HOME USE OF OXYGEN (NCD 240.2)

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Related Medicare Advantage Policy Guidelines

- Continuous Positive Airway Pressure (CPAP) 
  Therapy for Obstructive Sleep Apnea (OSA) (NCD 240.4) and Other Respiratory Assist Devices (RAD)
- Home Use of Oxygen in Approved Clinical Trials (NCD 240.2.1)
- Home Oxygen Use to Treat Cluster Headache (CH) (NCD 240.2.2)

Related Medicare Advantage Coverage Summaries

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

POLICY SUMMARY

Overview
Medicare coverage of home oxygen and oxygen equipment under the durable medical equipment (DME) benefit (see §1861(s)(6) of the Social Security Act) is considered reasonable and necessary only for patients with significant hypoxemia who meet the medical documentation, laboratory evidence, and health conditions specified below. The information below also includes special coverage criteria for portable oxygen systems. Finally, a statement on the absence of coverage of the professional services of a respiratory therapist under the DME benefit is included below.

Guidelines
Medical Documentation
Initial claims for oxygen services must include a completed span Form CMS-484 (Certificate of Medical Necessity: Oxygen) to establish whether coverage criteria are met and to ensure that the oxygen services provided are consistent with the physician's prescription or other medical documentation. The treating physician's prescription or other medical documentation must indicate that other forms of treatment (e.g., medical and physical therapy directed at secretions, bronchospasm and infection) have been tried, have not been sufficiently successful, and oxygen therapy is still required. While there is no substitute for oxygen therapy, each patient must receive optimum therapy before long-term home oxygen therapy is ordered. Use Form CMS-484 for recertifications. (See the Medicare Program Integrity Manual, Chapter 5, for completion of Form CMS-484.)

The medical and prescription information in section B of Form CMS-484 can be completed only by the treating physician, the physician's employee, or another clinician (e.g., nurse, respiratory therapist, etc.) as long as that person is not the DME supplier. Although hospital discharge coordinators and medical social workers may assist in arranging for physician-prescribed home oxygen, they do not have the authority to prescribe the services. Suppliers may not enter this information. While this section may be completed by nonphysician clinician or a physician employee, it must be reviewed and the form CMS-484 signed by the attending physician.

A physician's certification of medical necessity for oxygen equipment must include the results of specific testing before coverage can be determined.

Claims for oxygen must also be supported by medical documentation in the patient's record. Separate documentation is used with electronic billing. (See Medicare Carriers Manual, Part 3, §4105.5.) This documentation may be in the form of a prescription written by the patient's attending physician who has recently examined the patient (normally within a month of the start of therapy) and must specify:
• A diagnosis of the disease requiring home use of oxygen;
• The oxygen flow rate; and
• An estimate of the frequency, duration of use (e.g., 2 liters per minute, 10 minutes per hour, 12 hours per day), and duration of need (e.g., 6 months or lifetime).

**Note:** A prescription for "Oxygen PRN" or "Oxygen as needed" does not meet this last requirement. Neither provides any basis for determining if the amount of oxygen is reasonable and necessary for the patient.

A member of the A/B MAC (B) medical staff should review all claims with oxygen flow rates of more than 4 liters per minute before payment can be made.

The attending physician specifies the type of oxygen delivery system to be used (i.e., gas, liquid, or concentrator) by signing the completed form CMS-484. In addition the supplier or physician may use the space in section C for written confirmation of additional details of the physician's order. The additional order information contained in section C may include the means of oxygen delivery (mask, nasal, cannula, etc.), the specifics of varying flow rates, and/or the non-continuous use of oxygen as appropriate. The physician confirms this order information with their signature in section D.

New medical documentation written by the patient's attending physician must be submitted to the A/B MAC (B) in support of revised oxygen requirements when there has been a change in the patient's condition and need for oxygen therapy.

A/B MACs(B) are required to conduct periodic, continuing medical necessity reviews on patients whose conditions warrant these reviews and on patients with indefinite or extended periods of necessity as described in the Medicare Program Integrity Manual, Chapter 5, "Items and Services Having Special DMERC Review Considerations." When indicated, A/B MACs (B) may also request documentation of the results of a repeat arterial blood gas or oximetry study.

**Note:** Section 4152 of OBRA 1990 requires earlier recertification and retesting of oxygen patients who begin coverage with an arterial blood gas result at or above a partial pressure of 55 or an arterial oxygen saturation percentage at or above 89. (See the Medicare Claims Processing Manual, Chapter 20, "Durable Medical Equipment, Prosthetics and Orthotics, and Supplies (DMEPOS)," §100.2.3 for certification and retesting schedules.)

**Laboratory Evidence**

Initial claims for oxygen therapy must also include the results of a blood gas study that has been ordered and evaluated by the attending physician. This is usually in the form of a measurement of the partial pressure of oxygen (PO 2) in arterial blood. (See Medicare Carriers Manual, Part 3, §2070.1 for instructions on clinical laboratory tests.) A measurement of arterial oxygen saturation obtained by ear or pulse oximetry, however, is also acceptable when ordered and evaluated by the attending physician and performed under his or her supervision or when performed by a qualified provider or supplier of laboratory services.

When the arterial blood gas and the oximetry studies are both used to document the need for home oxygen therapy and the results are conflicting, the arterial blood gas study is the preferred source of documenting medical need. A DME supplier is not considered a qualified provider or supplier of laboratory services for purposes of these guidelines.

This prohibition does not extend to the results of blood gas test conducted by a hospital certified to do such tests. The conditions under which the laboratory tests are performed must be specified in writing and submitted with the initial claim, i.e., at rest, during exercise, or during sleep.

The preferred sources of laboratory evidence are existing physician and/or hospital records that reflect the patient's medical condition. Since it is expected that virtually all patients who qualify for home oxygen coverage for the first time under these guidelines have recently been discharged from a hospital where they submitted to arterial blood gas tests, the A/B MAC (B) needs to request that such test results be submitted in support of their initial claims for home oxygen. If more than one arterial blood gas test is performed during the patient's hospital stay, the test result obtained closest to, but no earlier than 2 days prior to the hospital discharge date is required as evidence of the need for home oxygen therapy.

