UnitedHealthcare®

Reimbursement Policy

Oxygen for Home Use

Policy Number	OXY02082012RP	Approved By	UnitedHealthcare Medicare Reimbursement Policy Committee	Current Approval Date	09/25/2013

IMPORTANT NOTE ABOUT THIS REIMBURSEMENT POLICY

This policy is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

You are responsible for submission of accurate claims. This reimbursement policy is intended to ensure that you are reimbursed based on the code or codes that correctly describe the health care services provided. UnitedHealthcare reimbursement policies use Current Procedural Terminology (CPT®*), Centers for Medicare and Medicaid Services (CMS), or other coding guidelines. References to CPT or other sources are for definitional purposes only and do not imply any right to reimbursement.

This reimbursement policy applies to all health care services billed on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450). Coding methodology, industry-standard reimbursement logic, regulatory requirements, benefits design and other factors are considered in developing reimbursement policy.

This information is intended to serve only as a general resource regarding UnitedHealthcare's reimbursement policy for the services described and is not intended to address every aspect of a reimbursement situation. Accordingly, UnitedHealthcare may use reasonable discretion in interpreting and applying this policy to health care services provided in a particular case. Further, the policy does not address all issues related to reimbursement for health care services provided to UnitedHealthcare enrollees. Other factors affecting reimbursement may supplement, modify or, in some cases, supersede this policy. These factors may include, but are not limited to: legislative mandates, the physician or other provider contracts, and/or the enrollee's benefit coverage documents. Finally, this policy may not be implemented exactly the same way on the different electronic claims processing systems used by UnitedHealthcare due to programming or other constraints; however, UnitedHealthcare strives to minimize these variations.

UnitedHealthcare may modify this reimbursement policy at any time by publishing a new version of the policy on this Website. However, the information presented in this policy is accurate and current as of the date of publication.

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Application

This reimbursement policy applies to services reported using the Health Insurance Claim Form CMS-1500 or its electronic equivalent or its successor form, and services reported using facility claim form CMS-1450 or its electronic equivalent or its successor form. This policy applies to all products, all network and non-network physicians, and other health care professionals.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing UnitedHealthcare. It is not enough to link the procedure code to a correct, payable ICD-9-CM diagnosis code. The diagnosis must be present for the procedure to be paid. Compliance with the provisions in this policy is subject to monitoring by pre-payment review and/or post-payment data analysis and subsequent medical review. The effective date of changes/additions/deletions to this policy is the committee meeting date unless otherwise indicated. Fee schedules, relative value units, conversion factors, and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Summary

Overview

Oxygen and oxygen equipment is covered under the Durable Medical Equipment benefit. In order for a member's equipment to be eligible for reimbursement the reasonable and necessary (R&N) requirements must be met. In addition, there are specific statutory payment policy requirements, which also must be met.

General Coverage Guidelines

Home oxygen is covered only when both the reasonable and necessary criteria discussed below are met.

Home oxygen therapy is reasonable and necessary only if all of the following conditions are met:

1. The treating physician has determined that the patient has a severe lung disease or hypoxia-related symptoms that might be expected to improve with oxygen therapy, and
2. The patient's blood gas study meets the criteria stated below, and
3. The qualifying blood gas study was performed by a physician or by a qualified provider or supplier of laboratory services, and
4. The qualifying blood gas study was obtained under the following conditions:
   - If the qualifying blood gas study is performed during an inpatient hospital stay, the reported test must be the one obtained closest to, but no earlier than 2 days prior to the hospital discharge date, or
   - If the qualifying blood gas study is not performed during an inpatient hospital stay, the reported test must be performed while the patient is in a chronic stable state – i.e., not during a period of acute illness or an exacerbation of their underlying disease, and
5. Alternative treatment measures have been tried or considered and deemed clinically ineffective.

