

A Collaboration Webinar presented by the A/B and DME Medicare Administrative Contractors

April,13 2023

















Disclaimer

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As a reminder, CMS does not allow recording of education opportunities such as this.

Participants

- CGS Administrators, LLC
- First Coast Service Options, Inc.
- National Government Services
- Noridian Healthcare Solutions, LLC
- Novitas Solutions
- Palmetto GBA
- WPS Government Health Administrators

Agenda

- Local Coverage Determination (LCD) and Policy Article Revisions published
 February 23, 2023
- Coverage Criteria/ Continued Coverage Criteria
- Testing Requirements
- Documentation Requirements
- Coverage Considerations Beyond Testing Results
- Coding and Billing Guidelines (Modifiers)
- Replacement
- COVID-19 Public Health Emergency (PHE)

Local Coverage Determination and Policy Article Revision

- Revisions published February 23, 2023
- Local Coverage Determination
 - Addition of N1, N2, N3 modifiers (Slide 50)
- Policy Article
 - Revised guidance for continued coverage for Groups II and III for dates of service on or after April 01, 2023 (Slides 23 and 26)
 - Clarification on modifiers N1, N2, N3 and KX (Slides 50-53)



Oxygen Coverage Criteria

- Initial coverage of home oxygen therapy and oxygen equipment is reasonable and necessary for Groups I and II if all the following conditions are met:
 - Treating practitioner has ordered and evaluated results of qualifying blood gas study performed at time of need; and,
 - Beneficiary's blood gas study meets criteria stated below; and,
 - Qualifying blood gas study was performed by treating practitioner or by qualified provider or supplier of laboratory services; and,
 - Provision of oxygen and oxygen equipment in home setting will improve beneficiary's condition
- Time of Need is defined as during patient's illness when presumption that provision of oxygen in home setting will improve beneficiary's condition

Oxygen Coverage Criteria Cont.

- Required qualifying arterial blood gas studies must be performed at time of need
 - Blood gas study in this policy refers to either oximetry test or arterial blood gas (ABG) test
 - Inpatient time of need is within 2 days of discharge
 - Outpatient time of need is during period when treating practitioner documents signs and symptoms which will improve with home oxygen
- NOTE: When applicable, beneficiary's medical record must have documentation that describes any concerns for variations in oxygen measurements that may result from such factors as patient's age, patient's skin pigmentation, altitude level, or decrease in oxygen carrying capacity.

Oxygen Group 1 Criteria

Room Air at Rest:

Arterial PO2 is 55 mm Hg or less or saturation is 88% or less taken at rest (awake)
 while breathing room air; or

During Sleep:

- 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 decrease in arterial PO2 more than 10 mm Hg; or a decrease in arterial oxygen saturation more than 5% from baseline saturation, taken during sleep associated with symptoms of hypoxemia such as impairment of cognitive processes and nocturnal restlessness or insomnia (not all inclusive); or
 - In either of these instances during sleep, coverage is provided only for use of oxygen during sleep

Oxygen Group I Criteria Cont.

During exercise:

 An arterial PO2 at or below 55 mm Hg or an arterial oxygen saturation at or below 88%, taken during exercise for a beneficiary who demonstrates an arterial PO2 at or above 56 mm Hg, or an arterial oxygen saturation at or above 89%, during the day while at rest

Continued Coverage Group I

- No formal requirement for re-evaluation and retesting
- Suppliers are encouraged to keep a comprehensive medical record ensuring it contains information demonstrating continued medical necessity

Oxygen Group II Criteria

- Arterial PO2 is 56 59 mm Hg or saturation is 89% and,
- Any of the following:
 - Dependent edema suggesting congestive heart failure, or
 - 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
 - Erythrocythemia with a hematocrit greater than 56 percent

Continued Coverage Group II

- Evaluation and documentation of repeat qualifying blood gas test by treating practitioner between 61st and 90th day
- New SWO by treating practitioner

Oxygen Group III Criteria

- Initial coverage of home oxygen therapy and oxygen equipment is reasonable and necessary for beneficiaries in Group III, if all of the following conditions are met:
 - Absence of hypoxemia defined in Group I and Group II; and,
 - A medical condition with distinct physiologic, cognitive, and/or functional symptoms documented in high-quality, peer-reviewed literature to be improved by oxygen therapy, such as cluster headaches (not all inclusive).