For those patients whose initial oxygen prescription did not originate during a hospital stay, blood gas studies should be done while the patient is in the chronic stable state, i.e., not during a period of an acute illness or an exacerbation of their underlying disease.

A repeat arterial blood gas study is appropriate when evidence indicates that an oxygen recipient has undergone a major change in their condition relevant to home use of oxygen. If the A/B MAC (B) has reason to believe that there
has been a major change in the patient's physical condition, it may ask for documentation of the results of another blood gas or oximetry study.

**Health Conditions**
Coverage is available for patients with significant hypoxemia in the chronic stable state if:

- The attending physician has determined that the patient has a health condition outlined above,
- The patient meets the blood gas evidence requirements specified above, and
- The patient has appropriately tried other alternative treatment measures without complete success. (See above.)

**Conditions for Which Oxygen Therapy May Be Covered**
- A severe lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, whether of known or unknown etiology; cystic fibrosis, bronchiectasis; widespread pulmonary neoplasm; or
- Hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy. Examples of these symptoms and findings are pulmonary hypertension, recurring congestive heart failure due to chronic cor pulmonale, erythrocytosis, impairment of the cognitive process, nocturnal restlessness, and morning headache.

**Conditions for Which Oxygen Therapy Is Not Covered**
- 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;
- Breathlessness without cor pulmonale or evidence of hypoxemia. Although intermittent oxygen use is sometimes prescribed to relieve this condition, it is potentially harmful and psychologically addicting;
- Severe peripheral vascular disease resulting in clinically evident desaturation in one or more extremities. There is no evidence that increased PO₂ improves the oxygenation of tissues with impaired circulation; or
- Terminal illnesses that do not affect the lungs.

**Covered Blood Gas Values**
If the patient has a condition specified in above, the A/B MAC (B) must review the medical documentation and laboratory evidence that has been submitted for a particular patient (see above) and determine if coverage is available under one of the three group categories outlined below.

**Group I** - Except as modified as listed above, coverage is provided for patients with significant hypoxemia evidenced by any of the following:
- An arterial PO₂ at or below 55 mm Hg, or an arterial oxygen saturation at or below 88%, taken at rest, breathing room air.
- An arterial PO₂ at or below 55 mm Hg, or an arterial oxygen saturation at or below 88%, taken during sleep for a patient who demonstrates an arterial PO₂ at or above 56 mm Hg, or an arterial oxygen saturation at or above 89%, while awake; or a greater than normal fall in oxygen level during sleep (a decrease in arterial PO₂ more than 10 mm Hg, or decrease in arterial oxygen saturation more than 5%) associated with symptoms or signs reasonably attributable to hypoxemia (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia). In either of these cases, coverage is provided only for use of oxygen during sleep, and then only one type of unit will be covered. Portable oxygen, therefore, would not be covered in this situation.
- An arterial PO₂ at or below 55 mm Hg or an arterial oxygen saturation at or below 88%, taken during exercise for a patient who demonstrates an arterial PO₂ at or above 56 mm Hg, or an arterial oxygen saturation at or above 89%, during the day while at rest. In this case, supplemental oxygen is provided for during exercise if there is evidence the use of oxygen improves the hypoxemia that was demonstrated during exercise when the patient was breathing room air.

**Group II** - Except as modified as listed above, coverage is available for patients whose arterial PO₂ is 56-59 mm Hg or whose arterial blood oxygen saturation is 89%, if there is evidence of:
- Dependent edema suggesting congestive heart failure;
- 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 AVFL; or
- Erythrocythemia with a hematocrit greater than 56%.

**Group III** - Except as modified as listed above, A/B MACs (B) must apply a rebuttable presumption that a home program of oxygen use is not medically necessary for patients with arterial PO₂ levels at or above 60 mm Hg, or arterial blood oxygen saturation at or above 90%. In order for claims in this category to be reimbursed, the A/B MAC (B)'s reviewing physician needs to review any documentation submitted in rebuttal of this presumption and grant specific approval of the claims. Few are expected claims to be approved for coverage in this category.

**Variable Factors That May Affect Blood Gas Values** - In reviewing the arterial PO₂ levels and the arterial oxygen saturation percentages specified above, the A/B MAC (B) medical staff must take into account variations in oxygen...
measurements that may result from such factors as the patient's age, the altitude level, or the patient's decreased oxygen carrying capacity.

**Portable Oxygen Systems**
A patient meeting the requirements specified below may qualify for coverage of a portable oxygen system either (1) by itself, or, (2) to use in addition to a stationary oxygen system. A portable oxygen system is covered for a particular patient if:

- The claim meets the requirements specified above, as appropriate; and
- The medical documentation indicates that the patient is mobile in the home and would benefit from the use of a portable oxygen system in the home. Portable oxygen systems are not covered for patients who qualify for oxygen solely based on blood gas studies obtained during sleep.

**Respiratory Therapists**
Respiratory therapists' services are not covered under the provisions for coverage of oxygen services under the Part B DME benefit as outlined above. This benefit provides for coverage of home use of oxygen and oxygen equipment, but does not include a professional component in the delivery of such services.

**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 members requiring greater than 4 liters per minute (LPM) of oxygen flow and decreased for members 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
- Member chooses to receive an upgrade and signs an Advance member Notice of Noncoverage (ABN)
- CMS or the DME MAC determines that a change in equipment is warranted

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

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

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 less than 60 days plus the days remaining in the month of discontinuation
- Break-in-billing
- Changing suppliers
**Months 37-60**

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

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

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

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

A new 36-month rental period can begin only in the following situation: There is a specific incident of damage beyond repair (e.g., dropped and broken, fire, flood, etc.) or the item is stolen or lost.

