Oxygen and Oxygen Equipment

DL33797

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PROPOSED LCD

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Contractor Information

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
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

Contractor Name	Contract Type	Contract Number	Jurisdiction	States
				Rhode Island Vermont
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

Proposed LCD Information

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Oxygen and Oxygen Equipment

Issue

Issue Description

The proposed LCD proposes reasonable and necessary coverage criteria for topical oxygen therapy for Medicare beneficiaries with diabetic foot ulcers that have failed to heal with four consecutive weeks of optimized diabetic foot ulcer care.

CMS National Coverage Policy

CMS Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Sections 240.2, 240.2.1, 270.4, 280.1

Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

The Centers for Medicare and Medicaid Services codifies nationally covered and non-covered indications for home oxygen and oxygen equipment in section 240.2 of the Medicare National Coverage Determination Manual under the durable medical equipment benefit (DME) and section 1862(a)(1)(A) of the Social Security Act for beneficiaries.

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 and oxygen equipment is covered only when both the "reasonable and necessary" criteria defined by NCD 240.2, and the statutory documentation and payment rules discussed in the LCD-related Policy Article (A52514) are met. Refer to the LCD-related Policy Article for additional information on statutory payment policy requirements.

Initial coverage of home oxygen therapy and oxygen equipment is reasonable and necessary for Groups I, II and III if all of the following conditions are met:

1. The treating practitioner has ordered and evaluated the results of a qualifying blood gas study performed at the time of need; 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 provision of oxygen and oxygen equipment in the home setting will improve the beneficiary’s condition.

Time of need is defined as during the patient’s illness when the presumption is that the provision of oxygen will improve the patient’s condition in the home setting. For an inpatient hospital patient anticipated to require oxygen upon going home, the time of need would be within 2 days of discharge.

Note: When applicable, the beneficiary’s medical record must have documentation that describes any concerns for variations in oxygen measurements that may result from such factors as the patient's age, the patient’s skin pigmentation, the altitude level, or a decrease in oxygen carrying capacity.

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:

A. An arterial PO_2 at or below 55 mm millimeters of mercury (mm Hg) or an arterial oxygen saturation at or below 88 percent taken at rest (awake) while breathing room air; or,
B. An arterial PO_2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, taken during sleep for a beneficiary who demonstrates an arterial PO2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent while awake. In this instance, oxygen and oxygen equipment is only reasonable and necessary during sleep; or,
C. A decrease in arterial PO_2 more than 10 mm Hg, or a decrease in arterial oxygen saturation more than 5 percent from baseline saturation, taken during sleep and associated with symptoms of hypoxemia such as impairment of cognitive processes and nocturnal restlessness or insomnia (not all inclusive). In this instance, oxygen and oxygen equipment is only reasonable and necessary during sleep; or,
D. An arterial PO_2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent, taken during exercise for a beneficiary who demonstrates an arterial PO_2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent during the day while at rest. In this instance, portable oxygen and oxygen equipment is only reasonable and necessary while awake and during exercise.

Group II criteria include all of the following:

A. An arterial PO_2 of 56-59 mm Hg or an arterial blood oxygen saturation of 89 percent; 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.

Group III criteria:

Initial coverage of home oxygen therapy and oxygen equipment is reasonable and necessary for beneficiaries in Group III, if all of the following conditions are met:

1. Absence of hypoxemia defined in Group I and Group II above; and,
2. A medical condition with distinct physiologic, cognitive, and/or functional symptoms documented in high-quality, peer-reviewed literature to be improved by oxygen therapy, such as cluster headaches (not all inclusive).

Note: DME MACs use the same methodologic principles of evidentiary review as those used for NCDs. For details, please see Appendix A of the National Coverage Analysis (NCA) Decision Memo Home Use of Oxygen and Home Oxygen Use to Treat Cluster Headaches CAG-00296R2.

Group IV criteria:

Oxygen therapy and oxygen equipment 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; or,
2. Dyspnea without cor pulmonale or evidence of hypoxemia; or,
3. Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities but in the absence of systemic hypoxemia. There is no evidence that increased PO_2 will improve the oxygenation of tissues with impaired circulation; or,
4. Terminal illnesses that do not affect the ability to breathe.

Group V criteria:

Topical Oxygen Therapy

INITIAL COVERAGE FOR TOPICAL OXYGEN THERAPY FOR THE FIRST MONTH

Initial coverage for the first month of topical oxygen therapy for the treatment of nonhealing diabetic foot ulcers (DFUs) as an adjunct to optimized diabetic foot ulcer care will be considered reasonable and necessary if the treating practitioner has completed an in-person visit with the beneficiary and has documented that all the following criteria (1 – 5) have been met:

1. The beneficiary has a non-gestational type of diabetes mellitus; and,
2. The DFU has not experienced at least 50% reduction in ulcer area despite at least four (4) consecutive weeks of optimized diabetic foot ulcer care (See the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section in the LCD-related Policy Article); and,
3. The beneficiary has had a glycosylated hemoglobin (HbA1c) of < 12% within the three (3) months prior to the initiation of topical oxygen therapy for the current DFU; and,
4. The beneficiary has adequate arterial perfusion to support healing as indicated by one of the following:
    a. Absolute toe systolic blood pressure of > 30 mm Hg; or,
    b. Ankle brachial index (ABI) of > 0.7; or,
    c. Normal pulse volume recordings on Doppler ultrasound; or,
    d. Transcutaneous oxygen measurements of the dorsum of the foot > 30 mm Hg with a skin perfusion pressure of > 30 mm Hg; and,
5. The beneficiary will continue to adhere to a regimen of optimized diabetic foot ulcer care (Refer to POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section of the LCD-related Policy Article).

