

# 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 New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands Virginia West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts 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 Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

## LCD Information

### Document Information

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L33797

**Original Effective Date**

For services performed on or after 10/01/2015

**LCD Title**

Oxygen and Oxygen Equipment

**Revision Effective Date**

For services performed on or after 08/02/2020

**Proposed LCD in Comment Period**

N/A

**Revision Ending Date**

N/A

**Source Proposed LCD**

DL33797

**Retirement Date**

N/A

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06/18/2020

**Notice Period End Date**

08/01/2020

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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, 270.4

### **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 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 practitioner 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 treating practitioner 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 PO<sub>2</sub> at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent taken at rest (awake), or
2. An arterial PO<sub>2</sub> 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 PO<sub>2</sub> at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent while awake, or
3. A decrease in arterial PO<sub>2</sub> 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 PO<sub>2</sub> 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 PO<sub>2</sub> 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 treating practitioner-specified length of need, whichever is shorter. (Refer to the Certification section for information on recertification.)

Group II criteria include the presence of:

- A. An arterial PO<sub>2</sub> 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 treating practitioner specified length of need, whichever is shorter. (Refer to the Certification section for information on recertification.) Group III includes beneficiaries with arterial PO<sub>2</sub> 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 PO<sub>2</sub> 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 PO<sub>2</sub> from 56 to 65 mm Hg or an oxygen saturation at or above 89 percent. The additional Group II 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 code list 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 (PAP) Devices for the Treatment of Obstructive Sleep Apnea (L33718) LCD 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 treating practitioner. 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 treating practitioner 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 treating practitioner 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 practitioner 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 practitioner. 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 treating practitioner. 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 practitioner 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 treating practitioner 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 practitioner within 90 days prior to the date of any Recertification. If the treating practitioner 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 treating practitioner 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 treating practitioner 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 practitioner 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 treating practitioner 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.

## PORTABLE 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 in Chapter 5 of the Medicare Program Integrity Manual.

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 in Chapter 5 of the Medicare Program Integrity Manual.

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

#### GENERAL

A Standard Written Order (SWO) must be communicated to the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving a completed SWO, 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 have received a signed SWO before the DMEPOS item is delivered to a beneficiary. If a supplier delivers a DMEPOS item without first receiving a WOPD, the claim shall be denied as not reasonable and necessary. Refer to the LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.

For DMEPOS base items that require a WOPD, and also require separately billed associated options, accessories, and/or supplies, the supplier must have received a WOPD which lists the base item and which may list all the associated options, accessories, and/or supplies that are separately billed prior to the delivery of the items. In this scenario, if the supplier separately bills for associated options, accessories, and/or supplies without first receiving a completed and signed WOPD of the base item prior to delivery, the claim(s) shall be denied as not reasonable and necessary.

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

### *Background*

Topical oxygen therapy (TOT) has been proposed to promote wound healing. This reconsideration considers the two TOT modalities that are used to deliver oxygen to a wound:

1. Intermittent TOT: Oxygen is delivered at low pressure (0.049 to 1.03 atmospheres, depending on the system) to a wound encased in a closed chamber for multiple treatments, typically for 90 minutes a day for four consecutive days, followed by three days without TOT.
2. Continuous TOT (also called continuous diffusion of oxygen or CDO): Low-flow oxygen (<1 liters/minute) is applied to the wound surface continuously via a cannula inserted into a specially designed dressing.

In 2017, CMS revised NCD 20.29 to indicate that coverage of TOT would be at the discretion of local MACs. The current Oxygen and Oxygen Equipment LCD (L33797) states that TOT is not "reasonable and necessary".

Three manufacturers of TOT devices requested that the current not "reasonable and necessary" determination be reconsidered:

- GWR Medical: Intermittent topical oxygen (O2Boot<sup>®</sup>) received 510(k) clearance by the Food & Drug Administration (FDA) in November 1997. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf/K971507.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf/K971507.pdf)
- AOTI: Intermittent topical oxygen (Hyper-Box) received FDA 510(k) clearance in August 2008. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K080966>
- EO2 Concepts: Continuous diffusion of oxygen (TransCu O2<sup>®</sup>) received FDA 510(k) clearance in August 2009. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf9/K090681.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf9/K090681.pdf)

For purposes of this reconsideration, the term TOT will refer to the use of topical oxygen in general and will include both intermittent and continuous modalities.

This reconsideration does not include hyperbaric oxygen (HBO) which remains under the guidance of National Coverage Determination (NCD) 20.29, for Hyperbaric Oxygen Therapy.

NCD 270.4 precludes the reimbursement of topical oxygen for the treatment of decubitus ulcers.

The MACs received literature with each reconsideration request, which was supplemented by conducting their own searches of peer-reviewed publications published in the English language within 10 years of receipt of the LCD reconsideration requests, external technology assessments, and evidence-based consensus statements and clinical

guidelines. Additional literature was submitted by commenters during the comment period. Peer reviewed research publications used to inform the proposed and final policy had the following characteristics:

- Prospective trials with well-defined comparators with a primary goal to examine wound healing
- Human adults with wounds from pressure ulcers, diabetic ulcers, venous ulcers, or arterial insufficiency ulcers present for at least 4 weeks or otherwise indicated as non-healing
- Investigations that studied wounds of varying types were included if the above etiologies were separated out for analysis

Studies that did not meet the above criteria were not included in the analysis but are listed in the bibliography.

#### *Summary of Evidence in Diabetic Foot Ulcers*

Eight publications based on five studies totaling 346 patients were identified for the use of TOT in treating Diabetic Foot Ulcers (DFUs). In a sham-controlled, double-blinded, randomized trial, Frykberg et al.<sup>1</sup> reported that intermittent TOT on 78 patients (36 in the active treatment arm) resulted in a higher percentage of completely healed DFUs over a 12-week period. Blackman et al.<sup>2</sup> used intermittent TOT on 28 patients (17 in the active treatment arm) in an unblinded, prospective, controlled, single-site study and reported that more wounds healed over a 90- day test period with intermittent TOT.

The remaining six studies evaluated continuous TOT. In a pilot study (2013) and a larger prospective, randomized, blinded, sham-controlled multicenter, parallel trial (2017), Driver et al.<sup>3,4</sup> reported on 122 patients (65 in the active treatment arm). In these publications, continuous TOT did not report significant differences in the rate of wound healing. In three separate publications, Niederauer et al. reported on one randomized, double-blind, sham-controlled, parallel group trial of continuous TOT.<sup>5-7</sup> In Niederauer et al. (2018),<sup>7</sup> continuous TOT reportedly led to significant improvements in full wound closure in 105 patients (52 in the active treatment arm) in the intention to treat population. Lastly, a small pilot randomized controlled trial in 18 patients by Yu et al.<sup>8</sup> concluded that continuous TOT improved DFU healing over an 8-week period in the 9 patients treated with it.