A new 36-month rental period does not start in the following situations:
- Replacing equipment due to malfunction, wear and tear, routine maintenance, repair
- Providing different equipment based on a physician order or member request for an upgrade
- Break-in-need
- Break-in-billing
- 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 member-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 began using portable gaseous or liquid equipment during the 36th rental month of stationary equipment, payment for both stationary contents (E0441 or E0442) and portable contents (E0443 or E0444) begins when the rental for the stationary equipment ends.

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.

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

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

**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, UnitedHealthcare Medicare Advantage will pay for an M&S visit no more often than every 6 months, beginning no sooner than 6 months following the end of the rental period. If the equipment is covered under a warranty that covers labor related to routine/general maintenance and servicing (e.g., inspection, changing filters, cleaning, and calibration), payment for the first M&S visit can be no sooner than 6 months following the end of that warranty. A supplier must actually make a visit to bill the service. If multiple M&S visits are made during a 6 month period, only one will be paid. There is no M&S payment for gaseous or liquid equipment.

**Month 61 and after**
If the 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.

**Certification**
An Initial, Recertification, or Revised CMN must be obtained and submitted in the situations described below. The Initial Date, Recertification Date, and Revised Date specified below refer to the dates reported in Section A of the CMN.

**Initial CMN is Required**
1. With the first claim for home oxygen, (even if the 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 CMN for situations 1 and 2**
- The blood gas study must be the most recent study obtained within 30 days prior to the Initial Date.
- For situation 1, there is an exception to the 30-day test requirement for members 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 Initial 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 Initial Certification.

**Initial CMN for scenarios 3 and 4 (replacement equipment)**
- Repeat blood gas testing is not required. Enter the most recent qualifying value and test date. This test does not have to be within 30 days prior to the Initial Date. It could be the test result reported on the most recent prior CMN.
- There is no requirement for a physician visit that is specifically related to the completion of the CMN for replacement equipment.
Recertification CMN is Required:
5. 12 months after Initial Certification, (i.e., with the thirteenth month’s claim) for Group I
6. 3 months after Initial Certification, (i.e., with the fourth month’s claim) for Group II

Recertification following initial certification 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 Recertification CMN.
• For members initially meeting Group II criteria, the most recent blood gas study that was performed between the 61st and 90th day following Initial Certification must be reported on the Recertification CMN. If a qualifying test is not obtained between the 61st and 90th day of home oxygen therapy but the 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 CMN.
• There is no requirement for a physician visit that is specifically related to the completion of the CMN for replacement equipment.

Revised CMN is Required:
7. When the prescribed maximum flow rate changes from one of the following categories to another:
   a. Less than 1 LPM,
   b. 1-4 LPM,
   c. Greater than 4 LPM
   If the change is from category (a) or (b) to category (c), a repeat blood gas study with the Member on 4 LPM must be performed.
8. When the length of need expires – if the physician specified less than lifetime length of need on the most recent CMN
9. When a portable oxygen system is added subsequent to Initial Certification of a stationary system
10. When a stationary system is added subsequent to Initial Certification of a portable system
11. When there is a new treating physician but the oxygen order is the same
12. If there is a new supplier and that supplier does not have the prior CMN

Submission of a Revised CMN does not change the Recertification schedule specified above.
If the indications for a Revised CMN are met at the same time that a Recertification CMN is due, file the CMN as a Recertification CMN.

Testing and Visit Requirements
None of the Revised Certification situations (7-12) require a physician visit.

Revised Certification situations 7 and 8
• The blood gas study must be the most recent study obtained within 30 days prior to the Initial Date.

Revised Certification situation 9
• There is no requirement for a repeat blood gas study unless the initial qualifying study was performed during sleep, in which case a repeat blood gas study must be performed while the Member is at rest (awake) or during exercise within 30 days prior to the Revised Date.

Revised Certifications situations 10-12
• No blood gas study is required
• For situations 11 and 12, the revised certification does NOT have to be submitted with the claim.
General:
Members do not change group classification going from an initial certification to a recertification based upon changes in blood oxygen testing results. For example: A Member initially qualifies for group II with an 89% oximetry value. At the 3-month retest a result of 87% is obtained. Despite the group I retesting value, the Member remains in group II. There is no reclassification to group I. Further recertification is not required unless:
- A non-qualifying test result is obtained at the time of recertification but the Member later obtains a qualifying test result; or,
- The specified length of need (LON) is reached.

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

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

A completed and signed Certificate of Medical Necessity (CMN) is required to receive payment for oxygen. Claims submitted without a valid CMN will be denied as not reasonable and necessary.

Portable Oxygen Systems
A portable oxygen system is covered if the 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 Member uses; UnitedHealthcare Medicare Advantage 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 or more LPM meets Group I or II criteria. If a flow rate greater than 4 LPM is billed and the coverage criterion for the higher allowance is not met, payment will be limited to the standard fee schedule allowance.

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

Emergency or stand-by oxygen systems for 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.

Oxygen services furnished by an airline to a member are noncovered. Payment for oxygen furnished by an airline is the responsibility of the member and not the responsibility of the supplier.

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

Only rented oxygen equipment is eligible for coverage. Purchased oxygen equipment is statutorily noncovered.

Oximeters (E0445) and replacement probes (A4606) will be denied as noncovered because they are monitoring devices that provide information to physicians to assist in managing the member’s treatment.

Respiratory therapist services are noncovered under the DME benefit.
Refills of Oxygen Contents
For Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items and supplies provided on a recurring basis, billing must be based on prospective, not retrospective use. Oxygen contents are reimbursed with a monthly allowance covering all contents necessary for the month. Supply allowances are not subject to the refill monitoring and documentation requirements specified by Medicare Program Integrity Manual section 5.2.6. All other supplies, e.g. tubing, masks or cannulas, etc., are included in the monthly rental payment. Supplies that are not separately payable are not subject to the refill monitoring and documentation requirements specified by Medicare Program Integrity Manual section 5.2.6.