If criteria 1 – 5 are not met, initial coverage for topical oxygen therapy will be denied as not reasonable and necessary.

CONTINUED TOPICAL OXYGEN THERAPY COVERAGE BEYOND THE FIRST MONTH OF INITIAL THERAPY

For continued coverage of topical oxygen therapy for the treatment of nonhealing DFUs as an adjunct to optimized diabetic foot ulcer care beyond the initial first month to be considered as reasonable and necessary, the treating practitioner must complete an in-person visit with the beneficiary for each month of additional coverage and must document that all of the following criteria (1 and 2) are met:

1. The beneficiary is benefiting from topical oxygen therapy as defined by one of the following (see the POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section of the LCD-related Policy Article):

a. A reduction in ulcer area (length x width) of ≥ 20% from the most recent month's measurement as determined by one of the following:
   i. For the second month of continued coverage – measurements taken after initiation of optimized diabetic foot ulcer care but prior to initiation of TOT; or,
   ii. For any additional month of continued coverage – measurements taken at the beginning and end of the prior month for continued coverage; or,
b. Improvement in the diabetic foot ulcer classification on a clinically validated standardized grading scale; and,

2. The beneficiary continues to adhere to a regimen of optimized diabetic foot ulcer care.

If criteria 1 and 2 are not met, continued coverage for topical oxygen therapy will be denied as not reasonable and necessary.

WHEN COVERAGE ENDS

For non-healing DFUs described under Group V above, topical oxygen therapy will be denied as not reasonable and necessary with any of the following, whichever occurs earliest:

1. Initial coverage criteria for topical oxygen therapy cease to occur;

2. In the judgment of the treating practitioner, adequate wound healing has occurred to the degree that topical oxygen therapy may be discontinued; or

3. Once equipment or supplies are no longer being used by the beneficiary, whether or not by the treating practitioner's order.

The use of topical oxygen therapy for indications other than nonhealing DFUs will be denied as not reasonable and necessary.

OTHER EXCLUSIONS FROM INITIAL AND CONTINUED TOPICAL OXYGEN THERAPY COVERAGE

Topical oxygen therapy will be denied as not reasonable and necessary if one or more of the following is present:

1. Diabetic foot ulcer-related:
   a. Abscess; or,
   b. Osteomyelitis; or,
   c. Joint sepsis; or,
   d. Gangrene; or,
2. Limb involvement on the same side as the DFU in the past three (3) months of:
   a. Deep vein thrombosis; or,
   b. Malignancy.

If all of the coverage conditions specified above for initial claims for beneficiaries in Groups I, II, III and V, or documentation requirements for continued payment of subsequent claims are not met, the oxygen therapy and oxygen equipment will be denied as not reasonable and necessary. Please refer to the LCD-related Policy Article (A52514) for additional information regarding documentation requirements necessary for continued payment of oxygen and oxygen equipment claims.

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 therapy and oxygen equipment 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; and,

(2) Testing during exercise without oxygen; and,

(3) Testing during exercise with oxygen applied (to demonstrate the improvement of the hypoxemia).

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 (#2 above) is used for qualification. All 3 test results must be available upon request.

Oximetry obtained after exercise while resting, sometimes referred to as "recovery" testing, is not part of the 3 required test elements and is not valid for determining eligibility for oxygen therapy and oxygen equipment 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.

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.

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 and oxygen equipment.

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 therapy and oxygen equipment coverage.

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

Some beneficiaries may require the simultaneous use of home oxygen therapy and oxygen equipment with a PAP device. To be considered for simultaneous coverage, all requirements in the "Coverage Indications, Limitations and/or Medical Necessity" sections of 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 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.

In the case of OSA, it is required that the OSA be appropriately and sufficiently treated before oxygen saturation results obtained during sleep testing are considered qualifying for oxygen therapy and oxygen equipment (see Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea LCD for additional information).

For beneficiaries with OSA, this means that the OSA must be sufficiently treated such that the underlying condition resulting in hypoxemia is unmasked. This must be demonstrated before oxygen saturation results obtained during polysomnography are considered qualifying for oxygen therapy and oxygen equipment.

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 of oxygen therapy and oxygen equipment 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 of ≤ 88%.