Continued Coverage Group III

- Evaluation and documentation of repeat normoxemic qualifying blood gas test by treating practitioner between 61st and 90th days after initiation of therapy
- New SWO by treating practitioner

Oxygen Group IV Criteria

Oxygen therapy and oxygen equipment will be denied as not reasonable and necessary if any of the following conditions are present:

- Angina pectoris in the absence of hypoxemia
- Dyspnea without cor pumonale or evidence of hypoxemia
- Severe peripheral vascular disease in absence of systemic hypoxemia
 - No evidence that increased PO2 will improve oxygenation of tissues with impaired circulation
- Terminal illnesses that do not affect ability to breathe

Oxygen and Obstructive Sleep Apnea (OSA)

- Some beneficiaries with OSA may require simultaneous use of home oxygen therapy and oxygen equipment with Positive Airway Pressure (PAP) device
- OSA must be sufficiently treated such that underlying condition resulting in hypoxemia is unmasked
- Qualifying oxygen saturation test may only occur during titration polysomnographic (PSG) study (either split night or stand-alone)

Oxygen and Obstructive Sleep Apnea (OSA)

- Titration conducted over minimum of two hours; and,
- During titration:
 - Apnea Hypopnea Index/Respiratory Disturbance Index (AHI/RDI) reduced to less than or equal to average of ten events per hour; or,If initial AHI/RDI was less than average of ten events per hour, titration demonstrates further reduction in AHI/RDI; and,
 - Nocturnal oximetry conducted for purpose for oxygen qualification may only be performed after optimal PAP settings determined and beneficiary using PAP device at those settings; and,
- Nocturnal oximetry conducted during PSG demonstrates oxygen saturation ≤ 88%

Oxygen Beneficiaries Entering Medicare

- Beneficiaries on oxygen covered by Private Insurance, Medicaid or Medicare Advantage Plan prior to eligibility/enrollment in Medicare Fee-for-Service (FFS)
 - Beneficiary does not have to obtain a new blood gas study, but the test must be the most recent qualifying study the beneficiary obtained previously and under guidelines specified in DME MAC policy
- Face-to-Face visit not required after Medicare FFS to establish medical necessity for Oxygen and Oxygen Equipment
- If they were on oxygen Medicare FFS then went to Medicare Advantage
 Plan, then back to Medicare FFS, they will pick up where they left off with
 Medicare FFS

Testing Requirements Oxygen April 2023 © 2023 Copyright, CGS Administrators, LLC

Testing Specifications

- Initial claims for oxygen therapy for hypoxemic patients must be based on results of clinical test that has been ordered and evaluated by treating practitioner
 - Blood Gas Study (ABG) or Pulse Oximetry
 - Oximetry "spot" pulse oximetry
 - Overnight Oximetry stand-alone pulse oximetry continuously recorded overnight
 - » Overnight oximetry does not include oximetry results done as part of other overnight testing such as polysomnography or home sleep testing
 - When both arterial blood gas (ABG) and pulse oximetry tests have been performed on same day under same conditions (.i.e., rest/awake, during exercise, or during sleep) ABG result will be used to determine if the coverage criteria is met
 - If an ABG test done at rest and awake is non-qualifying, but either an exercise or sleep oximetry test on same day is qualifying, exercise or oximetry test result will determine coverage

Testing Specifications

- All oxygen testing must be performed in-person by treating practitioner or other medical professional qualified to conduct oximetry testing
- DME supplier not considered qualified provider or supplier of laboratory services and may not qualify beneficiaries for home oxygen therapy
 - This prohibition does not extend to results of blood gas tests conducted by a hospital certified to do such tests

Qualifying Testing

- At Rest:
 - · Awake while sitting or lying, breathing room air
- During Sleep:
 - Overnight Sleep Oximetry may be performed in hospital or at home
 - Beneficiaries may self-administer home based overnight oximetry tests under direction of Medicare-enrolled Independent Diagnostic Testing Facility (IDTF)
 - Titration Polysomnogram (facility based) used for beneficiaries with concurrent Obstructive Sleep Apnea (OSA)
- Note: Beneficiaries who qualify for oxygen therapy during sleep are only eligible for stationary equipment, NOT portable oxygen equipment