Group I criteria include any of the following:

1. An arterial PO 2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent taken at rest (awake), or
2. An arterial PO 2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, for at least 5 minutes taken during sleep for a patient who demonstrates an arterial PO 2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent while awake, or
3. A decrease in arterial PO 2more than 10 mm Hg, or a decrease in arterial oxygen saturation more than 5 percent from baseline saturation, for at least 5 minutes taken during sleep associated with symptoms (e.g., impairment of cognitive processes and [nocturnal restlessness or insomnia]) or signs (e.g., cor pulmonale, "P" pulmonale on EKG, documented pulmonary hypertension and erythrocytosis) reasonably attributable to hypoxemia, or
4. An arterial PO 2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88 percent, taken

during exercise for a patient who demonstrates an arterial PO 2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent during the day while at rest. In this case, oxygen is provided for during exercise if it is documented that the use of oxygen improves the hypoxemia that was demonstrated during exercise when the patient was breathing room air.

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

Group II criteria include the presence of (a) an arterial PO 2 of 56-59 mm Hg or an arterial blood oxygen saturation of 89 percent at rest (awake), during sleep for at least 5 minutes, or during exercise (as described under Group I criteria) and (b) any of the following:

1. Dependent edema suggesting congestive heart failure, or
2. Pulmonary hypertension or cor pulmonale, determined by measurement of pulmonary artery pressure, gated blood pool scan, echocardiogram, or "P" pulmonale on EKG (P wave greater than 3 mm in standard leads II, III, or AVF), or
3. Erythrocythemia with a hematocrit greater than 56 percent.

Initial coverage for members meeting Group II criteria is limited to 3 months or the physician specified length of need, whichever is shorter. (Refer to the Medical Necessity section for information on recertification).

Group III includes members with arterial PO 2 levels at or above 60 mm Hg or arterial blood oxygen saturations at or above 90 percent. For these situations there is a rebuttable presumption of noncoverage.

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

1. Angina pectoris in the absence of hypoxemia.
2. Dyspnea without cor pulmonale or evidence of hypoxemia.
3. Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities but in the absence of systemic hypoxemia. There is no evidence that increased PO 2 will improve the oxygenation of tissues with impaired circulation.
4. Terminal illnesses that do not affect the respiratory system.

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

Cluster Headaches (NCD 240.2.2)

Home Oxygen Use to Treat Cluster Headaches (CH) is not covered by UnitedHealthcare Medicare Advantage plans.

Effective for claims with dates of services on or after January 4, 2011, the home use of oxygen to treat CH is covered by Medicare only for members with CH participating in an approved prospective clinical study comparing normobaric 100% oxygen (NBOT) with at least one clinically appropriate comparator for the treatment of CH.

Refer to NCD 240.2.2 Home Oxygen Use to Treat Cluster Headaches (CH) Reimbursement Policy for more information on this topic.

Testing Specifications

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

For sleep oximetry studies, the oximeter provided to the member 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.

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

When oxygen is covered based on an oxygen study obtained during exercise, there must be documentation of three (3) oxygen studies in the member's medical record. Testing at rest without oxygen, testing during exercise without oxygen, and testing during exercise with oxygen applied (to demonstrate the improvement of the hypoxemia) are required. All 3 tests must be performed within the same testing session. Only the testing during exercise without oxygen is used for qualification and reported on the medical record documentation. The other two results do not have to be routinely submitted but must be available on request.

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

When both arterial blood gas (ABG) and oximetry tests have been performed on the same day under the same conditions (i.e., at rest/awake, during exercise, or during sleep), the ABG result will be used to determine if the coverage criteria were met.

If an ABG test done at rest and awake is nonqualifying, but either an exercise or sleep oximetry test on the same day is qualifying, the exercise or sleep oximetry test result will determine coverage.