To be eligible for Medicare coverage and payment for home oxygen therapy and oxygen equipment for concurrent use with PAP therapy, the beneficiary must meet all other coverage requirements for oxygen therapy and oxygen equipment. Beneficiaries that qualify for oxygen therapy and oxygen equipment 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 the "Overnight Oximetry Studies" 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.

PORTABLE OXYGEN SYSTEMS:

A portable oxygen system is covered if the beneficiary is mobile within the home for Groups I and II, 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 LCD-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 initial oxygen coverage criteria for Group I, II or III 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. For Group I or II, coverage greater than 4 LPM requires a qualifying blood gas study performed while the beneficiary is on 4 or more LPM. 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 the LCD-related Policy Article for additional information on payment for greater than 4 LPM oxygen.)

MISCELLANEOUS:

Oxygen reimbursement is a bundled payment for both inhaled and topical modalities. 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.

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 (both inhaled and topical modalities) 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, disposable hyperbaric oxygen chambers, 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 NECESSITY COVERAGE AND PAYMENT RULES section of the LCD-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

Clinical Background

Diabetes is a common condition affecting 38 million people in the United States[1], including approximately 16.5 million Medicare beneficiaries who have an increased risk of diabetic foot ulcers (DFUs).[1-3] DFUs occur at an annual incidence rate of about 6% reported among Medicare beneficiaries with diabetes.[1,2] About 20 percent of diabetic patients who develop a diabetic foot ulcer will need an amputation.[3] Major lower extremity amputations are associated with an increase in the 5-year mortality rate of diabetic patients to about 50%.[3]

The term “standard of care” (SOC), when used in this summary of evidence, is synonymous with “optimized diabetic foot ulcer care”. The SOC for DFUs includes moist dressings with regular dressing changes, local debridement, offloading, revascularization, and treatment of infection where appropriate.[4]

Technology

Topical oxygen therapy (TOT) has been proposed as an adjunctive treatment used with optimized diabetic foot ulcer care to promote wound healing for over 50 years.[5] Two TOT modalities are used to deliver oxygen to a wound:

- 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.
- Continuous TOT (also called continuous diffusion of oxygen or CDO): Low-flow oxygen (<1 liters/minute) is applied to the wound surface continuously at atmospheric pressure via a cannula inserted into a specially designed dressing.

In this LCD, “TOT” refers to topical oxygen therapy, including intermittent and continuous modalities.

Literature Analysis

This summary of the evidence is formatted by type of intervention/comparator and outcome classification (efficacy/effectiveness, undesirable effects, patient experience, and health care utilization). The findings of published evidence syntheses (systematic reviews, evidence reports) are prioritized when applicable to specific key research questions. The literature analysis emphasizes the research designs most applicable to the key questions e.g., RCTs for efficacy-related questions. Studies providing real-world evidence were included if they allowed for causal inference, were designed to assess prognostic factors or adverse events, or they represented the only identified studies for the topic. When multiple studies of a singular population were reported for the same outcomes of interest, this analysis focused on the publication with the most complete data.

The Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) approach domains of study limitations (risk of bias), indirectness, imprecision, inconsistency, and publication bias formed the basis of appraisal of the certainty of evidence for efficacy/effectiveness studies [see Literature Analysis Tables attachment].

Tables 1–3 summarize the characteristics, findings, and assessments of included studies [see Literature Analysis Tables attachment].

Topical Oxygen Therapy + Standard of Care Versus Standard of Care (With/Without Sham)

Efficacy/Effectiveness

Healing Rate

Seven systematic reviews (5 included meta-analysis),[6-12] which were published between 2019 and 2022, synthesized data from 8 unique randomized controlled trials (RCTs),[13-20] and 5 non-randomized studies of an intervention (NRSI).[21-24] There were consistent results showing the use of adjuvant topical oxygen therapy (TOT) resulted in significantly more complete wound healing at 12 weeks in comparison to standard of care (SOC) in superficial, relatively well-vascularized diabetic foot ulcers (DFUs). The differences (>50%) were viewed as clinically significant. The certainty of evidence ranged from low to very low. The main reasons for downgrading the evidence included a high risk of bias (ROB) involving >70% of RCTs, imprecision, and that publication bias was strongly suspected.

Ulcer Reduction Rate

A comprehensive systematic review of RCTs provided low certainty evidence that showed benefit in ulcer area reduction at 12 weeks for SOC + TOT compared to SOC + sham therapy.[11] An earlier systematic review, which included mainly non-randomized studies of interventions (NRSI), stated that all high-grade ulcers (grades 2, 3, and above) showed a >50% reduction in ulcer area and ulcer tissue depth.[12]

The results of RCTs, most at a high ROB, reported that SOC with adjunctive TOT significantly decreased the mean wound area size from baseline values ($P < 0.05$) versus SOC.[13,14,16,17,19,20]

Time to Complete Closure

Four RCTs provided mixed results concerning the time to complete wound closure. All the trials were conducted on patients with DFUs that did not heal after 4 weeks and were non-responsive to SOC. Three studies favored the combination of SOC and TOT over SOC (with or without sham).[10,12,13] One RCT yielded a non-significant difference favoring the sham group.[11]