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.
- 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.
- 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.

Exercise Testing
When oxygen is covered based on an oximetry study obtained during exercise, there must be documentation of three (3) oximetry studies in the member’s medical record. (1) Testing at rest without oxygen, (2) testing during exercise without oxygen, and (3) testing during exercise with oxygen applied (to demonstrate the improvement of the hypoxemia) are required. All 3 tests must be performed within the same testing session. Exercise testing must be performed in-person by a physician or other medical professional qualified to conduct exercise oximetry testing. Unsupervised or remotely supervised home exercise testing does not qualify as a valid test for purposes of reimbursement of home oxygen and oxygen equipment. Only the testing during exercise without oxygen is used for qualification and reported on the CMN. The other two results do not have to be routinely submitted but must be available on request. Oximetry obtained after exercise while resting, sometimes referred to as “recovery” testing, is not part of the three required test elements and is not valid for determining eligibility for oxygen coverage.

Overnight Oximetry Studies
Overnight sleep oximetry may be performed in a facility or at home. For home overnight oximetry studies, the oximeter provided to the 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.
For all the overnight oximetry criteria described above, the 5 minutes does not have to be continuous. Baseline saturation is defined as the mean saturation level during the duration of the test. For purposes of meeting criterion 3 described in Group I above there must be a minimum of 2 hours test time recorded for sleep oximetry. The result must reach a qualifying test value otherwise the Group III presumption of noncoverage applies. Home overnight oximetry is limited solely to stand-alone overnight pulse oximetry performed in the member’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.

Members may self-administer home based overnight oximetry tests under the direction of an 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:

- The member’s treating physician has contacted the IDTF to order an overnight pulse oximetry test before the test is performed.
- The test is performed under the direction and/or instruction of an 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.
- 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 as described for home overnight oximetry (see above) 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.

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

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

Some members may require the simultaneous use of home oxygen therapy with a PAP device. To be considered for simultaneous coverage, all requirements in the Coverage Indications, Limitations and/or Medical Necessity for both the Oxygen and Oxygen Equipment and Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea LCDs must be met. See Continuous Positive Airway Pressure (CPAP) Therapy For Obstructive Sleep Apnea (OSA) (NCD 240.4) and other Respiratory Assist Devices (RAD) Reimbursement Policy for additional information.

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

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

- The titration is conducted over a minimum of two (2) hours; and
- During titration:
  - The AHI/RDI is reduced to less than or equal to an average of ten (10) events per hour; or
  - 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
- Nocturnal oximetry conducted for the purpose for oxygen reimbursement qualification may only be performed after optimal PAP settings have been determined and the member is using the PAP device at those settings; and
- The nocturnal oximetry conducted during the PSG demonstrates an oxygen saturation ≤ 88% for 5 minutes total (which need not be continuous)

If all of the above criteria are met, for the purposes of a qualifying oxygen saturation test, the member is considered to be in the "chronic stable state." To be eligible for coverage and payment for home oxygen therapy for concurrent use with PAP therapy, in addition to being in the chronic stable state, the member must meet all other coverage requirements for oxygen therapy. Members that qualify for oxygen therapy based on testing conducted only during the course of a sleep test are eligible only for reimbursement of stationary equipment. Overnight oximetry performed as part of home sleep testing or as part of any other home testing is not considered as eligible to be used for qualification for reimbursement of home oxygen and oxygen equipment (see overnight oximetry section above for additional information). Claims for oxygen equipment and supplies for members who do not meet the coverage requirements for home oxygen therapy will be denied as not reasonable and necessary.

**Long Term Oxygen Therapy Clinical (LTOT) Trials**
Refer to NCD 240.2.1 Home Use of Oxygen in Approved Clinical Trials.

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

**Documentation Requirements**
Before submitting a claim to UHC, the supplier must have on file a dispensing order (if applicable), a DWO, a WOPD (if applicable), a CMN (if applicable), a DIF (if applicable), information from the treating physician concerning the patient's diagnosis, and any information required for the use of specific modifiers or attestation statements as defined in certain DME MAC policies. The supplier should also obtain as much documentation from the patient's medical record in order to assure themselves that coverage criteria for an item have been met. If the information in the patient's medical record does not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved unless a properly executed Advance member Notice of Noncoverage (ABN) of possible denial has been obtained.

Documentation must be maintained in the supplier's files for seven (7) years from DOS.

**Prescription (Order) Requirements**
All claims for items billed to UnitedHealthcare Medicare Advantage require a prescription (order). “All claims” refers to all claims submitted for payment of purchases and initial rentals.

The legal name and National Provider Identifier (NPI) of the treating practitioner on the order for the item or service shall be used on the claim submitted to the DME MAC. The order shall be kept on file and made available upon request.

An order for each item billed must be signed and dated by the prescribing physician. 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 except for those items that require a written order prior to delivery. A dispensing order may be verbal or written. The supplier must keep a record of the dispensing order on file. It must contain:

- Description of the item
- Member's name
- Prescribing Physician's name
- Date of the order and the start date, if the start date is different from the date of the order
- Physician signature (if a written order) or supplier signature (if verbal order)

For the "date of the order" described above, use the date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician for written dispensing orders.
In some cases, the prescribing physician may specify a future start date for therapy that is different from the date of the order. This start date does not impact the date of the order, DOS entered on the claim, required forms (e.g., Certificate of Medical Necessity (CMN), DME Information Form (DIF)) or refill/delivery timelines. As long as the supplier has a properly completed dispensing order with a correctly determined prescription date, an item may be shipped or delivered on or after the date of the dispensing order (except for items that require written orders prior to delivery).

**Written Orders Prior To Delivery**
ACA 6407 requires a written order prior to delivery (WOPD) for the HCPCS codes specified in the table contained in the Policy Specific Documentation Requirements Section below. The supplier must have received a complete WOPD that has been both signed and dated by the treating physician and meets the requirements for a DWO before dispensing the item.