#### *Summary of Evidence in Venous Ulcers*

Two publications reported on the same parallel-group, observational, non-randomized, comparative study of 132 patients (67 in the active treatment group) comparing intermittent TOT to standard wound care for the treatment of venous ulcers.<sup>9,10</sup> The final study publication reported outcomes of healing after 12-weeks of treatment and wound recurrence at 36 weeks.<sup>10</sup> The authors reported that patients who received intermittent TOT experienced a statistically significant increase in the number of healed wounds, a reduction in time to healing, and a reduction in ulcer recurrence.

#### *Summary of Evidence in Pressure Ulcers*

One published study was identified, a 12-day, single-blinded, randomized study that compared intermittent TOT to standard wound care in 100 hospitalized patients (50 in the active treatment arm) with pressure wounds.<sup>11</sup> The authors reported that intermittent TOT significantly increased the number of wounds that healed and reduced the mean area of the wounds compared to the control group.

#### *Professional Society Recommendations and Guidelines*

- The Undersea and Hyperbaric Medical Society published a 2018 position statement that does not recommend

TOT for routine clinical care.<sup>12</sup>

- The International Working Group on the Diabetic Foot published a systematic review in 2016 (updated in March 2020) that does not support the use of TOT for diabetic foot ulcer healing.<sup>13,14</sup>
- The European Wound Management Association published a review in 2017 with a recommendation for the use of TOT in wound healing.<sup>15</sup>

### *External Assessments*

ECRI Institute completed three evidence reviews in 2019<sup>16-18</sup> on the use of TOT for DFUs, venous ulcers, and pressure ulcers. In 2020, they also reviewed newly published evidence for DFUs<sup>19</sup> and concluded the following:

- Using TOT does not seem to be more effective than standard of care for healing DFUs, based on evidence from a systematic review (SR).
- For the use of TOT for venous and pressure ulcers, evidence is inconclusive due to a lack of data.

### **Analysis of Evidence (Rationale for Determination)**

In an April 2017 Decision Memo, CMS examined published evidence on the use of TOT for treatment of chronic wounds and concluded that no National Coverage Determination was appropriate at the time due to lack of evidence for improvement in function among patients with chronic wounds and limited evidence for durability of wound healing.<sup>20</sup>

A total of 11 peer-reviewed publications were used to inform this determination. All reported somewhat positive findings; however, significant issues were present in most studies which reduced the overall quality and strength of evidence, including:

- Uncertainty about the standard of care used as a control;
- Small sample sizes;
- Variability in baseline characteristics between control and actively treated arms;
- Inappropriate statistical analyses;
- Uniformity of inclusion/exclusion criteria;
- Study design issues;
- Short timelines (4-12 weeks);
- Lack of randomization in some studies;
- Appropriate blinding;
- Demonstration of functional improvement;
- Limited evidence regarding durability;
- Potential conflicts of interest;
- Uncertainty about generalizability to Medicare population.

Two recent clinical guidelines do not recommend the use of TOT for wound healing due to insufficient supporting evidence. In addition, external assessments by ECRI Institute found evidence supporting the use of TOT to be inconclusive due to mixed results and lack of data.

### **Level of evidence**

**Quality – Low**  
**Strength – Low**  
**Weight – Low**

*Contractor Advisory Committee (CAC)*

Following an independent review of the literature, the DME MACs assembled a nine-member specialty-focused CAC, consisting of a national panel of academicians, a stakeholder representative, and practicing clinicians. The CAC meeting was held on October 29, 2019 in San Francisco, California. Seven (7) Key Questions were discussed by the CAC members, and confidence in each Key Question scored (Industry Representative was excluded from scoring). Confidence was rated on a scale of 1-5, with 1 indicative of low confidence and 5 indicating high confidence.

*CAC Committee Chair Summary*

The CAC had an excellent discussion of the state of the evidence on TOT and wound care, and all the Key Questions. All committee members were well-prepared, having read the background articles and all participated constructively. The consensus was consistent with the ECRI review; that is, there is potential for TOT in the future, but at this time we lack high-quality studies that suggest durable and clinically meaningful benefit for patients, particularly in the Medicare population.

The following is a summary of the CAC Panel scoring for each Key Question.

<b>1.</b>	<b>How confident are you that there is sufficient evidence to determine that adjunctive TOT leads to a greater incidence of complete wound closure of chronic non-healing wounds compared to standard of care?</b>	<b>Scoring Member Average</b>
	<i>1 Low Confidence – 2 – 3 Intermediate – 4 – 5 High Confidence</i>	<b>2.63</b>
<b>2.</b>	<b>How confident are you that there is sufficient evidence to determine that adjunctive TOT shortens the time to complete wound closure of chronic non-healing wounds compared to standard of care?</b>	<b>Scoring Member Average</b>
	<i>1 Low Confidence – 2 – 3 Intermediate – 4 – 5 High Confidence</i>	<b>2.50</b>
<b>3.</b>	<b>How confident are you that there is sufficient evidence to determine that TOT improves the durability of chronic non-healing wound closure compared to standard of care?</b>	<b>Scoring Member Average</b>
	<i>1 Low Confidence – 2 – 3 Intermediate – 4 – 5 High Confidence</i>	<b>1.50</b>
	<b>How confident are you that the available evidence for TOT in chronic, non-</b>	<b>Scoring Member</b>

4.	<b>healing wounds allows identification of a discrete population of Medicare-eligible beneficiaries who would benefit from TOT?</b>	<b>Average</b>
	<i>1 Low Confidence — 2 — 3 Intermediate — 4 — 5 High Confidence</i>	<b>1.50</b>
5.	<b>How confident are you that there are no significant gaps in evidence that may impact positive health outcomes in the Medicare-eligible population?</b>	<b>Scoring Member Average</b>
	<i>1 Low Confidence — 2 — 3 Intermediate — 4 — 5 High Confidence</i>	<b>1.13</b>
6.	<b>How confident are you that TOT is generally accepted by the medical community for the treatment of chronic non-healing wounds?</b>	<b>Scoring Member Average</b>
	<i>1 Low Confidence — 2 — 3 Intermediate — 4 — 5 High Confidence</i>	<b>1.13</b>
7.	<b>How confident are you that the evidence supports that the use of TOT results in clinically meaningful outcomes such as complete wound closure and/or quality of life improvement in Medicare beneficiaries?</b>	<b>Scoring Member Average</b>
	<i>1 Low Confidence — 2 — 3 Intermediate — 4 — 5 High Confidence</i>	<b>2.13</b>

*Conclusion*

TOT is not generally accepted as a standard treatment for chronic wounds, and strong evidence for the effectiveness of this treatment in the Medicare age population is currently lacking. Parenthetically, NCD 270.4 precludes the reimbursement of topical oxygen for the treatment of decubitus ulcers. The determination regarding the use of TOT for wound healing will remain as not “reasonable and necessary.” Thus, there will be no change to the Oxygen and Oxygen Equipment LCD (L33797).