Ulcer Recurrence

Two primary studies described ulcer recurrence rates at 12-month follow-up between participants receiving SOC + TOT or SOC. Frykberg, et al. (2019) found 6.7% of healed ulcers in the SOC + TOT arm recurred, compared with 40% in the SOC + sham arm, falling just short of statistical significance ($P = 0.070$).[16] Similarly, a follow-up study showed 85% of the TOT patients and 60% of the SOC group that had previously healed ulcers remained healed at 1 year.[25]

Amputation Rate

Data from 2 systematic reviews suggest there is no significant difference in amputation rate after 12 weeks between TOT and SOC.[8,11] These synthesized findings are supported by 3 RCTs.[13,15,16] A single RCT found a significant difference ($P = 0.045$) favoring SOC + TOT versus SOC or TOT on amputation rates at 1 year following intervention.[17] Real-world evidence results from a retrospective cohort study used propensity matching to compare amputation rates between patients who received SOC (with or without additional adjunctive therapies) with patients who received the same interventions plus TOT.[26] At 1-year follow-up, the cohort that received TOT demonstrated a 22.8% ($P = 0.0007$) lower amputation rate.

Undesirable Effects

One systematic review identified 2 studies with a high ROB that assessed mortality with TOT compared to SOC and reported no difference between the 2 groups.[11]

Five RCTs evaluated the occurrence of adverse events.[13,15,16,18,19] None of the studies found any significant differences in overall, device-related, or DFU-related adverse events between TOT and SOC.

Patient Experience

Aspects of quality-of-life (QoL) measures were reported in 2 RCTs. A small ($N = 20$) pilot RCT found the TOT group had a favorable difference of 4.4 points compared to SOC in the Institute for Health Services Research in Dermatology and Nursing Wound-QoL score.[13] In another small RCT ($N = 73$), there was a statistically significant difference between baseline and the end of 12-week treatment in the TOT arm compared with the sham arm in the well-being component of the Cardiff wound index scale score ($P = 0.033$).[16] Neither study described the clinical significance of these findings.

Healthcare Utilization

Yellin, et al. (2022) analyzed real-world evidence, using data retrospectively obtained from 2 U.S. Veterans Affairs hospitals.[26] Within the propensity-matched cohorts, patients who received SOC and TOT (with or without additional adjunctive therapies) had an absolute lower hospitalization rate of 32.9% ($P < 0.0001$) compared to SOC (with or without additional adjunctive therapies).

Topical Oxygen Therapy Versus Other Adjunctive Wound Care Therapies

Three network meta-analyses (NMA) and a single observational study provided indirect evidence evaluating the comparative effectiveness and safety of continuous and intermittent TOT with other adjunctive interventions used to treat individuals with DFUs.[22-24,41]

Efficacy/Effectiveness

Healing Rate

Yang, et al. (2025) included a total of 34 RCTs (N = 2268) that investigated the effects of different gas therapies i.e., TOT, hyperbaric oxygen therapy (HBOT), hyperbaric air therapy (HBAT), topical hyperbaric oxygen therapy (THOT), ozone therapy (OT), oxygen-ozone therapy (OOT), cold atmospheric plasma (CAP), nitric oxide therapy (NOT), and carbon dioxide (CO_2) on DFU healing rate.[27] TOT ranked 4th (surface under the cumulative ranking curve [SUCRA] = 0.413) in terms of effectiveness for healing rate. Only CO_2, HBOT and HBAT were ranked above TOT. The review presented with some methodological concerns (impact of potential effect modifiers, lack of consideration of studies at high ROB) that may have introduced bias into the conclusions.

OuYang, et al. (2024) included 57 RCTs (N = 4826) that provided indirect comparisons among TOT with HBOT, platelet-rich plasma (PRP), acellular dermal matrix (ADM), stem cells (SCs), negative pressure wound therapy (NPWT), ultrasonic debridement (UD), as well as several combinations of these therapies.[28] TOT ranked 8th, which was superior to ADM, SCs, and SOC. Limitations of the conclusions of this review include failure to take into consideration the clinical significance of the results and some concerns about bias due to unclear modelling choices, which may have led to the results being underestimated.

In another NMA, TOT was ranked eighth of 12 adjunctive therapies, ahead of low-frequency ultrasound, hyperbaric oxygen, electrical stimulation, and platelet-derived growth factor.[29] In the pairwise comparison between TOT and SOC, TOT significantly improved the wound healing rate (OR = 2.40; 95% CI 1.55, 3.37).

Mercurio, et al. (2025) employed a unique study that compared a case series of patients that received continuous diffusion of oxygen (CDO) with a separately published cohort that received negative pressure wound therapy (NPWT) for DFUs.[41] While the study had significant methodological and validity concerns attributed to comparing interventions using two distinct data sets (rather than a single unified source), the analysis showed a 75.5% success rate for DFUs in those receiving CDO. In contrast, the NPWT cohort achieved 43.2% full closure in the same timeframe for similar wound sizes and severity.