Home Sleep Oximetry Studies:

Members 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 member's home under the following circumstances:

1. The member's treating physician has contacted the IDTF to order an overnight pulse oximetry test before the test is performed.
2. The test is performed under the direction and/or instruction of a Medicare-approved IDTF. Because it is the member who self-administers this test, the IDTF must provide clear written instructions to the member 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 member, apply or demonstrate the application of the testing equipment to the member, or otherwise participate in the conduct of the test.
3. The test unit is sealed and tamper-proof such that test results cannot be accessed by anyone other than the IDTF which is responsible for transmitting a test report to the treating physician. The DME supplier may use related technology to download test results from the testing unit and transmit those results to the IDTF. In no case may the DME supplier access or manipulate the test results in any form.

The IDTF must send the test results to the physician. The IDTF may send the test results to the supplier if the supplier is currently providing or has an order to provide oxygen or other respiratory services to the member or if the member has signed a release permitting the supplier to receive the report.

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

Polysomnography and Home Sleep Tests

Coverage of home oxygen therapy requires that the member be tested in the "chronic stable state." Chronic stable state is a requirement of the National Coverage Determination (CMS Internet-only Manual, Pub. 100-3, Section 240.2) and is one of the key criteria when determining coverage of home oxygen therapy.

The NCD defines chronic stable state as "…not during a period of an acute illness or an exacerbation of their underlying disease." Based on this NCD definition, all co-existing diseases or conditions that can cause hypoxia must be treated and the member must be in a chronic stable state before oxygen therapy is considered eligible for payment. In the case of OSA, it is required that the OSA be appropriately and sufficiently treated such that the member is in the chronic stable state before oxygen saturation results obtained during sleep testing are considered qualifying for oxygen therapy.

Portable Oxygen Systems

A portable oxygen system is covered if the member is mobile within the home and the qualifying blood gas study was performed while at rest (awake) or during exercise. If the only qualifying blood gas study was performed during sleep, portable oxygen will be denied as not reasonable and necessary. If coverage criteria

are met, a portable oxygen system is usually separately payable in addition to the stationary system. See exception in the related Policy Article Nonmedical Necessity Coverage and Payment Rules, OXYGEN EQUIPMENT, Initial 36-Months section. If a portable oxygen system is covered, the supplier must provide whatever quantity of oxygen the patient uses; Medicare's reimbursement is the same, regardless of the quantity of oxygen dispensed.

Liter Flow Greater Than 4 LPM

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

Miscellaneous Oxygen Use

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

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

Suppliers must not dispense a quantity of supplies exceeding a member's expected utilization. Suppliers must stay attuned to changed or atypical utilization patterns on the part of their clients. Suppliers must verify with the ordering physicians that any changed or atypical utilization is warranted.

RENTAL GUIDELINES

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 member's portable oxygen equipment differs from the RUL of the member'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 member may elect to obtain replacement of both the stationary and the portable oxygen equipment. If the member 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 member 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 member 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 member 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 patients requiring greater than 4 liters per minute (LPM) of oxygen flow and decreased for member s requiring less than 1 LPM. If a member qualifies for additional payment for greater than 4 LPM of oxygen and also meets the requirements for portable oxygen, payment will be made for the stationary system at the higher allowance, but not for the portable system. In this situation, if both a stationary system and a portable system are billed for the same rental month, the portable oxygen system will be denied as not separately payable.

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:

- Member relocates temporarily or permanently outside of the supplier's service area
- Member 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, transfilling equipment) is not permitted unless one of the following requirements is met:

- Supplier replaces the equipment with the same or equivalent item
- Physician orders different equipment
- UHC 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 physician 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, E0434, E1392, K0738, E0433) 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 physician order or member 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 member may elect to receive new equipment, thus beginning a new 36-month rental period.

If the member 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 member was using gaseous or liquid oxygen equipment during the 36th rental month, payment can continue to be made for oxygen contents.

If the member 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 member, accessories, maintenance, and repairs are statutorily noncovered by Medicare. Contents are separately payable for patient-owned gaseous or liquid systems.

If a member enters Medicare FFS with member-owned equipment, accessories, maintenance, and repairs are statutorily noncovered by Medicare. Contents are separately payable for patient-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 member 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 member was using portable gaseous or liquid equipment during the 36th rental month of stationary equipment (gaseous, liquid, or concentrator), payment for portable contents (E0443 or E0444) begins when the rental period for the stationary equipment ends. If the member 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 member 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 member 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 physician order, contents may be paid.