## Coding Information

**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 SUPPLIES AND ACCESSORIES
E0447	PORTABLE OXYGEN CONTENTS, LIQUID, 1 MONTH'S SUPPLY = 1 UNIT,

CODE	DESCRIPTION
	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
E1352	OXYGEN ACCESSORY, FLOW REGULATOR CAPABLE OF POSITIVE INSPIRATORY PRESSURE

CODE	DESCRIPTION
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

## 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 treating practitioner'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:

- SWO
- 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 (PO<sub>2</sub>) on a sample of arterial blood. The PO<sub>2</sub> 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

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## Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
08/02/2020	R7	<p><b>Revision Effective Date: 08/02/2020</b>            COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:            Revised: "physicians" to "treating practitioners"            Removed: Statement to refer to ICD-10 Codes that are Covered section in the LCD-related PA            Added: Statement to refer to ICD-10 codes in the LCD-related Policy Article            GENERAL:            Revised: Order information as a result of Final Rule 1713            SUMMARY OF EVIDENCE:            Added: Information related to topical oxygen            ANALYSIS OF EVIDENCE:            Added: Information related to topical oxygen            CODING INFORMATION:            Removed: Field titled "Bill Type"            Removed: Field titled "Revenue Codes"            Removed: Field titled "ICD-10 Codes that Support Medical Necessity"            Removed: Field titled "ICD-10 Codes that DO NOT Support Medical Necessity"            Removed: Field titled "Additional ICD-10 Information"            GENERAL DOCUMENTATION REQUIREMENTS:            Revised: Prescriptions (orders) to SWO            BIBLIOGRAPHY:            Added: Section related to topical oxygen            RELATED LOCAL COVERAGE DOCUMENTS:            Added: Response to Comments (A58247)</p>	<ul style="list-style-type: none"> <li>• Provider Education/Guidance</li> <li>• Reconsideration Request</li> </ul>
01/01/2019	R6	<p><b>Revision Effective Date: 01/01/2019</b>            COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY:            Removed: NCD language            Removed: Statement to refer to diagnosis code section below            Added: Refer to Covered ICD-10 Codes in the LCD-related Policy Article            HCPCS CODES:            Added: HCPCS E0447            ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY:            Moved: All diagnosis codes to the LCD-related Policy Article diagnosis code section per CMS instruction            ICD-10 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY:            Moved: Statement about noncovered diagnosis code moved to LCD-related Policy Article noncovered</p>	<ul style="list-style-type: none"> <li>• Revisions Due To CPT/HCPCS Code Changes</li> <li>• Other (ICD-10 code relocation per CMS instruction)</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		diagnosis code section per CMS instruction	
08/01/2018	R5	<p><b>Revision Effective Date: 08/01/2018</b>            HCPCS MODIFIERS:            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 applicable as noted in this policy.</i></p>	<ul style="list-style-type: none"> <li>• Provider Education/Guidance</li> </ul>
04/01/2018	R4	<p><b>Revision Effective Date: 04/01/2018</b>            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"> <li>• Provider Education/Guidance</li> </ul>
01/01/2017	R3	<p><b>Revision Effective Date: 01/01/2017</b>            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            DOCUMENTATION REQUIREMENTS:            Removed: Standard Documentation Language            Added: General Documentation Requirements            Added: New reference language and directions to Standard Documentation Requirements            POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:            Removed: Standard Documentation Language            Added: Direction to Standard Documentation Requirements            Removed: Miscellaneous section            Removed: PIM citation from Appendices</p>	<ul style="list-style-type: none"> <li>• Provider Education/Guidance</li> </ul>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION	REASON(S) FOR CHANGE
		RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements article	
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"> <li>Change in Assigned States or Affiliated Contract Numbers</li> </ul>
10/01/2015	R1	Revision Effective Date: 10/31/2014 COVERAGE INDICATIONS, LIMITATIONS AND/OR MEDICAL NECESSITY: Revised: Standard Documentation Language to add covered prior to a beneficiary's Medicare eligibility DOCUMENTATION REQUIREMENTS: Revised: Standard Documentation Language to add who can enter date of delivery date on the POD POLICY SPECIFIC DOUMENTATION REQUIREMENTS: Revised: Diagnosis code references for Cluster Headaches	<ul style="list-style-type: none"> <li>Provider Education/Guidance</li> </ul>

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## Associated Documents

### Attachments

Oxygen CMN CMS 484  
(PDF - 2,598 KB )

### Related Local Coverage Documents

Article(s)

A52514 - Oxygen and Oxygen Equipment - Policy Article

A58247 - Response to Comments: Oxygen and Oxygen Equipment - DL33797

A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

### Related National Coverage Documents

N/A

### Public Version(s)

Updated on 06/12/2020 with effective dates 08/02/2020 - N/A

Updated on 02/08/2019 with effective dates 01/01/2019 - 08/01/2020

Some older versions have been archived. Please visit the MCD Archive Site to retrieve them.

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## Keywords

N/A

**END OF LOCAL COVERAGE DETERMINATION**

Per the Code of Federal Regulations, 42 C.F.R § 426. 325, only those portions of the currently effective Local Coverage Determination (LCD) that are based on section 1862(a)(1)(A) of the Social Security Act, may be challenged through an acceptable complaint as described in 42 C.F.R § 426.400. Also, per 42 C.F.R § 426.325 items that are not reviewable, and therefore cannot be challenged, include the Policy Article. Please note the distinction of the documents when reviewing the materials.

# Local Coverage Article: Oxygen and Oxygen Equipment - Policy Article (A52514)

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

## 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 New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands Virginia West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts 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 Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

## Article Information

### General Information

**Article ID**

A52514

**Original Effective Date**

10/01/2015

**Original ICD-9 Article ID**

[A33768](#)

[A33750](#)

[A33677](#)

[A47097](#)

**Revision Effective Date**

08/02/2020

**Revision Ending Date**

N/A

**Article Title**

Oxygen and Oxygen Equipment - Policy Article

**Retirement Date**

N/A

**Article Type**

Article

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## Article Guidance

### Article Text:

#### **NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES**

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. Information provided in this policy article relates to determinations other than those based on Social Security Act §1862(a)(1)(A) provisions (i.e. "reasonable and necessary").

Oxygen and oxygen equipment is covered under the Durable Medical Equipment benefit (Social Security Act §1861(s)(6)). In order for a beneficiary's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements set out in the related Local Coverage Determination must be met. In addition, there are specific statutory payment policy requirements, discussed below, that also must be met.

## REASONABLE USEFUL LIFETIME (RUL):

The reasonable useful lifetime for oxygen equipment is 5 years. The RUL is not based on the chronological age of the equipment. It starts on the initial date of service and runs for 5 years from that date.