Ulcer Reduction Rate

An NMA of different gaseous therapies for the adjunctive treatment of DFUs found that of nine interventions, TOT ranked 6th (SUCRA = 0.413) below CO_2, HBOT, CAP, OT, NOT for ulcer area reduction rate.[27] Another NMA found, while TOT ranked 7th, there were no significant differences in the incidence of reduced ulcer area among the 11 interventions.[28] A third NMA evaluated six interventions for DFUs that focused on the area reduction rate.[29] TOT ranked last compared to low-level laser therapy, extracorporeal shockwave therapy, platelet-rich plasma, hyperbaric oxygen therapy, and low-frequency ultrasound.

Time to Complete Closure

An NMA examined nine interventions that described the mean healing times of DFUs.[29] TOT ranked below amniotic membrane therapy, platelet-rich plasma, extracorporeal shockwave therapy, negative pressure wound therapy, stem cells, platelet-derived growth factor, and epidermal growth factor.

Ulcer Recurrence

Not reported.

Amputation Rate

Of six gaseous interventions included in an NMA, TOT ranked as having the second lowest amputation rate. However, these observed differences were not statistically significant ($P > 0.05$).[27] An NMA of different treatment measures (TOT, PRP, ADM, SCs, NPWT, UD, HBOT) for patients with DFUs found no significant differences in amputation rate among the adjunctive interventions.[28] Hu, et al. (2025) indirectly meta-analyzed data for nine adjunctive interventions that focused on amputation rate outcomes.[29] TOT ranked above negative pressure wound therapy, epidermal growth factor, amniotic membrane therapy, and hyperbaric oxygen therapy.

Undesirable Effects

TOT showed no statistically significant differences in adverse events compared to other gas therapies (P > 0.05).[27] Another NMA reported there were no significant differences observed between TOT and other interventions (PRP, ADM, SCs, NPWT, UD, HBOT).[28] A case series reported no serious adverse events with the real-world application of CDO.[41]

Patient Experience

Not reported

Healthcare Utilization

Not reported

Quality Appraisal

The three NMA provided indirect evidence, as no studies directly compared TOT with other adjunctive interventions for DFUs. One NMA was judged to have a high ROB.[29] The meta-analysis duplicated data by recording overlapping portions of the same study population as three separate studies. The analysis also did not take into consideration known effect modifiers (age, gender, duration of DFU). Two NMA were rated as having some concerns about their conclusions due to the potential for bias. Yang, et al. (2025) failed to consider the impact of potential effect modifiers and studies at high ROB in their conclusions.[27] OuYang, et al. (2024) did not consider bias due to missing relevant studies and did not clearly describe modelling choices in their NMA.[28]

Systematic reviews with meta-analysis were rated as providing low to very-low certainty evidence (study limitations, imprecision, inconsistency, and the potential for publication bias).[6-9] Two qualitative systematic reviews were rated as low to very low quality.[11,12]

Three RCTs were judged to have a low ROB.[15,18,19] Five RCTs were rated at a high ROB.[13,14,16,17,20] Most were small, underpowered, industry-sponsored trials or included too few events to arrive at confident conclusions.

Applicability of Evidence

The assessment of the included studies suggests the adjunctive use of TOT for the treatment of DFUs is applicable to the Medicare beneficiary population. About half of the total participants were in studies that took place in the United States. The mean ages of participants across studies approximated Medicare eligibility. The results from trials deemed generalizable to the U.S. Medicare population were consistent with the findings of studies with more narrow inclusion criteria. Additionally, TOT has fewer contraindications when compared to other adjunctive therapies for the treatment of individuals with DFUs, making its use more generalizable. For example, systemic diseases (hepatic, cardiac, renal), bleeding disorders, implants (pacemakers), and arthropathies are contraindications to some alternative interventions.[30-35]

Clinical Guidelines, Agency Reports, Professional Society Positions

The 2023 International Working Group on the Diabetic Foot (IWGDF) evidence-based guideline [36]

Consider the use of topical oxygen as an adjunct therapy to standard of care for wound healing in people with diabetes- related foot ulcers where standard of care alone has failed and resources exist to support this intervention (Conditional; Low).

The American Diabetic Association Standards of Care in Diabetes—2026 [37]

For chronic diabetic foot ulcers that have failed to heal with optimal standard care alone, adjunctive treatment with randomized controlled trial–proven advanced agents should be considered (e.g., negative-pressure wound therapy, several skin substitutes, or topical oxygen therapy). A-level evidence is based on large, well-designed randomized controlled trials or well-done meta-analyses of randomized controlled trials.

“Most DFUs should heal if pressure is removed from the ulcer site, the arterial circulation is sufficient, and infection is managed and treated aggressively...While there is literature to support many modalities currently used to treat diabetic foot wounds, robust RCTs

are often lacking. However, it is agreed that the initial treatment and evaluation of ulcerations include the following five basic principles of ulcer treatment:

- Offloading or pressure relief of ulcerations
- Debridement of hyperkeratotic, necrotic, or nonviable tissue
- Revascularization of ischemic wounds when necessary
- Management of infection: soft tissue or bone
- Use of wound-appropriate topical dressings

However, despite following the above principles, some ulcerations will become chronic and fail to heal...It has been determined that if a wound fails to show a reduction of 50% or more after 4 weeks of appropriate wound management (i.e., the five basic principles above), consideration should be given to the use of advanced wound therapy."