**Detailed Written Orders**
A detailed written order (DWO) is required before billing. Someone other than the ordering physician may produce the DWO. However, the ordering physician must review the content and sign and date the document. It must contain:
- Member's name
- Physician's name
- Date of the order and the start date, if start date is different from the date of the order
- Detailed description of the item(s) (see below for specific requirements for selected items)
- Physician signature and signature date

For items provided on a periodic basis, including drugs, the written order must include:
- Item(s) to be dispensed
- Dosage or concentration, if applicable
- Route of Administration
- Frequency of use
- Duration of infusion, if applicable
- Quantity to be dispensed
- Number of refills, if applicable

For the "date of the order" described above, use the date the supplier is contacted by the physician (for verbal orders) or the date entered by the physician (for written dispensing orders).

Frequency of use information on orders must contain detailed instructions for use and specific amounts to be dispensed. Reimbursement shall be based on the specific utilization amount only. Orders that only state "PRN" or "as needed" utilization estimates for replacement frequency, use, or consumption are not acceptable.

The detailed description in the written order may be either a narrative description or a brand name/model number.

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements.

The DWO must be available upon request.

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 (NCD 240.2)**
Documentation for initial coverage requires information in the medical record showing:
- Evidence of qualifying test results done within 30 days before the initial date of service
- Evidence of an in-person visit with a treating physician done within 30 days before the initial date of service

As required by the NCD Home Use of Oxygen (240.2), coverage of home oxygen therapy requires that the member be tested in the "chronic stable state" and that all co-existing diseases or conditions that can cause hypoxia must be treated sufficiently. Moreover, the member must have a severe lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, widespread pulmonary neoplasm, or hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy.

In order to provide coverage for these members, there must be evidence in the medical record documenting:
• A severe underlying lung disease, such as chronic obstructive pulmonary disease, diffuse interstitial lung disease, cystic fibrosis, bronchiectasis, widespread pulmonary neoplasm or hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy; and
• The member is not experiencing an exacerbation of their underlying lung disease described in (A) or other acute condition(s) impacting the member’s oxygen saturation;
• For members with concurrent PAP therapy, the qualifying oxygen saturation test is performed following optimal treatment of the OSA as described in the Coverage Indications, Limitations and/or Medical Necessity.

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

Continued Use
Continued use describes the ongoing utilization of supplies or a rental item by a member.

Suppliers are responsible for monitoring utilization of DMEPOS rental items and supplies. No monitoring of purchased items or capped rental items that have converted to a purchase is required. Suppliers must discontinue billing UnitedHealthcare Medicare Advantage when rental items or ongoing supply items are no longer being used by the member.

Member medical records or supplier records may be used to confirm that a DMEPOS item continues to be used by the member. Any of the following may serve as documentation that an item submitted for reimbursement continues to be used by the member:

• Timely documentation in the member’s medical record showing usage of the item, related option/accessories and supplies
• Supplier records documenting the request for refill/replacement of supplies in compliance with the Refill Documentation Requirements (This is deemed to be sufficient to document continued use for the base item, as well)
• Supplier records documenting member confirmation of continued use of a rental item

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in this policy.

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

For ongoing supplies and rental DME items, 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 be used by the member and remains reasonable and necessary. Information used to justify continued medical need must be timely for the DOS under review. Any of the following may serve as documentation justifying continued medical need:

• A recent order by the treating physician for refills
• A recent change in prescription
• A properly completed CMN or DIF with an appropriate length of need specified
• Timely documentation in the member’s medical record showing usage of the item.

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in this policy.

Proof of Delivery (POD)
42 CFR 424.57(c)(12) requires suppliers to maintain POD documentation in their files. POD documentation, as well as claims documentation, must be maintained in the supplier’s files for 7 years (starting from the DOS).

Suppliers, their employees, or anyone else having a financial interest in the delivery of the item(s) are prohibited from signing and accepting an item on behalf of a member (i.e., acting as a designee on behalf of the member). The relationship of the designee to the member should be noted on the delivery slip obtained by the supplier (i.e., spouse, neighbor). The signature of the designee should be legible. If the signature of the designee is not legible, the supplier/shipping service should note the name of the designee on the delivery slip. For the purpose of the delivery
methods noted below, designee is defined as any person who can sign and accept the delivery of DMEPOS on behalf of the member.

The supplier should have on file any documentation containing a description of the item delivered to the member to determine the accuracy of claims coding including, but not limited to, a voucher, invoice or statement in the supplier records. There must be a sufficient level of detail in the item description to definitively determine the appropriate HCPCS to be appended to the claim. The long description of the HCPCS code, may be used as a means to provide a detailed description of the item being delivered. POD documentation must be available to UnitedHealthcare Medicare Advantage on request.

There are three methods of delivery. Regardless of the method of delivery, the UnitedHealthcare Medicare Advantage must be able to determine that the item(s) delivered are the same item(s) submitted for reimbursement and that the item(s) were received by a specific member:

- Delivery directly to the member or authorized representative
- Delivery via shipping or delivery service
- Delivery of items to a nursing facility on behalf of the member

Method 1—Direct Delivery to the member by the Supplier
Suppliers may deliver directly to the member or the designee. In this case, POD to a member must be a signed and dated delivery document. The POD document must include:

- Member’s name
- Delivery address
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description). The long description of the HCPCS code, may be used as a means to provide a detailed description of the item being delivered
- Quantity delivered
- Date delivered
- Member (or designee) signature

The date delivered on the POD must be the date that the DMEPOS item was received by the member or designee. The date of delivery may be entered by the member, designee, or the supplier. When the supplier's delivery documents have both a supplier-entered date and a Member or member's designee signature date on the POD document, the member (or designee) entered date is the DOS.

In instances where the supplies are delivered directly by the supplier, the date the member received the DMEPOS supply must be the DOS on the claim.