Qualifying Testing Continued

- Exercise Testing:
 - Exercise testing must be performed in-person by treating practitioner or other medical professional qualified to conduct exercise oximetry testing
- There must be documentation of three (3) oximetry studies in beneficiary's medical record:
 - Testing at rest without oxygen; and,
 - Testing during exercise without oxygen; and,
 - Testing during exercise with oxygen applied (to demonstrate improvement of hypoxemia)
 - » Only testing during exercise without oxygen (#2 above) used for qualification
 - » Oximetry obtained after exercise while resting (e.g., recovery testing) not valid for determining coverage
 - All three tests must be performed within same testing session



Documentation Requirements

Oxygen

CMS Elimination of Oxygen CMN

- Requirement of Oxygen CMN 484 eliminated for claims with dates of service on or after January 1, 2023
 - For claims with dates of service on or after January 1, 2023, suppliers must not submit CMN 484 with claim.
 - If CMN is included with claim, claim will be rejected

Oxygen Therapy Initial Claims

- Documentation for initial coverage requires information in medical record showing:
 - Evidence of qualifying test results at time of need; and,
 - Evidence of evaluation of the qualifying test results by treating practitioner
- In order to provide initial coverage for beneficiaries in Groups I, II and III, there must be evidence in medical record documenting one of the following A-C criteria:
 - · Symptomatic, hypoxemic patient who meets criteria for Group I or II; or,
 - Symptomatic, normoxemic patient with medical condition that improves with oxygen therapy; or,
 - For beneficiaries with concurrent Obstructive Sleep Apnea (OSA), qualifying oxygen saturation test performed following optimal treatment of OSA as described in Coverage Indications, Limitations and/or Medical Necessity

Standard Written Order (SWO)

- Beneficiary's name or Medicare Beneficiary Identifier (MBI)
- Order date
- General description of item
 - Description can be either general (e.g., concentrator), HCPCS code, HCPCS code narrative, or brand name/model number
 - For equipment In addition to description of base item, SWO may include all concurrently ordered options, accessories, or additional features separately billed or require upgraded code (List each separately)
 - For supplies In addition to description of base item, DMEPOS order/prescription may include all concurrently ordered supplies separately billed (List each separately)
- Quantity to be dispensed, if applicable
- Treating practitioner name or National Provider Identifier (NPI)
- Treating practitioner's signature

Documentation Requirements

- SWO required for All DMEPOS items ordered for Medicare beneficiaries
- Must be signed and dated by treating practitioner
 - Physician (MD, DO)
 - Nurse Practitioner (NP)
 - Clinical Nurse Specialist (CNS)
 - Physician Assistant (PA)

Orders vs. Medical Record

- Prescription not considered part of medical record
- Medical information intended to demonstrate compliance with coverage criteria may be included on prescription but must be corroborated by information contained in medical record (Program Integrity Manual (PIM) 5.2.2)

Documentation Requirements New Order

- New order required by Medicare for any one of the following:
 - For all claims for purchases or initial rental;
 - If there is a change in DMEPOS order/prescription
 - On a regular basis (even if there is no change in the order/prescription) only if specified in medical policy)
 - · When an item is replaced; or
 - When there is change in supplier, and new supplier is unable to obtain copy of valid order and documentation from original supplier.
- Note: Pay close attention to your state laws regarding ordering and dispensing of oxygen



Coverage Considerations Beyond Testing Results

Oxygen

Additional Oxygen Coverage Rules

Coverage for flow rate greater than 4 LPM:

- Higher allowance for stationary system for flow rate of greater than 4 liters per minute (LPM) will be paid
 - Initial oxygen coverage criteria for Group I, II or III have been met
 - Group I or II, coverage greater than 4 LPM requires a qualifying blood gas study performed while the beneficiary is on 4 or more LPM
- If flow rate greater than 4 LPM and coverage criteria for higher allowance is not met, payment will be limited to standard fee schedule allowance