The National Institute for Health and Care Excellence (NICE, UK)—2020 [38]

The main points from the evidence summarized in this briefing are from 3 studies, a randomized controlled trial and 2 observational studies – a total of 172 adults in secondary care. They showed that NATROX effectively treats a range of chronic wounds and is more effective than standard care in people with grade 2 and grade 3 diabetic foot ulcers.

HEALTH TECHNOLOGY WALES (HTW) GUIDANCE 043: Continuous topical oxygen therapy to treat people with chronic non-healing and complex diabetic foot ulcers—2022 [39]

The evidence supports the routine adoption of continuous topical oxygen therapy to treat patients with chronic non-healing and complex diabetic foot ulcers. The use of continuous topical oxygen therapy, in addition to standard of care, increases the number of wounds with complete wound healing and reduces the wound area and time to healing, as compared with standard of care alone.

Wound Healing Society (WHS) guidelines update: Diabetic foot ulcer treatment guidelines—2024 [40]

Topical oxygen has been shown to increase the incidence of healing and decrease the time to heal. (Level I).

Patient Eligibility

Eligibility criteria for adjunctive TOT were described in most of the included primary studies (RCTs, NRSI).[13-21,25] Individuals with either type 1 or 2 DM were generally viewed as eligible to receive TOT.[13-16,18] When specified, a minimum of 4 weeks of optimal SOC needed to have been administered prior to the addition of TOT.[16,19,20,25] Seventy percent of studies included only ulcers graded as 1-2 using the Infectious Diseases Society of America, Wagner-Meggitt, or University of Texas classifications.[14-16,18,19,25] An ulcer duration of at least 4 weeks and no longer than 1 year was a requirement in 60% of trials.[13,15,16,18,19,25] The reported DFU area measurement in studies ranged from 0.5 cm^2 up to 150 cm^2.[13-16,18,20,25] To be eligible for adjunctive TOT, most studies required patients to have adequate arterial perfusion, commonly measured as an ankle brachial index of >0.7 (0.5-1.3) or skin perfusion of >30 mmHg.[13-16,19,21]

Frequently cited exclusions for the administration of TOT in clinical studies were uncontrolled DM (HbA1c >12%), infections (e.g., osteomyelitis, gangrene), neuroarthropathy (Charcot's foot) in the affected limb, deep vein thrombosis, malignancy in the area of the ulcer, immune deficiency or suppression, and severe systemic disease (renal, cardiac, liver). Raynaud's disease was viewed as a contraindication to TOT in one study.[19]

Assessment of Treatment Response

Ulcers that fail to show measurable progress within four weeks of treatment are considered recalcitrant.[41] There is a consistent body of evidence demonstrating that ulcers that do not heal by 40-50% [percentage area reduction (PAR)] in 4 weeks have a low probability of healing at 12 or 14 weeks.[41-44] Thus, the 4-week timeframe is a recognized interval for assessing the healing in DFUs.[45] After at least 4 weeks of treatment, if a DFU still does not improve (area reduction >50%), treatment options should be re-evaluated.[43]

Other studies have established presumptive thresholds of meaningful ulcer size reduction at different time points. Stratman, at al. (2020) defined a clinically meaningful change as a 10% area reduction compared with the start of treatment 14 days earlier.[46] An ad hoc analysis within the same study employed the meaningful wound reduction criterion set to 20%. After 14 days of treatment, more than 80% of chronic wounds showed a minimum 20% reduction in wound surface area. At least two clinical trials have

employed a threshold of 20–40% reduction in area after 2–4 weeks of optimal treatment as relevant for chronic wounds.[47,48] One RCT defined clinical improvement as a 25–75% reduction in the wound area within 8 weeks.[12]

Analysis of Evidence (Rationale for Determination)

Contractor Advisory Committee (CAC)

Following an independent review of the literature, the DME MACs assembled an eight-member, seven voting members and one industry representative, specialty-focused CAC, comprised of a national panel of methodological experts, academicians and clinicians. The CAC meeting was held on December 11, 2024, virtually. Sixteen Key Questions were discussed by the CAC members and confidence in each Key Question scored. Confidence was rated on a scale of 1-5, with 1 indicative of low confidence and 5 indicating high confidence.