Method 2—Delivery via Shipping or Delivery Service Directly to a member
If the supplier utilizes a shipping service or mail order, the POD documentation must be a complete record tracking the item(s) from the DMEPOS supplier to the member. An example of acceptable POD would include both the supplier’s own detailed shipping invoice and the delivery service’s tracking information. The supplier’s record must be linked to the delivery service record by some clear method like the delivery service’s package identification number or supplier’s invoice number for the package sent to the member. The POD document must include:

- Member’s name
- Delivery address
- Delivery service’s package identification number, supplier invoice number, or alternative method that links the supplier’s delivery documents with the delivery service’s records
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description). The long description of the HCPCS code, may be used as a means to provide a detailed description of the item being delivered
- Quantity delivered
- Date delivered
- Evidence of delivery

If a supplier utilizes a shipping service or mail order, suppliers must use the shipping date as the DOS on the claim. The shipping date may be defined as the date the delivery/shipping service label is created or the date the item is retrieved for delivery. However, such dates should not demonstrate significant variation.

Suppliers may also utilize a return postage-paid delivery invoice from the member or designee as a POD. This type of POD document must contain the information specified above.
Method 3—Delivery to Nursing Facility on Behalf of a Member
For items directly delivered by the supplier to a nursing facility or when a delivery service or mail order is used to
deliver the item(s) to a nursing facility, the supplier must have:

- Documentation demonstrating delivery of the item(s) to the facility by the supplier or delivery entity; and,
- Documentation from the nursing facility demonstrating receipt and/or usage of the item(s) by the member. The
  quantities delivered and used by the member must justify the quantity billed.

Replacement Equipment
Initial Date should be the date that the replacement equipment is initially needed. This is generally understood to be
the date of delivery of the oxygen equipment.

The Recertification Date should be 12 months following the Initial Date when the value on the Initial CMN (for the
replacement equipment) meets Group I criteria or 3 months following the Initial Date when the qualifying blood gas
value on the Initial CMN meets the Group II criteria. (Note: The Initial Date [for the replacement equipment] should
also be entered on the Recertification CMN.)

Claims for the initial rental month (and only the initial rental month) must have the RA modifier (Replacement of DME
item) added to the HCPCS code for the equipment when there is replacement due to reasonable useful lifetime or
replacement due to damage, theft, or loss.

Claims for the initial rental month must include a narrative explanation of the reason why the equipment was replaced
and supporting documentation must be maintained in the supplier's files.

Coding Guidelines
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 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
E0424 (Stationary Compressed Gaseous Oxygen System, Rental; Includes Container, Contents, Regulator, Flowmeter,
Humidifier, Nebulizer, Cannula Or Mask, And Tubing).

Refill contents used with equipment to treat cluster headaches must be coded using E0441 (Stationary Oxygen
Contents, Gaseous, 1 Month’s Supply = 1 Unit).

E1352 (Oxygen Accessory, Flow Regulator Capable Of Positive Inspiratory Pressure) provides positive pressure
inspiratory support for patients using oxygen. This product consists of multiple components - control unit, flow
regulator, connecting hose and nasal interface (pillows). E1352 is an all-inclusive code for this product that includes
all components.

Face-To-Face Examination for Specified DMEPOS Items
42 CFR 410.38(g) contains provisions that are applicable to certain specified DMEPOS items. In this policy the specified items are: HCPCS E0424, E0431, E0433, E0434, E0439, E0441, E0442, E0443, and E0444.

These items require an in-person, face-to-face interaction between the member and their treating physician prior to prescribing the item. This face-to-face requirement includes examinations conducted via the CMS-approved use of telehealth examinations (as described in Chapter 15 of the Medicare Benefit Policy Manual and Chapter 12 of the Medicare Claims Processing Manual - CMS Internet-Only Manuals, Publ. 100-02 and 100-04, respectively). This face-to-face evaluation must specifically document that the member was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered. A dispensing order is not sufficient to provide these items.

**Face-to-Face Visit Requirements**

As a condition for payment, 42 CFR 410.38(g) requires that a treating physician has had a face-to-face examination with a member within the six (6) months prior to the written order for certain items of DME.

For the treating physician prescribing a specified DME item:

- The face-to-face examination with the member must be conducted within the six (6) months prior to the date of the prescription.
- The face-to-face examination must document that the member was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered.

Remember that all other coverage and documentation requirements for DMEPOS also apply. There must be sufficient medical information included in the medical record to demonstrate that all other applicable coverage criteria are met. Refer to the applicable Local Coverage Determination for information about the medical necessity criteria for the item(s) being ordered.

The treating physician that conducted the face-to-face examination does not need to be the prescriber for the DME item; however, the prescriber must:

- Verify that the qualifying in-person visit occurred within the 6-months prior to the date of their prescription; and,
- Have documentation of the qualifying face-to-face examination that was conducted.

A new face-to-face examination is required each time a new prescription for one of the specified items is ordered.

Upon request by UnitedHealthcare Medicare Advantage, all DMEPOS suppliers must provide documentation of the face-to-face examination.