RUL also does not take into account exchanges of equipment, new suppliers, or changes of modality (concentrator, gaseous, liquid).

Stationary and portable oxygen equipment is often provided at the same time therefore the RUL for both items runs concurrently. When the RUL of a beneficiary's portable oxygen equipment differs from the RUL of the beneficiary's stationary oxygen equipment, the RUL of the stationary oxygen equipment shall govern the application of RUL-based rules and processes for both types, stationary and portable, of oxygen equipment.

Until such time as the end date of the RUL of the stationary oxygen equipment is reached, the supplier must continue to furnish both the portable and stationary oxygen equipment.

1. If the end date of the RUL of the portable oxygen equipment precedes the end date of the RUL of the stationary oxygen equipment, the end date of the RUL of the portable oxygen equipment is adjusted (extended) to coincide with the end date of the RUL of the stationary oxygen equipment.
2. If the end date of the RUL of the portable oxygen equipment follows the end date of the RUL of the stationary oxygen equipment, the end date of the RUL of the portable oxygen equipment is adjusted (shortened) to coincide with the end date of the RUL of the stationary oxygen equipment.

When the end date of the RUL of the stationary oxygen equipment occurs, the beneficiary may elect to obtain replacement of both the stationary and the portable oxygen equipment.

If the beneficiary elects to obtain replacement of the stationary and the portable oxygen equipment, both types of oxygen equipment must be replaced at the same time.

When the stationary and the portable oxygen equipment are replaced, a new 36-month rental period and new RUL is started for both the replacement stationary oxygen equipment and the replacement portable oxygen equipment.

Beginning January 1, 2011, a beneficiary who resides in a DMEPOS competitive bidding area (CBA) may obtain replacement of both the stationary and portable oxygen systems only from a contract supplier having a competitive bidding contract for the CBA in which the beneficiary permanently resides.

A grandfathered supplier for oxygen and other grandfathered equipment as of January 1, 2011, who has continued to furnish such equipment that has not yet reached the 36-month rental cap, does not qualify to furnish replacement equipment once the end date of the RUL of the stationary equipment is reached, if the beneficiary resides in the CBA when the end of the RUL has been reached, unless the status of the grandfathered supplier has changed to a contract supplier for the current round of the competitive bidding program.

## OXYGEN EQUIPMENT:

### Initial 36 months

Reimbursement for oxygen equipment is limited to 36 monthly rental payments. Payment for accessories (e.g.,

cannula, tubing, etc.), delivery, back-up equipment, maintenance, and repairs is included in the rental allowance. Payment for oxygen contents (stationary and/or portable) is included in the allowance for stationary equipment (E0424, E0439, E1390, E1391).

Payment for stationary equipment is increased for beneficiaries requiring greater than 4 liters per minute (LPM) of oxygen flow and decreased for beneficiaries requiring less than 1 LPM. If a beneficiary qualifies for additional payment for greater than 4 LPM of oxygen and also meets the requirements for portable oxygen, the appropriate modifiers (QB or QF) must be used.

The supplier who provides oxygen equipment for the first month must continue to provide any necessary oxygen equipment and all related items and services through the 36-month rental period, unless one of the following exceptions is met:

- Beneficiary relocates temporarily or permanently outside of the supplier's service area
- Beneficiary elects to obtain oxygen from a different supplier
- Individual case exceptions made by CMS or DME MAC
- Item becomes subject to competitive bidding

Providing different oxygen equipment/modalities (e.g., concentrator [stationary or portable], gaseous, liquid, trans-filling equipment) is not permitted unless one of the following requirements is met:

- Supplier replaces the equipment with the same or equivalent item
- Treating practitioner's orders different equipment
- Beneficiary chooses to receive an upgrade and signs an Advance Beneficiary Notice of Non-coverage (ABN)
- CMS or the DME MAC determines that a change in equipment is warranted

A new 36-month rental period can begin only in the following situations:

- Specific incident of damage beyond repair (e.g., dropped and broken, fire, flood, etc.) or the item is stolen or lost
- Break-in-need for at least 60 days plus the days remaining in the month of discontinuation and new medical necessity is established (see "BREAK-IN-SERVICE" below)

A new 36-month rental period does not start in the following situations:

- Replacing equipment due to malfunction, wear and tear, routine maintenance, repair
- Providing different equipment based on a treating practitioner order or beneficiary request for an upgrade
- Break-in-need less than 60 days plus the days remaining in the month of discontinuation (see "BREAK-IN-SERVICE" below)
- Break-in-billing (see "BREAK-IN-SERVICE" below)
- Changing suppliers

### Months 37-60

There is no further payment for oxygen equipment during the 5-year reasonable useful lifetime (RUL) of the equipment after 36 rental payments have been made. If use of portable equipment (E0431, E0433, E0434, E1392, K0738) begins after the use of stationary equipment begins, payment for the portable equipment can continue after payment for the stationary equipment ends until 36 rental payments have been made for the portable equipment.

For information on payment for contents and maintenance, see separate sections below.

The supplier who provided the equipment during the 36th rental month is required to continue to provide the equipment, accessories, contents (if applicable), maintenance, and repair of the oxygen equipment during the 5 year reasonable useful lifetime of the equipment.

Rules for providing different equipment/modalities are the same in months 37-60 as they are in the initial 36 months (see above).

A new 36-month rental period can begin only in the following situation:

- There is a specific incident of damage beyond repair (e.g., dropped and broken, fire, flood, etc.) or the item is stolen or lost

A new 36-month rental period does not start in the following situations:

- Replacing equipment due to malfunction, wear and tear, routine maintenance, repair
- Providing different equipment based on a treating practitioner order or beneficiary request for an upgrade
- Break-in-need (see "BREAK-IN-SERVICE" below)
- Break-in-billing (see "BREAK-IN-SERVICE" below)
- Changing suppliers

#### Months 61 and after

At any time after the end of the 5-year reasonable useful lifetime for oxygen equipment, the beneficiary may elect to receive new equipment, thus beginning a new 36-month rental period.

If the beneficiary elects not to receive new equipment after the end of the 5-year reasonable useful lifetime and if the supplier retains title to the equipment, all elements of the payment policy for months 37-60 remain in effect. There is no separate payment for accessories or repairs. If the beneficiary was using gaseous or liquid oxygen equipment during the 36th rental month, payment can continue to be made for oxygen contents.

If the beneficiary elects not to receive new equipment after the end of the 5-year reasonable useful lifetime and if the supplier transfers title of the equipment to the beneficiary, accessories, maintenance, and repairs are statutorily non-covered by Medicare. Contents are separately payable for beneficiary-owned gaseous or liquid systems.

If a beneficiary enters Medicare FFS with beneficiary-owned equipment, accessories, maintenance, and repairs are statutorily non-covered by Medicare. Contents are separately payable for beneficiary-owned gaseous or liquid systems.