If the member 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 member'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 members receiving more the than 4 LPM or less than 1 LPM.

Maintenance of Equipment

Initial 36 Months: There is no separate payment for maintenance and servicing (M&S)

Months 37 Through 60: If a member was using a stationary concentrator, portable concentrator, or transfilling equipment during the 36th rental month, Medicare will pay for a 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 member elects not to replace a concentrator or transfilling equipment and if the supplier retains title to the equipment, coverage for M&S is the same as in months 37-60.

If the member elects not to replace a concentrator or transfilling equipment and if the supplier transfers title to the member, M&S is statutorily noncovered.

Medical Necessity Requirements

An Initial, Recertification, or Revised Medical Record Documentation must be obtained and submitted in the situations described below.

Initial Medical Record Documentation is Required:

1. With the first claim for home oxygen, (even if the member 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 member'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.
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 Medical Record Documentation for situations 1 and 2:

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

Initial Medical Record Documentation 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 Medical Record Documentation Date. It could be the test result reported on the most recent prior questionnaire.
- There is no requirement for a physician visit that is specifically related to the completion of the Medical Record Documentation for replacement equipment.

Recertification Medical Record Documentation is Required:

5. 12 months after Initial Medical Record Documentation has been completed (i.e., with the thirteenth month's claim) for Group I.
6. 3 months after the Initial Medical Record Documentation has been completed (i.e., with the fourth month's claim) for Group II.

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Recertification following the completion of the Initial Medical Record Documentation for situations 1 and 2:

- For members initially meeting Group I criteria, the most recent **qualifying** blood gas study prior to the thirteenth month of therapy must be reported on the Medical Record Documentation.
- For members initially meeting Group II criteria, the most recent blood gas study that was performed between the 61st and 90th day following the Initial Medical Record Documentation must be reported on the Medical Record Documentation. If a qualifying test is not obtained between the 61st and 90th day of home oxygen therapy but the member 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 members initially meeting group I or II criteria, the member must be seen and re-evaluated by the treating physician within 90 days prior to the date of any Recertification. If the physician visit is not obtained within the 90-day window but the member 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 Medical Record Documentation.
- There is no requirement for a physician visit that is specifically related to the completion of the Medical Record Documentation for replacement equipment.

Revised Medical Record Documentation is Required:

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

If the change is from category (a) or (b) to category (c), a repeat blood gas study with the patient on 4 LPM must be performed.

8. When the length of need expires – if the physician specified less than lifetime length of need on the most recent Medical Record Documentation.
9. When a portable oxygen system is added subsequent to the Initial Medical Record Documentation for a stationary system.
10. When a stationary system is added subsequent to Initial Medical Record Documentation for a portable system
11. When there is a new treating physician but the oxygen order is the same.
12. If there is a new supplier and that supplier does not have the prior Medical Record Documentation.

Submission of a Revised Medical Record Documentation does not change the Recertification schedule specified above.

*None of the Revised Record Medical Documentation situations (7-12) require a phy*sician visit.

Revised Medical Record Documentation situations 7 and 8:

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

Revised Medical Record Documentation 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 member is at rest (awake) or during exercise within 30 days prior to the Revised Date.

Revised Medical Record Documentation situations 10-12:

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

A completed and signed Medical Record Documentation is required to receive payment for oxygen.

Documentation Guidelines

Section 1833(e) of the Social Security Act precludes payment to any provider of services unless "there has been furnished such information as may be necessary in order to determine the amounts due such provider". It is expected that the patient's medical records will reflect the need for the care provided. The patient's medical records include the physician's office records, hospital records, nursing home records, home health

agency records, records from other healthcare professionals and test reports. This documentation must be available upon request.