**APPLICABLE CODES**

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>E0424</td>
<td>Stationary compressed gaseous oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing</td>
</tr>
<tr>
<td>E0425</td>
<td>Stationary compressed gas system, purchase; includes regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing (Not covered by Medicare)</td>
</tr>
<tr>
<td>E0430</td>
<td>Portable gaseous oxygen system, purchase; includes regulator, flowmeter, humidifier, cannula or mask, and tubing (Not covered by Medicare)</td>
</tr>
<tr>
<td>E0431</td>
<td>Portable gaseous oxygen system, rental; includes portable container, regulator, flowmeter, humidifier, cannula or mask, and tubing</td>
</tr>
<tr>
<td>E0433</td>
<td>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</td>
</tr>
<tr>
<td>E0434</td>
<td>Portable liquid oxygen system, rental; includes portable container, supply reservoir, humidifier, flowmeter, refill adaptor, contents gauge, cannula or mask, and tubing</td>
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<tr>
<td>E0435</td>
<td>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)</td>
</tr>
<tr>
<td>HCPCS Code</td>
<td>Description</td>
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<tr>
<td>E0439</td>
<td>Stationary liquid oxygen system, rental; includes container, contents, regulator, flowmeter, humidifier, nebulizer, cannula or mask, &amp; tubing</td>
</tr>
<tr>
<td>E0440</td>
<td>Stationary liquid oxygen system, <strong>purchase</strong>; includes use of reservoir, contents indicator, regulator, flowmeter, humidifier, nebulizer, cannula or mask, and tubing (Not covered by Medicare)</td>
</tr>
<tr>
<td>E0441</td>
<td>Stationary oxygen contents, gaseous, 1 month's supply = 1 unit</td>
</tr>
<tr>
<td>E0442</td>
<td>Stationary oxygen contents, liquid, 1 month's supply = 1 unit</td>
</tr>
<tr>
<td>E0443</td>
<td>Portable oxygen contents, gaseous, 1 month's supply = 1 unit</td>
</tr>
<tr>
<td>E0444</td>
<td>Portable oxygen contents, liquid, 1 month's supply = 1 unit</td>
</tr>
<tr>
<td>E0445</td>
<td>Oximeter device for measuring blood oxygen levels noninvasively</td>
</tr>
<tr>
<td>E0446</td>
<td>Topical oxygen delivery system, not otherwise specified, includes all supplies and accessories (Not covered by Medicare)</td>
</tr>
<tr>
<td>E1390</td>
<td>Oxygen concentrator, single delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate</td>
</tr>
<tr>
<td>E1391</td>
<td>Oxygen concentrator, dual delivery port, capable of delivering 85 percent or greater oxygen concentration at the prescribed flow rate, each</td>
</tr>
<tr>
<td>E1392</td>
<td>Portable oxygen concentrator, rental</td>
</tr>
<tr>
<td>E1405</td>
<td>Oxygen and water vapor enriching system with heated delivery</td>
</tr>
<tr>
<td>E1406</td>
<td>Oxygen and water vapor enriching system without heated delivery</td>
</tr>
<tr>
<td>K0738</td>
<td>Portable gaseous oxygen system, rental; home compressor used to fill portable oxygen cylinders; includes portable containers, regulator, flowmeter, humidifier, cannula or mask, and tubing</td>
</tr>
</tbody>
</table>

**Accessories**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A4575</td>
<td>Topical hyperbaric oxygen chamber, disposable (Not covered by Medicare)</td>
</tr>
<tr>
<td>A4606</td>
<td>Oxygen probe for use with oximeter device, replacement</td>
</tr>
<tr>
<td>A4608</td>
<td>Transtracheal oxygen catheter, each</td>
</tr>
<tr>
<td>A4615</td>
<td>Cannula, nasal</td>
</tr>
<tr>
<td>A4616</td>
<td>Tubing (oxygen), per foot</td>
</tr>
<tr>
<td>A4617</td>
<td>Mouth piece</td>
</tr>
<tr>
<td>A4619</td>
<td>Face tent</td>
</tr>
<tr>
<td>A4620</td>
<td>Variable concentration mask</td>
</tr>
<tr>
<td>A7525</td>
<td>Tracheostomy mask, each</td>
</tr>
<tr>
<td>A9900</td>
<td>Miscellaneous DME supply, accessory, and/or service component of another HCPCS code</td>
</tr>
<tr>
<td>E0455</td>
<td>Oxygen tent, excluding croup or pediatric tents</td>
</tr>
<tr>
<td>E0555</td>
<td>Humidifier, durable, glass or autoclavable plastic bottle type, for use with regulator or flowmeter</td>
</tr>
<tr>
<td>E0580</td>
<td>Nebulizer, durable, glass or autoclavable plastic, bottle type, for use with regulator or flowmeter</td>
</tr>
<tr>
<td>E1352</td>
<td>Oxygen accessory, flow regulator capable of positive inspiratory pressure</td>
</tr>
<tr>
<td>E1353</td>
<td>Regulator</td>
</tr>
<tr>
<td>E1354</td>
<td>Oxygen accessory, wheeled cart for portable cylinder or portable concentrator, any type, replacement only, each</td>
</tr>
<tr>
<td>E1355</td>
<td>Stand/rack</td>
</tr>
<tr>
<td>E1356</td>
<td>Oxygen accessory, battery pack/cartridge for portable concentrator, any type, replacement only, each</td>
</tr>
<tr>
<td>E1357</td>
<td>Oxygen accessory, battery charger for portable concentrator, any type, replacement only, each</td>
</tr>
<tr>
<td>E1358</td>
<td>Oxygen accessory, dc power adapter for portable concentrator, any type, replacement only, each (Not Covered by Medicare)</td>
</tr>
</tbody>
</table>
Modifier | Description
--- | ---
EY | No physician or other licensed health care provider order for this item
QH | Oxygen conserving device is being used with an oxygen delivery system
RA | Replacement of a DME item
RR | Rental (use the RR modifier when DME is to be rented)

**QUESTIONS AND ANSWERS**

| Q: | Have you verified the CPT/HCPCS code(s) on your claim may have limited coverage under CED (Coverage with Evidence Development)? |
| A: | • If no, clinical trial number, modifier Q0 and diagnosis code Z00.6 should not be submitted.  
• If yes, the three requirements listed above are required. Claims without the required information will be denied. |

**PURPOSE**

The Medicare Advantage Policy Guideline documents are generally used to support UnitedHealthcare Medicare Advantage claims processing activities and facilitate providers’ submission of accurate claims for the specified services. The document can be used as a guide to help determine applicable:

- Medicare coding or billing requirements, and/or
- Medical necessity coverage guidelines; including documentation requirements.