#### OXYGEN CONTENTS:

Payment for stationary and portable contents is included in the fee schedule allowance for stationary equipment. No payment can be made for oxygen contents in a month in which payment is made for stationary equipment.

If the beneficiary was using stationary gaseous or liquid oxygen equipment during the 36th rental month, payment

for stationary contents (E0441 or E0442) begins when the rental period for the stationary equipment ends.

If the beneficiary was using portable gaseous or liquid equipment during the 36th rental month of stationary equipment (gaseous, liquid, or concentrator), payment for portable contents (E0443, E0444 or E0447) begins when the rental period for the stationary equipment ends. If the beneficiary began using portable gaseous or liquid equipment after starting on stationary equipment, payment for the portable equipment would continue until the end of the 36-month rental period for that equipment even though payment was also being made for the portable contents.

If the beneficiary was using both stationary and portable gaseous or portable equipment during the 36th rental month of stationary equipment, payment for both stationary contents (E0441 or E0442) and portable contents (E0443, E0444 or E0447) begins when the rental for the stationary equipment ends.

If the beneficiary is using only portable gaseous or liquid equipment and not stationary equipment during months 1 through 36 of the portable equipment rental, payment for portable contents begins when the rental period for the portable equipment begins. If stationary equipment is subsequently added, separate payment for portable contents ends because payment for contents is included in the payment for stationary equipment.

If the beneficiary was not using gaseous or liquid equipment (stationary or portable) in the 36th month, but was subsequently switched to gaseous or liquid oxygen based on a treating practitioner order, contents may be paid.

If the beneficiary has a stationary concentrator, portable liquid equipment, and a stationary liquid tank to fill the portable cylinders, when payment for contents begins, payment will only be made for portable liquid contents.

Suppliers must provide whatever quantity of oxygen contents are needed for a beneficiary's activities both inside and outside the home.

A maximum of 3 months of oxygen contents may be delivered at any one time. (Refer to Billing Information section [below] for additional information concerning billing oxygen contents.)

There is no difference in payment for oxygen contents for beneficiaries receiving more than 4 LPM or less than 1 LPM.

No more than 1 unit of service (UOS) for stationary contents and/or 1 UOS for portable contents per month are billable.

Refer to the Coverage Indications, Limitations and/or Medical Necessity section of the LCD for additional information about refills of oxygen contents.

#### MAINTENANCE OF EQUIPMENT:

##### Initial 36 months

There is no separate payment for maintenance and servicing (M&S).

##### Months 37 through 60

If a beneficiary was using a stationary concentrator, portable concentrator, or trans-filling equipment during the 36th rental month, Medicare will pay for an M&S visit no more often than every 6 months, beginning no sooner than 6 months following the end of the rental period. If the equipment is covered under a warranty that covers labor related to routine/general maintenance and servicing (e.g., inspection, changing filters, cleaning, and calibration), payment for the first M&S visit can be no sooner than 6 months following the end of that warranty.

A supplier must actually make a visit to bill the service. If multiple M&S visits are made during a 6 month period, only one will be paid.

There is no M&S payment for gaseous or liquid equipment.

#### Month 61 and after

If the beneficiary elects not to replace a concentrator or trans-filling equipment and if the supplier retains title to the equipment, coverage for M&S is the same as in months 37-60.

If the beneficiary elects not to replace a concentrator or trans-filling equipment and if the supplier transfers title to the beneficiary, M&S is statutorily non-covered.

#### OXYGEN ACCESSORIES:

Accessories, including but not limited to, trans-tracheal catheters (A4608), cannulas (A4615), tubing (A4616), mouthpieces (A4617), face tent (A4619), masks (A4620, A7525), oxygen conserving devices (A9900), oxygen tent (E0455), humidifiers (E0555), nebulizer for humidification (E0580), regulators (E1353), and stand/rack (E1355) are included in the allowance for rented oxygen equipment. The supplier must provide any accessory ordered by the treating practitioner. Accessories used with beneficiary-owned oxygen equipment will be denied as non-covered.

#### RELOCATION and TRAVEL:

##### Months 1 through 36

If the beneficiary relocates outside the supplier's service area (either short-term travel, extended temporary relocation, or permanent relocation), then for the remainder of the rental month for which it billed, the home supplier is required to provide the equipment and related items/service itself or make arrangements with a different supplier to provide the equipment, items, and services. For subsequent rental months that the beneficiary is outside the service area, the home supplier is encouraged to either provide the equipment and related items/services itself or assist the beneficiary in finding another supplier in the new location. The home supplier may not bill for or be reimbursed by Medicare if it is not providing oxygen equipment or has not made arrangements with a different supplier to provide the equipment on the anniversary billing date. Medicare will pay only one supplier to provide oxygen during any one-rental month.

##### Months 37 through 60

If the beneficiary relocates outside the supplier's service area (either short-term travel, extended temporary relocation, or permanent relocation), the home supplier is required to either provide the equipment and related items/services itself or make arrangements with a different supplier to provide the equipment and related items/services.

## Miscellaneous

Oxygen services furnished by an airline to a beneficiary are non-covered. Payment for oxygen furnished by an airline is the responsibility of the beneficiary and not the responsibility of the supplier.

Medicare does not cover items or services provided/used outside the United States and its territories. The supplier is not required to provide or arrange for oxygen use in those situations.

### BREAK-IN-SERVICE:

- Break-in-billing/Part B payment without break-in-medical necessity
  - If beneficiary enters hospital or SNF or joins Medicare HMO and continues to need/use oxygen, when beneficiary returns home or rejoins Medicare FFS, payment resumes where it left off
- Break-in-medical necessity (break-in-need)
  - If need/use of oxygen ends for less than 60 days plus the remainder of the rental month of discontinuation and then resumes, payment resumes where it left off
  - During the 36-month rental period, if need/use of oxygen ends for more than 60 days plus the remainder of the rental month of discontinuation and new medical necessity is established, a new 36 month rental period would begin
  - During months 37-60, if need/use of oxygen ends for more than 60 days plus the remainder of the rental month of discontinuation and new medical necessity is established, a new rental period does not begin. The supplier who provided the oxygen equipment during the 36th rental month must provide all necessary items and services for the duration of the reasonable useful lifetime.

### MISCELLANEOUS:

Only rented oxygen equipment is eligible for coverage. Purchased oxygen equipment is statutorily non-covered.

Oximeters (E0445) and replacement probes (A4606) will be denied as non-covered because they are monitoring devices that provide information to the treating practitioner to assist in managing the beneficiary's treatment.

Respiratory therapist services are non-covered under the DME benefit.

### **REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO Final Rule 1713 (84 Fed. Reg Vol 217)**

Final Rule 1713 (84 Fed. Reg Vol 217) requires a face-to-face encounter and a Written Order Prior to Delivery (WOPD) for specified HCPCS codes. CMS and the DME MACs provide a list of the specified codes, which is periodically updated. The link will be located here once it is available.