Question Number	Question	Scoring Member Average
1	Intermittent Oxygen: 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 diabetic foot ulcers compared to standard of care alone? 1 Low Confidence - 2 - 3 Intermediate - 4 - 5 High Confidence	3.29
2	Continuous Oxygen: 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 diabetic foot ulcers compared to standard of care alone? 1 Low Confidence - 2 - 3 Intermediate - 4 - 5 High Confidence	2.86
3	Intermittent Oxygen: How confident are you that there is sufficient evidence to determine that adjunctive TOT shortens the time to complete resolution of diabetic foot ulcers compared to standard of care alone? 1 Low Confidence - 2 - 3 Intermediate - 4 - 5 High Confidence	3.00
4	Continuous Oxygen: How confident are you that there is sufficient evidence to determine that adjunctive TOT shortens the time to complete resolution of diabetic foot ulcers compared to standard of care alone? 1 Low Confidence - 2 - 3 Intermediate - 4 - 5 High 3Confidence	2.57
5	Intermittent Oxygen: How confident are you that there is sufficient evidence to determine that adjunctive TOT results in durable wound healing of diabetic foot ulcers compared to standard of care alone? 1 Low Confidence - 2 - 3 Intermediate - 4 - 5 High Confidence	3.00
6	Continuous Oxygen: How confident are you that there is sufficient evidence to determine that adjunctive TOT results in durable wound healing of diabetic foot ulcers compared to standard of care alone? 1 Low Confidence - 2 - 3 Intermediate - 4 - 5 High Confidence	2.14
7	Intermittent Oxygen: How confident are you that there is sufficient evidence to determine that adjunctive TOT lowers the risk of amputation in adults with diabetic foot ulcers compared to standard of care alone? 1 Low Confidence - 2 - 3 Intermediate - 4 - 5 High Confidence	2.14
8	Continuous Oxygen: How confident are you that there is sufficient evidence to determine that adjunctive TOT lowers the risk of amputation in adults with diabetic foot ulcers compared to standard of care alone? 1 Low Confidence - 2 - 3 Intermediate - 4 - 5 High Confidence	1.86

Question Number	Question	Scoring Member Average
9	Intermittent Oxygen: How confident are you that TOT is generally accepted by the medical community for the treatment of diabetic foot ulcers? 1 Low Confidence - 2 - 3 Intermediate - 4 - 5 High Confidence	3.00
10	Continuous Oxygen: How confident are you that TOT is generally accepted by the medical community for the treatment of diabetic foot ulcers? 1 Low Confidence - 2 - 3 Intermediate - 4 - 5 High Confidence	3.00
11	Intermittent Oxygen: How confident are you that the available evidence for TOT in diabetic foot ulcers allows identification of a discrete population of Medicare-eligible beneficiaries who would benefit from TOT? 1 Low Confidence - 2 - 3 Intermediate - 4 - 5 High Confidence	3.00
12	Continuous Oxygen: How confident are you that the available evidence for TOT in diabetic foot ulcers allows identification of a discrete population of Medicare-eligible beneficiaries who would benefit from TOT? 1 Low Confidence - 2 - 3 Intermediate - 4 - 5 High Confidence	2.57
13	Intermittent Oxygen: How confident are you that there are no significant gaps in evidence that may impact health outcomes in the Medicare-eligible population? 1 Low Confidence - 2 - 3 Intermediate - 4 - 5 High Confidence	2.57
14	Continuous Oxygen: How confident are you that there are no significant gaps in evidence that may impact health outcomes in the Medicare-eligible population? 1 Low Confidence - 2 - 3 Intermediate - 4 - 5 High Confidence	2.14
15	Intermittent Oxygen: How confident are you that the evidence supports that the use of TOT results in an improvement in quality of life in Medicare beneficiaries? 1 Low Confidence - 2 - 3 Intermediate - 4 - 5 High Confidence	2.71
16	Continuous Oxygen: How confident are you that the evidence supports that the use of TOT results in an improvement in quality of life in Medicare beneficiaries? 1 Low Confidence - 2 - 3 Intermediate - 4 - 5 High Confidence	2.29

For patients with non-healing DFUs that are refractory to optimized diabetic foot ulcer care[37], evidence of efficacy and safety obtained from RCTs and systematic reviews generally favored a clinically relevant net benefit with the application of TOT. Limited evidence suggests TOT in conjunction with optimized diabetic foot ulcer care may result in improvements in quality-of-life measures compared to optimized DFU care alone. Very limited data indicate that TOT, in addition to optimized diabetic foot ulcer care, may reduce the need for subsequent hospitalizations and amputations. There is indirect evidence comparing TOT to other adjunctive therapies that broadly showed no statistically significant differences in efficacy or safety outcomes.

This evidentiary analysis supports the reasonable and necessary use of TOT as an adjunct to optimized DFU care in individuals with certain classes of DFUs. While robust literature is lacking, the overall evidence for TOT as a treatment of DFUs is consistently favorable and applicable to U.S. Medicare beneficiaries. This aligns with clinical society and regulatory body recommendations.

It is well established that DFUs are difficult to treat and produce significant morbidity and mortality. In cases where the patient is refractory to optimized diabetic foot ulcer management[37], there are limited non-surgical treatment options, which also lack robust evidence. Given that the risk of undesirable effects with TOT is consistently low and contraindications are few, limited coverage criteria are included to ensure access for these high-risk patient populations with few alternative therapeutic options. This approach facilitates access to TOT while ensuring that clinically meaningful, net-positive outcomes are supported by an evidence-based review. Specifically, wound closure attributable to TOT with a meaningful degree of certainty is required.