Portable Oxygen Coverage

- Beneficiary mobile within the home
- For Groups I and II, and qualifying blood gas study performed while at rest (awake) or during exercise
 - If only qualifying blood gas study performed during sleep, portable oxygen will be denied as not reasonable and necessary
- If coverage criteria are met, portable oxygen system usually separately payable in addition to stationary system
 - Supplier must provide whatever quantity of oxygen beneficiary uses
 - · Medicare's reimbursement same, regardless of the quantity of oxygen dispensed

Oxygen Contents

- Cost of oxygen contents are included in oxygen stationary rentals
- Payment for Contents (gaseous/liquid) is separately payable when stationary rental period ends
- If the beneficiary is using only portable gaseous or liquid equipment during rental months 1 through 36, payment for portable contents begins when rental period for portable equipment begins
- If beneficiary enters Medicare FFS with beneficiary owned gaseous or liquid systems, contents are separately payable
- Suppliers must provide whatever quantity of oxygen contents are needed

Coding and Billing Guidelines

Oxygen

Interruptions in a Period of Continuous Use: Break-in-Billing vs Break-In-Need

Break-in-Billing/Part B payment

- Billing interrupted without break in medical necessity
- If beneficiary enters hospital or SNF or joins Medicare HMO and continues to need/use oxygen, when beneficiary returns to Medicare FFS, payment resumes where it left off
- Does not start new 36-month rental period

Break-in-Medical Need:

- Beneficiary no longer needs oxygen for more than 60 days, plus days remaining in last rental month paid and new medical necessity for oxygen is established
 - Requires new testing and SWO
 - Include narrative on claim for new rental explaining why medical necessity ended
 - New 36-month rental period begins



Replacement

Oxygen

Replacement Guidelines

Payment allowed when original equipment is:

- Lost (includes replacement due to bankruptcy)
- Stolen
- Irreparably damaged due to a specific incident or natural disaster (e.g., fire, flood, hurricane)
 - Irreparable damage does not refer to wear and tear over time

Reasonable Useful Lifetime (RUL)

- RUL = five years
 - Supplier responsible for furnishing all accessories, contents, repairs during RUL
- Options once RUL reached
 - Replace equipment and begin new 36-month rental period and RUL
 - Beneficiary elects to keep existing equipment and supplier retains title
 - Continue servicing beneficiary, billing only for contents and M&S
 - Beneficiary elects to keep existing equipment and supplier transfers title to beneficiary
 - Accessories, maintenance, and repairs are statutorily non-covered by Medicare
 - Contents are separately payable for beneficiary owned gaseous or liquid systems
- Stationary equipment governs RUL-based rules

Replacement Guidelines

- RUL reached and beneficiary elects to receive new equipment
- Replacement rules:
 - New 36-month rental period and RUL begins
 - Must include RA modifier on only 1st rental claim of replacement equipment and narrative explaining why replacement is being provided
 - For RUL replacements, narrative must also include date equipment being replaced was received
 - Need new SWO

Replacement Guidelines

- Supplier who provided oxygen equipment during 36th rental month must provide all necessary items and services for duration of RUL
- New RUL or 36-month rental period does not start when:
 - Replacing equipment due to malfunction, wear and tear, routine maintenance, repair
 - Equipment modalities are changed
 - Equipment needs to be replaced due to not functioning properly
 - Beneficiary switches to new supplier and/or new equipment
 - During months 37-60, if need/use of oxygen ends for more than 60 days plus remainder of rental month of discontinuation and new medical necessity is established



COVID-19 Public Health Emergency (PHE) Status

- End of PHE has been announced as May 11, 2023
 - · All waivers and flexibilities remain in place until end date
- DME MACs to educate when CMS releases post PHE guidance

Clinical Indications for Coverage COVID-19 Public Health Emergency

- Effective for claims with dates of service on or after March 1, 2020, and for duration of this COVID-19 PHE, clinical indications for coverage found in Oxygen and Oxygen Equipment Local Coverage Determination (LCD) L33797, Oxygen Policy Article (PA) A52514 are not being enforced
- Treating practitioners and suppliers must still:
 - Provide a SWO for all items
 - Ensure items or services are reasonable and necessary
 - Continue documenting medical necessity for all services
 - Make documentation available, upon request
 - This enforcement discretion will only apply during COVID-19 PHE



Thank you for attending!