Claims for the specified items subject to Final Rule 1713 (84 Fed. Reg Vol 217) that do not meet the face-to-face encounter and WOPD requirements specified in the LCD-related Standard Documentation Requirements Article (A55426) will be denied as not reasonable and necessary.

If a supplier delivers an item prior to receipt of a WOPD, it will be denied as not reasonable and necessary. If the WOPD is not obtained prior to delivery, payment will not be made for that item even if a WOPD is subsequently obtained by the supplier. If a similar item is subsequently provided by an unrelated supplier who has obtained a WOPD, it will be eligible for coverage.

## **POLICY SPECIFIC DOCUMENTATION REQUIREMENTS**

In addition to policy specific documentation requirements, there are general documentation requirements that are applicable to all DMEPOS policies. These general requirements are located in the DOCUMENTATION REQUIREMENTS section of the LCD.

Refer to the LCD-related Standard Documentation Requirements article, located at the bottom of this Policy Article under the Related Local Coverage Documents section for additional information regarding GENERAL DOCUMENTATION REQUIREMENTS and the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS discussed below.

Documentation for initial coverage requires information in the medical record showing:

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

Coverage of home oxygen therapy requires that the beneficiary be tested in the “chronic stable state” and that all co-existing diseases or conditions that can cause hypoxia must be treated sufficiently. Moreover, 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 order to provide coverage for these beneficiaries, there must be evidence in the medical record documenting:

- A. A severe underlying 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; and
- B. The beneficiary is not experiencing an exacerbation of their underlying lung disease described in (A) or other acute condition(s) impacting the beneficiary’s oxygen saturation;
- C. For beneficiaries with concurrent PAP therapy, the qualifying oxygen saturation test is performed following optimal treatment of the OSA as described in the Coverage Indications, Limitations and/or Medical Necessity.

### **LONG TERM OXYGEN THERAPY TRIALS (LTOT):**

For LTOT Trial claims, the “clinicaltrials.gov” identifier number of the CMS approved clinical trial must be included in the narrative field on each claim.

Claims for LTOT Trial participants that meet the approved clinical trial and testing requirements described in the Coverage Indications, Limitations and/or Medical Necessity section of the related LCD must be submitted with the Q0 (Q-zero) modifier. Claims for oxygen that do not meet these criteria must not use this modifier.

### **CLUSTER HEADACHES:**

A CMN is not required for claims for cluster headaches.

The diagnosis code(s) for the qualifying cluster headache condition must be included on the claim (reference Group 1 ICD-10 Codes listed below).

The diagnosis code for EXAMINATION OF PARTICIPANT IN CLINICAL TRIAL (reference Group 2 ICD-10 Codes listed below) must also be included on the claim for cluster headache if the beneficiary is enrolled in an approved study.

For cluster headache claims there must be information in the medical record justifying:

- Participation in an approved study
- The qualifying diagnosis code(s)

For cluster headache claims, the "clinicaltrials.gov" identifier number of the CMS approved clinical trial must be included in the narrative field on each claim.

Claims for oxygen used for the treatment of cluster headaches that meet the approved clinical trial and diagnosis requirements described in the Coverage Indications, Limitations and/or Medical Necessity section of the related LCD 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.

#### REPAIRS:

The supplier must maintain detailed records describing the need for and nature of all repairs including a detailed explanation of the justification for any component or part replaced as well as the labor time to restore the item to its functionality.

#### REPLACEMENT EQUIPMENT:

For situations 3 and 4 described in the CERTIFICATION section of the "Coverage Indications, Limitations and/or Medical Necessity" of the LCD, 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.

A treating practitioner's order and/or new Certificate of Medical Necessity (CMN), when required, is needed to reaffirm the medical necessity of the item for replacement of an item.

#### **CERTIFICATE OF MEDICAL NECESSITY (CMN)**

A Certificate of Medical Necessity (CMN), which has been completed, signed, and dated by the treating practitioner, must be kept on file by the supplier and made available upon request. The CMN may act as a substitute for the Standard Written Order (SWO) if it contains the same information as required in a SWO. The CMN for home oxygen is CMS Form 484. In addition to the order information that the treating practitioner 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 treating practitioner 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 non-continuous use of oxygen.

For beneficiaries who qualify for oxygen coverage based only on an overnight 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 home overnight study documenting the qualifying desaturation must be available upon request.

If both an arterial blood gas and oximetry test have been performed on the same day under the condition reported on the CMN (i.e., at rest/awake, during exercise, or during sleep), the ABG PO 2 must be reported on the CMN.

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, trans-filling system)

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

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

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

## **MODIFIERS**

### KX, GA, GY, and GZ MODIFIERS:

Suppliers must add a KX modifier only if all of the criteria in the Coverage Indications, Limitations and/or Medical Necessity section of the related LCD have been met.

If all of the criteria in the Coverage Indications, Limitations and/or Medical Necessity section have not been met, the GA, GY or GZ modifier must be added to the code. When there is an expectation of a medical necessity denial, suppliers must enter GA modifier on the claim line if they have obtained a properly executed Advance Beneficiary Notice (ABN), a GZ modifier if they have not obtained a valid ABN, or a GY modifier if the item or service is statutorily excluded.

Claim lines billed without a KX, GA, GY or GZ modifier will be rejected as missing information.

## QA, QB, QE, QF, QG and QR MODIFIERS:

42 CFR Section 414.226(e) stipulates:

1. If prescribed flow rate is different for stationary versus portable, the flow rate for stationary is used.
2. If prescribed flow rate is different for the patient at rest versus the patient with exercise, the flow rate at rest is used.
3. If prescribed flow rate is different for nighttime versus daytime use, the flow rates are averaged.

QA: For scenarios where the beneficiary has different daytime and nighttime oxygen flow requirements. Used if the average documented flow requirement from a daytime "at rest" qualifying test and flow rate for nocturnal oxygen requirement (standard arithmetic rounding rules apply) is <1 LPM.

QB: For scenarios where the beneficiary has different daytime and nighttime oxygen flow requirements. Used if the average documented flow requirement from a daytime "at rest" qualifying test and flow rate for nocturnal oxygen requirement (standard arithmetic rounding rules apply) is >4 LPM, and portable oxygen is prescribed.

QE: Used if the documented flow requirement on an "at rest" qualifying test is <1 LPM.

QF: Used if the documented flow requirement on an "at rest" qualifying test is >4 LPM, and portable oxygen is prescribed. DO NOT use a flow requirement from a "with exercise" qualifying test.

QG: Used if the documented flow requirement on an "at rest" qualifying test is >4 LPM. DO NOT use a flow requirement from a "with exercise" qualifying test.

QR: For scenarios where the beneficiary has different daytime and nighttime oxygen flow requirements. Used if the average documented flow requirement from a daytime "at rest" qualifying test and flow rate for nocturnal oxygen requirement (standard arithmetic rounding rules apply) is >4 LPM.

