Provider Documentation Manual
Chapter 1 – Durable Medical Equipment

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10.1 – OVERVIEW FOR HOME OXYGEN THERAPY

(Rev.)

A. OVERVIEW

This section is for Medicare Suppliers.

Home oxygen therapy is considered reasonable and necessary only for beneficiaries with significant hypoxemia who meet the following:

1. Diagnosed health condition supporting the need for supplemental oxygen (NCD 240.2)
2. Laboratory test results; and
3. Medical documentation requirements

The supplier must obtain documentation from the patient’s medical record to ensure coverage criteria are met.

The supplier must maintain documentation for seven years from the date of service.

10.1.2 - COVERAGE REQUIREMENT FOR HOME OXYGEN THERAPY

(Rev.)

The National Coverage Determination (NCD) for Home Use of Oxygen (NCD 240.2) requires that the beneficiary have significant hypoxemia in the chronic stable state.

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

A. The attending physician has determined that the patient has a health condition that supports the need for home oxygen therapy,
B. The patient meets the blood gas evidence requirements (See Appendix C: Blood Gas Values) and,
C. The patient has appropriately tried other alternative treatment measures without complete success.

10.1.2.1 – FACE TO FACE (F2F) ENCOUNTER

(Rev.)

Medicare requires that a physician or Non-Physician Practitioner (NPP), [this includes a physician assistant (PA), nurse practitioner (NP), or clinical nurse specialist (CNS)] have a face-to-face (F2F) encounter with the beneficiary on the date of the written order up to 6 months before the date of the written order for the following home oxygen items:


A. DOCUMENTATION REQUIREMENT:

The supplier must have documentation of the F2F encounter conducted by a physician/NPP within the required 6-month timeframe. It should support that the beneficiary was evaluated and/or treated for a condition that supports the need for home oxygen therapy.

10.1.3 - ORDERS
(Rev.)

A. GENERAL

The supplier must have an order from the treating physician/NPP before dispensing any item to a beneficiary.

10.1.3.1 - WRITTEN ORDER PRIOR TO DELIVERY (WOPD)
(Rev.)

A. COVERAGE REQUIREMENTS:

A written order prior to delivery is required for certain DMEPOS items. For these items, the supplier must have received a written order that has been both signed and dated by the treating physician/NPP before dispensing the item. If a supplier bills for an item without a written order prior to delivery, the item will be denied.

The following home oxygen therapy equipment items require a WOPD.


B. DOCUMENTATION REQUIREMENT:

A written order prior to delivery must include ALL of the following [42 CFR 410.38(g) (4)], elements:

- Beneficiary’s name
- Item of DME ordered
- NPI of the prescribing practitioner
- Signature of the prescribing practitioner
- Date of the order

10.1.3.2 – DETAILED WRITTEN ORDERS
A. DOCUMENTATION REQUIREMENT:

All DMEPOS items other than those referenced in 42 CFR 410.38(c)(4) and 410.38(g)(2) require detailed written orders prior to billing. Detailed written orders may take the form of a photocopy, facsimile image, electronically maintained, or original "pen-and-ink" document. (See chapter 3, section 3.3.2.4).

The written order must be sufficiently detailed, including all options or additional features that will be separately billed or that will require an upgraded code. The description can be either a narrative description (e.g., lightweight wheelchair base) or a brand name/model number. All orders must clearly specify the start date of the order. (PIM 5.2.3)

*Description can be either a narrative description, brand name/model number, or HCPCS and must include all options or additional features that will be separately billed or that will require an upgraded code.

For home oxygen therapy supplies provided on a periodic basis, these elements are required IN ADDITION to the basic elements listed above for DWOs:

- Quantity used
- Frequency of change
- Duration of need (PIM 5.2.3)

10.1.4 - CERTIFICATE OF MEDICAL NECESSITY (CMN)

CMN CMS-484 Oxygen (OMB Form 484) is a form required to help document the medical necessity and other coverage criteria for certain oxygen equipment.

A. COVERAGE REQUIREMENT:

Suppliers must include a completed CMS-484 form (https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS484.pdf) for an initial, recertification or revised home oxygen therapy equipment claim. It must be completed, signed and dated prior to the submission of the claim.

Suppliers may complete Sections A and C of the CMN. The physician must complete Sections B and D of the CMN and may authorize a NPP or designated employee to assist. The treating physician must sign and date the CMN.

