundled payment. All options, supplies and accessories are considered included in the monthly rental payment for oxygen equipment. Oxygen rental is billed using the appropriate code for the provided oxygen equipment. Separately billed options, accessories or supply items will be denied as unbundling.

Emergency or stand-by oxygen systems for beneficiaries 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.

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

REFILLS OF OXYGEN CONTENTS:

For Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use.

Oxygen contents are reimbursed with a monthly allowance covering all contents necessary for the month. Supply allowances are not subject to the refill monitoring and documentation requirements specified by Medicare Program Integrity Manual section 5.2.6.

All other supplies, e.g. tubing, masks or cannulas, etc., are included in the monthly rental payment. Supplies that are not separately payable are not subject to the refill monitoring and documentation requirements specified by Medicare Program Integrity Manual section 5.2.6.

See the Non-Medical Coverage and Payment Rules section of the related Policy Article for additional information about coverage of oxygen contents.

GENERAL

A Detailed Written Order (DWO) (if applicable) 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 a completed DWO, the claim shall be denied as not reasonable and necessary.

For Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) base items that require a Written Order Prior to Delivery (WOPD), the supplier must also obtain a DWO before submitting a claim for any associated options, accessories, and/or supplies that are separately billed. In this scenario, if the supplier bills for associated options, accessories, and/or supplies without first receiving a completed DWO, the claim shall be denied as not reasonable and necessary.

A WOPD (if applicable) must be received by the supplier before a DMEPOS item is delivered to a beneficiary. If a

supplier delivers a DMEPOS item without first receiving a completed WOPD, the claim shall be statutorily denied. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles. Claims that do not meet coding guidelines shall be denied as not reasonable and necessary/incorrectly coded.

Proof of delivery (POD) is a Supplier Standard and DMEPOS suppliers are required to maintain POD documentation in their files. Proof of delivery documentation must be made available to the Medicare contractor upon request. All services that do not have appropriate proof of delivery from the supplier shall be denied as not reasonable and necessary.

Summary of Evidence

NA

Analysis of Evidence (Rationale for Determination)

NA

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.

N/A

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.

N/A

CPT/HCPCS Codes**Group 1 Paragraph:**

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

GA - Waiver of liability (expected to be denied as not reasonable and necessary, ABN on file)

GY - Item or service statutorily excluded or does not meet the definition of any Medicare benefit

GZ - Item or service not reasonable and necessary (expected to be denied as not reasonable and necessary, no ABN on file)

KX - Requirements specified in the medical policy have been met

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

QA - Prescribed amounts of stationary oxygen for daytime use while at rest and nighttime use differ and the average of the two amounts is less than 1 liter per minute (LPM)

QB - Prescribed amounts of stationary oxygen for daytime use while at rest and nighttime use differ and the average of the two amounts exceeds 4 liters per minute (LPM) and portable oxygen is prescribed

QE - Prescribed amount of stationary oxygen while at rest is less than 1 liter per minute (LPM)

QF - Prescribed amount of stationary oxygen while at rest exceeds 4 liters per minute (LPM) and portable oxygen is prescribed

QG - Prescribed amount of stationary oxygen while at rest is greater than 4 liters per minute (LPM)

QH - Oxygen conserving device is being used with an oxygen delivery system

QR - Prescribed amounts of stationary oxygen for daytime use while at rest and nighttime use differ and the average of the two amounts is greater than 4 liters per minute (LPM)

RA - Replacement of a DME item

HCPCS CODES:**EQUIPMENT:****Group 1 Codes:**

CODE	DESCRIPTION
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

CODE	DESCRIPTION
	SUPPLIES AND ACCESSORIES
E0447	PORTABLE OXYGEN CONTENTS, LIQUID, 1 MONTH'S SUPPLY = 1 UNIT, PRESCRIBED AMOUNT AT REST OR NIGHTTIME EXCEEDS 4 LITERS PER MINUTE (LPM)
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

Group 2 Paragraph:

ACCESSORIES:

Group 2 Codes:

CODE	DESCRIPTION
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

CODE	DESCRIPTION
E1352	OXYGEN ACCESSORY, FLOW REGULATOR CAPABLE OF POSITIVE INSPIRATORY PRESSURE
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-10 Codes that Support Medical Necessity

Group 1 Paragraph:

N/A

Group 1 Codes:

N/A

Group 2 Paragraph:

N/A

Group 2 Codes:

N/A

Group 3 Paragraph:

N/A

Group 3 Codes:

N/A

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Additional ICD-10 Information

N/A

General Information

Associated Information

DOCUMENTATION 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 beneficiary's medical records will reflect the need for the care provided. The beneficiary'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

In order to justify payment for DMEPOS items, suppliers must meet the following requirements:

- Prescription (orders)
- Medical Record Information (including continued need/use if applicable)
- Correct Coding
- Proof of Delivery

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information regarding these requirements.