Prescription (Order) Requirements

An order for each item billed must be signed and dated by the treating physician, kept on file by the supplier, and made available upon request. Items dispensed and/or billed that do not meet these prescription requirements and those below must be submitted with an EY modifier added to each affected HCPCS code.

Dispensing Orders

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

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

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

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

Detailed Written Orders

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

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

Policy Specific Documentation Requirements

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

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

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

If no frequency or duration of use is specified “continuous use” is assumed. Duration of need may be specified on the Medical Record Documentation.

Documentation for initial coverage requires:

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

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

Continued Use

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

Continued Medical Need

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

whether reimbursement was justified based upon the applicable coverage policy.

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

Refill Documentation

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

- There is a change of supplier
- There is a change in treating physician
- There is a change in the item(s), frequency of use, or amount prescribed
- There is a change in the length of need or a previously established length of need expires

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

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

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

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

Medical Record Documentation

Medical Record Documentation which has been completed, signed, and dated by the treating physician must be kept on file by the supplier and made available upon request. In addition to the order information that the physician enters, the supplier can add a written confirmation of other details of the oxygen order or the physician can enter the other details directly–e.g., the means of oxygen delivery (cannula, mask, etc.) and the specifics of varying oxygen flow rates and/or noncontinuous use of oxygen.

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

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

Replacement Equipment:

For situations 3 and 4 described in the Medical Record Documentation section of the policy, 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 Medical Record Documentation (for the replacement equipment) meets Group I criteria or 3 months following the Initial Date when the qualifying blood gas value on the Initial Medical Record Documentation meets the Group II criteria. (Note: The Initial Date [for the replacement equipment] should also be entered on the Medical Record Documentation.)
- 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.

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Miscellaneous:

In the following situations, a new order must be obtained and kept on file by the supplier, but a new repeat blood gas study is NOT required:

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

CLUSTER HEADACHES (NCD 240.2.2)

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

Refer to NCD 240.2.2 Home Oxygen Use to Treat Cluster Headaches (CH) Reimbursement Policy for more information on this topic.

BILLING AND CODING GUIDELINES:

The appropriate modifier must be used if the prescribed flow rate is less than 1 LPM (QE) or greater than 4 LPM (QF or QG). These modifiers may only be used with stationary gaseous (**E0424**) or liquid (**E0439**) systems or with an oxygen concentrator (**E1390, E1391**). They must not be used with codes for portable systems or oxygen contents.

- Code **E1391** (Oxygen concentrator, dual delivery port) is used in situations in which two members are both using the same concentrator. In this situation, this code should only be billed for one of the members.
- 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 Pricing, Data Analysis, and Coding (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 member-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 member 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 member 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 using **E1399**. (Refer to the Cluster Headache section in the Coverage Guidelines section of the policy for coverage information)

Refill contents used with equipment treat cluster headaches must be coded using **E1399**. One (1) unit of service equals one (1) month's supply.

CPT / HCPCS Codes

Accessories: The appearance of a code in this section does not necessarily indicate coverage

Code	Description
A4575	Topical hyperbaric oxygen chamber, disposable (Not covered by Medicare in any payment system)

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A4606	Oxygen probe for use with oximeter device, replacement
A4608	Transtracheal oxygen catheter, each
A4615	Cannula, nasal
A4616	Tubing (oxygen), per foot
A4617	Mouth piece
A4619	Face tent
A4620	Variable concentration mask
A7525	Tracheostomy mask, each
A9900	Miscellaneous DME supply, accessory, and/or service component of another HCPCS code
E0455	Oxygen tent, excluding croup or pediatric tents
E0555	Humidifier, durable, glass or autoclavable plastic bottle type, for use with regulator or flowmeter
E0580	Nebulizer, durable, glass or autoclavable plastic, bottle type, for use with regulator or flowmeter
E1353	Regulator
E1354	Oxygen accessory, wheeled cart for portable cylinder or portable concentrator, any type, replacement only, each
E1355	Stand/rack
E1356	Oxygen accessory, battery pack/cartridge for portable concentrator, any type, replacement only, each
E1357	Oxygen accessory, battery charger for portable concentrator, any type, replacement only, each
E1358	Oxygen accessory, dc power adapter for portable concentrator, any type, replacement only, each
E1399	Durable medical equipment, miscellaneous
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 *(Not covered by Medicare in any payment system)*
E0430	Portable gaseous oxygen system, purchase; includes regulator, flowmeter, humidifier, cannula or mask, and tubing *(Not covered by Medicare in any payment system)*
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 *(Not covered by Medicare in any payment system)*
E0439	Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, & tubing