*Note: For detailed information regarding the CMN, please refer to Appendix B.

10.1.5 ADVANCED BENEFICIARY NOTICE (ABN)

A. COVERAGE REQUIREMENT:
You must give written notice to a Fee-for-Service Medicare patient before dispensing items that are usually covered by Medicare, but are not expected to be paid in a specific instance, for certain reasons, such as lack of medical necessity.


10.1.6 - PHYSICIAN/ NON-PHYSICIAN CHECKLIST

(Rev.)

The Centers for Medicare & Medicaid Services (CMS) provides a checklist solely for educational purposes and as a helpful resource for physicians and non-physician practitioners (NPPs) to help ensure their orders and medical record documentation include all relevant information required to support Medicare coverage of home oxygen therapy.

The use of this checklist is not mandatory and does not ensure Medicare reimbursement of home oxygen therapy equipment or supplies.

*The Physician/NPP checklist is in Appendix D.

10.1.7 – SUPPLIER CHECKLIST

(Rev.)

The Centers for Medicare & Medicaid Services (CMS) provides a checklist solely for educational purposes and as a helpful resource for suppliers to help ensure their orders and medical record documentation include all relevant information required to support Medicare coverage of home oxygen therapy.

The use of this checklist is not mandatory and does not ensure Medicare reimbursement of home oxygen therapy equipment or supplies.

*The Supplier Checklist is in Appendix E.
ADDITIONAL DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS AND SUPPLIES (DMEPOS) CMS TESTING AND VISIT REQUIREMENTS (Rev.)

The most recent qualifying blood gas testing results are sufficient in the following situations. It does not have to be dated within 30 days prior to the initial CMN date.

- When Medicare beneficiaries who began home oxygen therapy while enrolled under a Medicare Part C plan, then transitioned to Fee-For-Service (FFS) Medicare receive home oxygen therapy equipment.
- When home oxygen therapy equipment is replaced because the reasonable useful lifetime of prior equipment has been reached or irreparable damage, theft, or loss of the originally equipment has occurred.
- The beneficiary must be seen and evaluated by the treating physician within 30 days prior to the date of Initial Certification.
CERTIFICATE OF MEDICAL NECESSITY (CMN)

An initial CMN is required:

1. With the first claim for home oxygen therapy, (even if the beneficiary was on oxygen prior to Medicare eligibility or oxygen was initially covered by a Medicare Part C Plan);

2. During the first 36 months of the rental period when a change in the beneficiary’s condition 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; or

4. When the equipment is replaced because of irreparable damage, theft, or loss of the originally dispensed equipment;
   - “Irreparable damage” refers to a specific accident or to a natural disaster [e.g., fire, flood],
   - “Irreparable damage” does not refer to wear and tear over time.

5. Documentation requirements for initial coverage certification:
   - The medical record (e.g. physician/NPP progress note, hospital discharge summary) documents the patient had an in-person visit or face to face (F2F) encounter within 6 months as required and prior to the date of the order for home oxygen equipment.
   - The F2F encounter addressed the patient’s underlying condition requiring supplemental oxygen.

6. The patient was seen and evaluated by a physician within 30 days prior to the start of home oxygen therapy.

7. The patient has severe lung disease or hypoxia-related symptoms that is/are expected to benefit from oxygen therapy.

8. Oxygen testing was ordered and performed within 30 days prior to date of initial certification and meets the criteria for home oxygen therapy (see the reference for Covered Blood Gas Values below).

9. The patient was in a chronic stable state at the time of the test.
10. If the test was performed when the patient was an inpatient, it was performed within 2 days prior to discharge from the hospital.

11. The patient requires an oxygen flow greater than 4 liters per minute (LPM).

12. Documented oxygen testing results confirm low blood oxygen levels at qualifying levels while breathing oxygen at a flow rate of 4 LPM or greater.

13. The patient is mobile within the home, which supports the use of a portable oxygen system.

14. Alternative treatment measures have been tried or considered and deemed clinically ineffective, for example:

- Medical and physical therapy directed at secretions;
- Medical management of bronchospasm;
- Medical management of infection has been tried, has not been sufficiently successful, and oxygen therapy is still required; or
- Optimum therapy received prior to the order for long-term home oxygen therapy

Recertification CMN:

Recertification for continued coverage of home oxygen therapy for Group I patients:

1. Is required 12 months after the initial certification (with the 13th month’s claim).
   - There must be documentation he/she was seen and evaluated within 90 days of recertification.
   - There must also be a copy of the most recent qualifying arterial blood gas study prior to the 13th month of home oxygen therapy.