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

Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS

Items covered in this LCD have additional policy-specific requirements that must be met prior to Medicare reimbursement.

Refer to the LCD-related Policy article, located at the bottom of this policy under the Related Local Coverage Documents section for additional information.

MISCELLANEOUS:

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.

Oxygen used to treat cluster headaches and for participants in an LTOT Trial is provided under special coverage rules. Reimbursement is only available for beneficiaries who are enrolled in an approved clinical trial. CMS maintains a list of policies that require study participation as a condition of coverage on the CMS web site. For each policy the approved studies are listed and a link provided to the study on the clinicaltrials.gov web site. The clinicaltrials.gov

identifier number required on each claim is listed on this site.

UTILIZATION GUIDELINES

Refer to Coverage Indications, Limitations and/or Medical Necessity

Sources of Information

CR7235 for cluster headache trial

Bibliography

NA

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
01/01/2019	R6	<p>Revision Effective Date: 01/01/2019</p> <p>COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:</p> <p>Removed: NCD language</p> <p>Removed: Statement to refer to diagnosis code section below</p> <p>Added: Refer to Covered ICD-10 Codes in the LCD-related Policy Article</p> <p>HCPCS CODES:</p> <p>Added: HCPCS E0447</p> <p>ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY:</p> <p>Moved: All diagnosis codes to the LCD-related Policy Article diagnosis code section per CMS instruction</p> <p>ICD-10 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY:</p> <p>Moved: Statement about noncovered diagnosis code moved to LCD-related Policy Article noncovered diagnosis code section per CMS instruction</p>	<ul style="list-style-type: none">• Revisions Due To CPT/HCPCS Code Changes• Other (ICD-10 code relocation per CMS instruction)
08/01/2018	R5	<p>Revision Effective Date: 08/01/2018</p> <p>HCPCS MODIFIERS:</p> <p>Added: Modifiers GA, GY, GZ, KX</p> <p><i>06/07/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are</i></p>	<ul style="list-style-type: none">• Provider Education/Guidance

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<i>applicable as noted in this policy.</i>	
04/01/2018	R4	<p>Revision Effective Date: 04/01/2018</p> <p>Coding Information Revised: Modifier QE, QF, QG Added: Modifier QA, QB QR</p> <p><i>04/19/2018: At this time 21st Century Cures Act will apply to new and revised LCDs that restrict coverage which requires comment and notice. This revision is not a restriction to the coverage determination; and, therefore not all the fields included on the LCD are applicable as noted in this policy.</i></p>	<ul style="list-style-type: none"> Provider Education/Guidance
01/01/2017	R3	<p>Revision Effective Date: 01/01/2017</p> <p>COVERAGE INDICATIONS, INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Removed: Standard Documentation Language Added: New reference language and directions to Standard Documentation Requirements Added: General Requirements</p> <p>DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: General Documentation Requirements Added: New reference language and directions to Standard Documentation Requirements</p> <p>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Removed: Standard Documentation Language Added: Direction to Standard Documentation Requirements Removed: Miscellaneous section Removed: PIM citation from Appendices</p> <p>RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements article</p>	<ul style="list-style-type: none"> Provider Education/Guidance
07/01/2016	R2	Effective July 1, 2016 oversight for DME MAC LCDs is the responsibility of CGS Administrators, LLC 18003 and 17013 and Noridian Healthcare Solutions, LLC 19003 and 16013. No other changes have been made to the LCDs.	<ul style="list-style-type: none"> Change in Assigned States or Affiliated Contract Numbers
10/01/2015	R1	Revision Effective Date: 10/31/2014 COVERAGE INDICATIONS, LIMITATIONS AND/OR	<ul style="list-style-type: none"> Provider

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		<p>MEDICAL NECESSITY: Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility</p> <p>DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation Language to add who can enter date of delivery date on the POD</p> <p>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Revised: Diagnosis code references for Cluster Headaches</p>	Education/Guidance

Associated Documents

Attachments

CMS-484 Oxygen-Oxygen Equipment CMN
(PDF - 163 KB)

Oxygen CMN DME Form 484
(PDF - 2,554 KB)

Related Local Coverage Documents

Article(s)
A52514 - Oxygen and Oxygen Equipment - Policy Article
A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

Related National Coverage Documents

N/A

Public Version(s)

Updated on 02/08/2019 with effective dates 01/01/2019 - N/A
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Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

Keywords

N/A