UnitedHealthcare follows Medicare guidelines such as LCDs, NCDs, and other Medicare manuals for the purposes of determining coverage. It is expected providers retain or have access to appropriate documentation when requested to support coverage. Please utilize the links in the [References](#) section below to view the Medicare source materials used to develop this resource document. This document is not a replacement for the Medicare source materials that outline Medicare coverage requirements. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

**REFERENCES**

**CMS National Coverage Determinations (NCDs)**

NCD 240.2 Home Use of Oxygen

Reference NCDs: NCD 240.2.1 Home Use of Oxygen in Approved Clinical Trials, NCD 240.2.2 Home Oxygen Use to Treat Cluster Headaches (CH), NCD 240.4 Continuous Positive Airway Pressure (CPAP) Therapy For Obstructive Sleep Apnea (OSA)

**CMS Local Coverage Determinations (LCDs)**

<table>
<thead>
<tr>
<th>LCD</th>
<th>DME</th>
</tr>
</thead>
</table>
| L33797 (Oxygen and Oxygen Equipment) | **CGS:** AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV  
**Noridian:** AK, AS, AZ, CA, CT, DC, DE, GU, HI, IA, ID, KS, MA, MD, ME, MO, MP, MT, ND, NE, NH, NJ, NV, NY, OR, PA, RI, SD, UT, VT, WA, WV |

**CMS Articles**

<table>
<thead>
<tr>
<th>Article</th>
<th>DME</th>
</tr>
</thead>
</table>
| A52514 (Oxygen and Oxygen Equipment - Policy Article) | **CGS:** AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV  
**Noridian:** AK, AS, AZ, CA, CT, DC, DE, GU, HI, IA, ID, KS, MA, MD, ME, MO, MP, MT, ND, NE, NH, NJ, NV, NY, OR, PA, RI, SD, UT, VT, WA, WV |
| A55426 (Standard Documentation Requirements for All Claims Submitted to DME MACs) | **CGS:** AL, AR, CO, FL, GA, IL, IN, KY, LA, MI, MN, MS, NC, NM, OH, OK, PR, SC, TN, TX, VA, VI, WI, WV  
**Noridian:** AK, AS, AZ, CA, CT, DC, DE, GU, HI, IA, ID, KS, MA, MD, ME, MO, MP, MT, ND, NE, NH, NJ, NV, NY, OR, PA, RI, SD, UT, VT, WA, WV |

**CMS Benefit Policy Manual**

Chapter 15; § 110 Durable Medical Equipment - General
CMS Claims Processing Manual

Chapter 10: § 10B Services to Include on the Claim for Home Health Benefits, § 10.1.10.4 Claim Submission and Processing
Chapter 20: § 30.6 Oxygen and Oxygen Equipment, § 60 Payment for Delivery and Service Charges for Durable Medical Equipment, § 100.2.3 Evidence of Medical Necessity for Oxygen, § 100.2.3.1 Scheduling and Documenting Recertifications of Medical Necessity for Oxygen, § 100.2.3.2 HHA Recertification for Home Oxygen Therapy, § 100.2.3.3 Contractor Review of Oxygen Certifications, § 130.6 Billing for Oxygen and Oxygen Equipment, § 130.6.1 Oxygen Equipment and Contents Billing Chart

CMS Transmittals
Transmittal 57, Change Request 4389, Dated 05/26/2006 (Home Use of Oxygen in Approved Clinical Trials)
Transmittal 961, Change Request 4389, Dated 05/26/2006 (Home Use of Oxygen in Approved Clinical Trials)
Transmittal 3895, Change Request 10158, Dated October 27, 2017 (Revised and New Modifiers for Oxygen Flow Rate)

MLN Matters
Article MM5790, Use of an 8-Digit Registry Number on Clinical Trial Claims
Article MM8401, Revised, Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims
Article MM10158, Revised and New Modifiers for Oxygen Flow Rate
Article SE1344, Further Information on Mandatory Reporting of an 8-Digit Clinical Trial Number on Claims

GUIDELINE HISTORY/REVISION INFORMATION
Revisions to this summary document do not in any way modify the requirement that services be provided and documented in accordance with the Medicare guidelines in effect on the date of service in question.

<table>
<thead>
<tr>
<th>Date</th>
<th>Action/Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>04/01/2019</td>
<td>• Reorganized policy template; relocated Terms and Conditions and Purpose section</td>
</tr>
<tr>
<td>12/12/2018</td>
<td>• Annual review</td>
</tr>
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</table>

TERMS AND CONDITIONS

The Medicare Advantage Policy Guidelines are applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates.

These Policy Guidelines are provided for informational purposes, and do not constitute medical advice. Treating physicians and healthcare providers are solely responsible for determining what care to provide to their patients. Members should always consult their physician before making any decisions about medical care.

Benefit coverage for health services is determined by the member specific benefit plan document* and applicable laws that may require coverage for a specific service. The member specific benefit plan document identifies which services are covered, which are excluded, and which are subject to limitations. In the event of a conflict, the member specific benefit plan document supersedes the Medicare Advantage Policy Guidelines.

Medicare Advantage Policy Guidelines are developed as needed, are regularly reviewed and updated, and are subject to change. They represent a portion of the resources used to support UnitedHealthcare coverage decision making. UnitedHealthcare may modify these Policy Guidelines at any time by publishing a new version of the policy on this website. Medicare source materials used to develop these guidelines include, but are not limited to, CMS National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Medicare Benefit Policy Manual, Medicare Claims Processing Manual, Medicare Program Integrity Manual, Medicare Managed Care Manual, etc. The information presented in the Medicare Advantage Policy Guidelines is believed to be accurate and current as of the date of publication, and is provided on an "AS IS" basis. Where there is a conflict between this document and Medicare source materials, the Medicare source materials will apply.

You are responsible for submission of accurate claims. Medicare Advantage Policy Guidelines are intended to ensure that coverage decisions are made accurately based on the code or codes that correctly describe the health care services provided. UnitedHealthcare Medicare Advantage Policy Guidelines 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 or guarantee claims payment.

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*For more information on a specific member's benefit coverage, please call the customer service number on the back of the member ID card or refer to the Administrative Guide.