## **CODING GUIDELINES**

The appropriate modifier must be used if the prescribed flow rate is less than 1 LPM (QA or QE) or greater than 4 LPM (QG or QR).

For claims with dates of service on or after 04/01/2018 the modifier QB or QF should be used in conjunction with claims submitted for stationary oxygen (codes E0424, E0439, E1390, or E1391) and portable oxygen (codes E0431, E0433, E0434, E1392, or K0738) when the prescribed amount of oxygen is greater than 4 liters per minute (LPM).

Code E1391 (Oxygen concentrator, dual delivery port) is used in situations in which two beneficiaries are both using the same concentrator. In this situation, this code should only be billed for one of the beneficiaries.

Codes E1405 and E1406 describe oxygen and water vapor enriching systems with or without heated delivery respectively. These devices both extract oxygen from the surrounding air (similar to an oxygen concentrator) and add humidification. They require substantially higher oxygen flow rates in order to deliver the same concentration of oxygen as that achieved by standard oxygen delivery systems (for example, concentrators or liquid/gaseous systems). Since codes E1405 and E1406 require a higher flow rate but do not provide a benefit to the beneficiary in terms of the inspired concentration of oxygen, modifiers QB, QF, QG, and QR, which are appended to claim lines to

indicate oxygen flow rates greater than 4 liters/minute, must not be used with codes E1405 and E1406. Codes E1405 and E1406 (oxygen and water vapor enriching systems) may only be used for products for which a written coding verification has been received from the PDAC.

Code E1392 describes an oxygen concentrator which is designed to be portable, is capable of delivering 85% or greater oxygen concentration, and is capable of operating on either AC or DC (e.g., auto accessory outlet) power. Code E1392 includes the device itself, an integrated battery or beneficiary-replaceable batteries that are capable of providing at least 2 hours of remote portability at a minimum of 2 LPM equivalency, a battery charger, an AC power adapter, a DC power adapter, and a carry bag and/or cart. The combined weight of the concentrator and the battery/batteries capable of 2 hours of portability must be 20 pounds or less. If a concentrator meets all of these criteria and is also capable of functioning as a stationary concentrator, operating 24 hours per day, 7 days per week, the stationary concentrator code (E1390) is billed in addition to code E1392.

Code K0738 describes a feature of an oxygen concentrator that allows the beneficiary to fill portable gaseous oxygen cylinders from a stationary concentrator. This feature may be integrated into the stationary concentrator or be a separate component. When code K0738 is billed, code E0431 (portable gaseous oxygen system, rental) must not be used.

Code E0433 describes a feature of an oxygen concentrator that allows the beneficiary to fill portable liquid oxygen cylinders from a stationary concentrator. This feature may be integrated into the stationary concentrator or be a separate component. When code E0433 is billed, code E0434 (portable liquid oxygen system, rental) must not be used.

When oxygen is supplied as part of a CMS approved clinical trial for cluster headaches, equipment must be coded E0424 (STATIONARY COMPRESSED GASEOUS OXYGEN SYSTEM, RENTAL; INCLUDES CONTAINER, CONTENTS, REGULATOR, FLOWMETER, HUMIDIFIER, NEBULIZER, CANNULA OR MASK, AND TUBING).

Refill contents used with equipment to treat cluster headaches must be coded using E0441 (STATIONARY OXYGEN CONTENTS, GASEOUS, 1 MONTH'S SUPPLY = 1 UNIT).

E1352 (OXYGEN ACCESSORY, FLOW REGULATOR CAPABLE OF POSITIVE INSPIRATORY PRESSURE) provides positive pressure inspiratory support for patients using oxygen. This product consists of multiple components - control unit, flow regulator, connecting hose and nasal interface (pillows). E1352 is an all-inclusive code for this product that includes all components.

Code E0467 (HOME VENTILATOR, MULTI-FUNCTION RESPIRATORY DEVICE, ALSO PERFORMS ANY OR ALL OF THE ADDITIONAL FUNCTIONS OF OXYGEN CONCENTRATION, DRUG NEBULIZATION, ASPIRATION, AND COUGH STIMULATION, INCLUDES ALL ACCESSORIES, COMPONENTS AND SUPPLIES FOR ALL FUNCTIONS) describes a ventilator that integrates the function of multiple types of equipment into a single device. Code E0467 combines the function of a ventilator with those of any combination or all of the following:

- Oxygen equipment
- Nebulizer and compressor
- Aspirator (suction device)
- Cough stimulator (multiple products)
- Positive airway pressure devices (PAP and RAD)
- Custom fabricated oral appliances

The following oxygen and oxygen equipment HCPCS codes for individual items are included in the functionality of code E0467:

- HCPCS codes E0424, E0431, E0433, E0434, E0439, E0441, E0442, E0443, E0444, E0447, E1390, E1391, E1392, E1405, E1406 and K0738

Claims for any of the HCPCS codes listed above that are submitted on the same claim or that overlap any date(s) of service for E0467 is considered to be unbundling.

In addition, any claim for repair (HCPCS code K0739 for labor and any HCPCS code for replacement items) of beneficiary-owned equipment identified by HCPCS codes listed above is considered as unbundling if the date(s) of service for the repair overlaps any date(s) of service for code E0467.

Claims for code E0467 with a date(s) of service that overlaps date(s) of service for any of the following scenarios are considered as a claim for same or similar equipment when the beneficiary:

- Is currently in a rental month for any of the items listed above
- Owns any of the equipment listed above that has not reached the end of its reasonable useful lifetime.
- Has oxygen equipment that reached the 36-month rental but has not reached the end of its reasonable useful lifetime.

Suppliers should contact the Pricing, Data Analysis, and Coding (PDAC) contractor for guidance on the correct coding of these items.

## **BILLING INFORMATION**

When billing oxygen contents (refer to the Policy Article, Non-Medical Necessity Coverage and Payment Rules section), suppliers should use a date of service (DOS) that is the anniversary date of the equipment whose rental period has ended. The billed DOS will usually not be the actual delivery date. The supplier must have a delivery slip for the actual delivery date.

A supplier does not have to deliver contents every month in order to bill every month. In order to bill for contents, the supplier must have previously delivered quantities of oxygen that are expected to be sufficient to last for one month following the DOS on the claim. Suppliers should monitor usage of contents. Billing may continue on a monthly basis as long as sufficient supplies remain to last for one month as previously described. If there are insufficient contents to be able to last for a month additional contents should be provided.

Suppliers may bill a flat rate for contents each month. The submitted charges do not have to vary with the quantity of tanks delivered.

Claims for oxygen contents and/or oxygen accessories should not be submitted in situations in which they are not separately payable.