There is a clear need for further investigation and understanding of TOT and its role in the management of chronic non-healing DFUs. Future investigations should address knowledge gaps and aim to produce high-certainty evidence that contributes to the overall understanding of the role of TOT. Empirical studies should seek to compare methods of administration, directly compare TOT with other adjunctive therapies, and establish standardized practices (patient selection, utilization, and outcome assessment).

Proposed Process Information

Synopsis of Changes

Changes	Fields Changed
N/A	N/A

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_2) on a sample of arterial blood. The PO_2 is reported as mmHg. An oximetry test is the indirect measurement of arterial oxygen saturation using a sensor on the ear or finger. The saturation is reported as a percent.

UTILIZATION GUIDELINES

Refer to Coverage Indications, Limitations and/or Medical Necessity

Sources of Information

Home use of Oxygen and Home Oxygen Use to Treat Cluster Headaches (CAG-00296R2) – Decision Memorandum – Published September 27, 2021

Home Use of Oxygen (CAG-00296R3) – Decision Memorandum – Published July 8, 2022

ACIP GRADE Handbook for Developing Evidence-based Recommendations: Formulating Questions, Conducting the Systematic Review, and Assessing the Certainty of the Evidence Using GRADE. Chapter 8: Domains Decreasing Certainty in the Evidence. Updated April 22, 2024. Accessed May 5, 2025.
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Open Meetings

Meeting Date	Meeting States	Meeting Information
08/26/2026	Alaska Alabama Arkansas American Samoa Arizona	Virtual Meeting Time: 12:30pm ET Please refer to the DME MACs' websites for more information.

Meeting Date	Meeting States	Meeting Information
	California - Entire State Colorado Connecticut District of Columbia Delaware Florida Georgia Guam Hawaii Iowa Idaho Illinois Indiana Kansas Kentucky Louisiana Massachusetts Maryland Maine Michigan Minnesota Missouri - Entire State Mississippi Montana North Carolina North Dakota Nebraska New Hampshire New Jersey New Mexico Nevada New York - Entire State Ohio Oklahoma Oregon Pennsylvania Puerto Rico Rhode Island South Carolina South Dakota Tennessee Texas Utah Virginia Virgin Islands Vermont Northern Mariana Islands	

Contractor Advisory Committee (CAC) Meetings

Meeting Date	Meeting States	Meeting Information
12/11/2024	Alaska Alabama Arkansas American Samoa Arizona California - Entire State Colorado Connecticut District of Columbia Delaware Florida Georgia Guam Hawaii Iowa Idaho Illinois Indiana Kansas Kentucky Louisiana Massachusetts Maryland Maine Michigan Minnesota Missouri - Entire State Mississippi Montana North Carolina North Dakota Nebraska New Hampshire New Jersey New Mexico Nevada New York - Entire State Ohio Oklahoma Oregon Pennsylvania Puerto Rico Rhode Island South Carolina South Dakota Tennessee Texas Utah Virginia Virgin Islands Vermont Washington Wisconsin	Virtual Meeting Time: 12 PM CT

Meeting Date	Meeting States	Meeting Information
	West Virginia Wyoming Northern Mariana Islands	

MAC Meeting Information URLs
N/A

Proposed LCD Posting Date
07/23/2026

Comment Period Start Date
07/23/2026

Comment Period End Date
09/05/2026

Reason for Proposed LCD
- Other (1. Request for Coverage by a Manufacturer
  2. Request for Coverage by a Group of Wound Care Specialists)

Requestor Information

Requestor Name	Requestor Letter
Inotec AMD Inc.	View Letter
ALSTON & BIRD Law Firm representing a group of wound care specialists	View Letter

Contact for Comments on Proposed LCD
DME MAC Medical Directors
ATTN: OXY Proposed LCD Comments
4510 13th Ave. S, STE1
Fargo, ND 58103-6646
TOTRecon@noridian.com

Coding Information

CPT/HCPCS Codes

Group 1 (22 Codes)

Group 1 Paragraph
The appearance of a code in this section does not necessarily indicate coverage.

HCPCS MODIFIERS:

CG – Policy criteria applied

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

N1 - Group 1 oxygen coverage criteria met

N2 - Group 2 oxygen coverage criteria met

N3 - Group 3 oxygen coverage criteria met

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

Code	Description
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, 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 (20 Codes)

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
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

Associated Documents

Attachments

OXY Policy Article for DL33797 (411 KB) (Uploaded on 07/09/2026)
Literature Analysis Tables (474 KB) (Uploaded on 07/16/2026)

Related Local Coverage Documents

N/A

Related National Coverage Documents

NCDs

280.1 - Durable Medical Equipment Reference List
240.2 - Home Use of Oxygen
240.2.1 - Home Use of Oxygen in Approved Clinical Trials
270.4 - Treatment of Decubitus Ulcers

Keywords

N/A