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E0440	Stationary liquid oxygen system, purchase; includes use of reservoir, contents indicator, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing *(Not covered by Medicare in any payment system)*
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 noninvasively
E0446	Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories *(Not covered by Medicare in any payment system)*
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
K0741	Portable gaseous oxygen system, rental, includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing, for cluster headaches *(**Non-Covered**) (Expired 12/31/2012; No Code Replacement)*
K0742	Portable oxygen contents, gaseous, 1 month's supply = 1 unit, for cluster headaches, for initial months supply or to replace used contents *(**Non-Covered**) (Expired 12/31/2012; No Code Replacement)*

Modifiers

Code	Description
EY	No physician or other licensed health care provider order for this item or service
RA	Replacement of a DME item
Q0	Investigational clinical service provided in a clinical research study that is in an approved clinical research study
QE	Prescribed amount of oxygen is less than 1 liter per minute (LPM)
QF	Prescribed amount of oxygen is greater than 4 liter per minute (LPM) and portable oxygen is also prescribed
QG	Prescribed amount of oxygen is greater than 4 liters per minute (LPM) and portable oxygen is not prescribed
QH	Oxygen conserving device is being used with an oxygen delivery system

References Included (but not limited to):

CMS NCD(s)

NCD 240.2 Home Use of Oxygen

NCD 240.2.1 Home Use of Oxygen in Approved Clinical Trials

NCD 240.2.2 Home Oxygen Use to Treat Cluster Headaches (CH)

CMS Article(s)

Numerous Articles

Oxygen for Home Use

CMS LCD(s)

Numerous LCDs

CMS Benefit Policy Manual

Chapter 15; § 110 Durable Medical Equipment - General

CMS Claims Processing Manual

Chapter 20; § 30.6 Oxygen and Oxygen Equipment

CMS Transmittals

Transmittal 2465, Change Request 7820, Dated 05/11/2012 (Assigned Codes for Home Oxygen Use for Cluster Headache (CH) in a Clinical Trial (ICD-10))

Transmittal 130, Change Request 7235, Dated 01/14/2011 (Home Oxygen Use to Treat Cluster Headache (CH))

UnitedHealthcare Medicare Advantage Coverage Summaries

Oxygen for Home Use

Durable Medical Equipment (DME), Prosthetics, Corrective Appliances/Orthotics (Non-Foot Orthotics) and Medical Supplies Grid

UnitedHealthcare Reimbursement Policies

Home Use of Oxygen Reimbursement Policy

Home Use of Oxygen in Approved Clinical Trials Reimbursement Policy

Home Oxygen Use to Treat Cluster Headaches (CH) Reimbursement Policy

MLN Matters

Article MM7820, Assigned Codes for Home Oxygen Use for Cluster Headache (CH) in a Clinical Trial (ICD-10)

Article MM7235, Home Oxygen Use to Treat Cluster Headache (CH)

Others

MLN Network ICN 904883: Oxygen Therapy Supplies: Complying with Documentation and Coverage Requirements, December 2011

Medicare Program Integrity Manual: Chapter 5-Items and Services Having Special DME Review Considerations

History

Date	Revisions
08/27/2014	Policy content modified to remove reference to the Advance Beneficiary Notice of Noncoverage (ABN)
09/25/2013	Re-review presented to MRPC for approval
07/09/2012	Administrative updates
02/09/2012	Administrative updates
02/08/2012	• Policy Implemented • Policy created and approved