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## **Coding Information**

**CPT/HCPCS Codes**

N/A

**ICD-10 Codes that Support Medical Necessity****Group 1 Paragraph:**

The presence of an ICD-10 code listed in this section is not sufficient by itself to assure coverage. Refer to the section on "**Coverage Indications, Limitations and/or Medical Necessity**" for other coverage criteria and payment information.

For HCPCS Code E0424 used for cluster headaches:

**Group 1 Codes:**

ICD-10 CODE	DESCRIPTION
G44.001	Cluster headache syndrome, unspecified, intractable
G44.009	Cluster headache syndrome, unspecified, not intractable
G44.011	Episodic cluster headache, intractable
G44.019	Episodic cluster headache, not intractable
G44.021	Chronic cluster headache, intractable
G44.029	Chronic cluster headache, not intractable

**Group 2 Paragraph:**

Z00.6 (must be used concurrently with one of the above diagnosis codes)

**Group 2 Codes:**

ICD-10 CODE	DESCRIPTION
Z00.6	Encounter for examination for normal comparison and control in clinical research program

**ICD-10 Codes that DO NOT Support Medical Necessity****Group 1 Paragraph:**

For HCPCS code E0424 all other diagnosis codes not specified above

For all codes used for long term oxygen therapy – not specified

**Group 1 Codes:**

N/A

**Additional ICD-10 Information**

N/A

**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

## Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
08/02/2020	R9	<p><b>Revision Effective Date: 08/02/2020</b></p> <p>NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:  Revised: "physician" to "treating practitioner"  REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO 42 CFR 410.38(g):  Removed: Section removed  REQUIREMENTS FOR SPECIFIC DMEPOS ITEMS PURSUANT TO FINAL RULE 1713 (84 Fed. Reg Vol 217):  Added: Section and related information based on Final Rule 1713</p> <p>POLICY SPECIFIC DOCUMENTATION REQUIREMENTS:  Revised: "physician" to "treating practitioner"  CERTIFICATE OF MEDICAL NECESSITY (CMN):  Revised: "physician" to "treating practitioner"  Revised: "detailed written order" to "standard written order"</p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		<p>Removed: Outdated CMN Form number            ICD-10 CODES THAT SUPPORT MEDICAL NECESSITY:            Revised: Section header "ICD-10 Codes that are Covered" updated to "ICD-10 Codes that Support Medical Necessity"            ICD-10 CODES THAT DO NOT SUPPORT MEDICAL NECESSITY:            Revised: Section header "ICD-10 Codes that are Not Covered" updated to "ICD-10 Codes that DO NOT Support Medical Necessity"</p> <p><i>06/18/2020: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
01/01/2019	R8	<p><b>Revision Effective Date: 01/01/2019</b>            CODING GUIDELINES:            Revised: E0467 Coding Guidelines to include custom fabricated oral appliances            Added: E0447, E1405, and E1406 to HCPCS codes included in E0467</p> <p><i>04/04/2019: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
01/01/2019	R7	<p><b>Revision History Effective Date: 01/01/2019</b>            NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES:            Added: E0447 to Oxygen Content guidelines            CODING GUIDELINES:            Added: E0467 Coding Guidelines            Revised: E1405 and E1406 Coding Guidelines            ICD-10 CODES THAT ARE COVERED:            Added: All diagnosis codes formerly listed in the LCD            ICD-10 CODES THAT ARE NOT COVERED:            Added: Notation excluding all unlisted diagnosis codes from coverage</p> <p><i>02/14/2019: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
08/01/2018	R6	<p><b>Revision History Effective Date: 08/01/2018</b>            CERTIFICATE OF MEDICAL NECESSITY (CMN):            Removed: Flow rate instructions when answering CMN question 5            MODIFIERS:            Added: GA, GY, GZ, and KX modifier requirement instructions            Added: "Q" modifier instructions</p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		<p><i>06/07/2018: At this time 21st Century Cures Act applies to new and revised LCDs that restrict coverage, which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
04/01/2018	R5	<p><b>Revision History Effective Date: 04/01/2018</b>  NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES  Oxygen Equipment: Initial 36 months  Added: "the appropriate modifiers (QB or QF) must be used." in paragraph regarding flow rate greater than 4 LPM and also meets requirements for portable oxygen  Added: 42 CFR 410.38(g) language, previously in POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section  CERTIFICATE OF MEDICAL NECESSITY  Added: Flow rate guidelines for beneficiaries who require differing day and night rates  CODING GUIDELINES  Revised: Flow rate modifiers for beneficiaries who require differing day and night rates  Revised: Coding guidelines for E1405 and E1406 to indicate that high flow rate modifiers (QB, QF, QG or QR) must not be used with these two HCPCS codes.</p> <p><i>04/19/2018: At this time 21st Century Cures Act applies to new and revised LCDs that restrict coverage, which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
01/01/2018	R4	<p><b>Revision History Effective Date: 01/01/2018</b>  NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES  Oxygen Equipment: Initial 36 months  Added: "the appropriate modifiers (QB or QF) must be used." in paragraph regarding flow rate greater than 4 LPM and also meets requirements for portable oxygen  Added: 42 CFR 410.38(g) language, previously in POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section  CERTIFICATE OF MEDICAL NECESSITY  Added: Flow rate guidelines for beneficiaries who require differing day and night rates  CODING GUIDELINES  Revised: Flow rate modifiers for beneficiaries who require differing day and night rates  Revised: Coding guidelines for E1405 and E1406 to indicate that high flow rate modifiers (QB, QF, QG or QR) must not be used with these two HCPCS codes.</p> <p><i>04/19/2018: At this time 21st Century Cures Act applies to new and revised LCDs that restrict coverage, which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
01/01/2017	R3	Revision Effective Date: 01/01/2017 POLICY SPECIFIC DOCUMENTATION REQUIREMENTS: Added: NCD 240.2, Long Term Oxygen Therapy Trails, Cluster Headaches, 42 CFR 410.38(g), Repair, Replacement and CMN requirements CODING GUIDELINES: Effective 04/01/2017, modifier QF may be used with portable systems or oxygen. RELATED LOCAL COVERAGE DOCUMENTS: Added: LCD-related Standard Documentation Requirements Language Article
07/01/2016	R2	Effective July 1, 2016 oversight for DME MAC Articles 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 Articles.
10/01/2015	R1	Revision Effective Date: 10/31/2014 NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES: Removed: "When required by state law" from ACA new prescription requirements  Revised: Face-to-Face Requirements for treating practitioner

## Associated Documents

### Related Local Coverage Document(s)

Article(s)

A55426 - Standard Documentation Requirements for All Claims Submitted to DME MACs

LCD(s)

L33797 - Oxygen and Oxygen Equipment

### Related National Coverage Document(s)

N/A

### Statutory Requirements URL(s)

N/A

### Rules and Regulations URL(s)

N/A

### CMS Manual Explanations URL(s)

N/A

### Other URL(s)

N/A

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## **Keywords**

N/A