Recertification for continued coverage of home oxygen therapy for Group II patients:

1. Is required 3 months after the initial certification.
   - There must be documentation he/she was seen and evaluated within 90 days of recertification.
   - There must also be documentation of a repeat blood gas study between days 61–90 of the start of home oxygen therapy.

Recertification for continued use of home oxygen therapy is also required:

1. When the equipment is replaced because the reasonable useful lifetime was reached;

2. When equipment was replaced due to a specific incident of irreparable damage (equipment is dropped or broken, fire, flood) or the item is lost or stolen;

3. For the patient that meets Group I criteria (see Appendix C):
   - Twelve months after initial CMN
• Most recent blood gas study is prior to the 13th month of therapy
• Beneficiary was seen and reevaluated by the treating physician within 90 days prior to the Recertification date
• There is documentation, including a copy of the most recent qualifying arterial blood gas study; or

4. For the patient that meets Group II criteria (see Appendix C):

• Three months after initial CMN
• The documentation substantiates the patient was seen and re-evaluated by the treating physician within 90 days prior to the recertification date and
• There is documentation and a copy of a repeat blood gas study performed between days 61–90 following the initial certification.

**Revised CMN:**

*A revised CMN for home oxygen therapy should be submitted as soon as possible if the patient’s condition and need for oxygen therapy changes.*

*A revised CMN is required:*

1. *When the prescribed oxygen flow rate (based on test performed using stationary equipment while the patient is at rest)* changes from one of these categories to another;
   a. <1 liter per minute (LPM);
   b. 1–4 LPM; or
   c. >4 LPM.

2. *When length of need expires (physician/NPP specified <99 years or lifetime length of need on the most recent CMN;*

3. *When a portable oxygen system is added subsequent to an initial CMN for a stationary oxygen system;*

4. *When a stationary oxygen system is added subsequent to an initial CMN for a portable oxygen system;*

5. *When there is a new treating physician/NPP and the oxygen order remains unchanged*

6. *When there is a new supplier who does not have the prior CMN for home oxygen therapy.*

*When the indications for a revised CMN of home oxygen therapy are met at the same time a recertification is due, only a recertification CMN is required to be submitted.*

**NOTE:** See Appendix C for additional information.
7. For the patient that meets Group II criteria (see Appendix C):

- **When the prescribed flow rate (based on tests performed using stationary equipment while the patient is at rest)** changes from one of the following categories to another:
  
  - Less than 1 LPM,
  - 1-4 LPM,
  - Greater than 4 LPM

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

- **When the length of need expires** – if the physician specified less than lifetime length of need on the most recent CMN.

- **When a portable oxygen system is added subsequent to initial certification of a stationary system.**

- **When a stationary system is added subsequent to initial certification of a portable system.**

- **When there is a new treating physician, but the oxygen order is the same.**

- **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.*
APPENDIX: C

COVERED BLOOD GAS VALUES

(Rev.)

For Initial Certifications, the patient’s blood gas study (either an arterial blood gas or an oximetry test) values meet all requirements for one or more of the following criteria:

**Group I Criteria:**

- **Patient tested at rest (awake) on room air:**
  - Arterial oxygen saturation is at or below 88 percent; or
  - Arterial partial pressure of oxygen (PO2) is at or below 55 mm Hg; or

- **Patient tested during sleep on room air:**
  - Arterial PO2 < 55 mm Hg or an arterial oxygen saturation < 88 percent taken during sleep;
  - For a patient who demonstrated arterial PO2 ≥ 56 mmHg while awake, or arterial oxygen saturation ≥ 89 percent while awake, or
  - A greater than normal decrease in oxygen level during sleep (a decrease in arterial PO2 > 10 mm Hg, or decrease in arterial oxygen saturation > 5 from baseline saturation);
  - More than 5 percent for at least 5 minutes, and
  - Associated with symptoms or signs consistent or attributed to hypoxemia (e.g., impairment of cognitive processes and nocturnal restlessness or insomnia), or

**NOTE:** Coverage for supplemental oxygen is only provided for use during sleep for a patient meeting either criteria above. Portable oxygen is not covered in this situation.

- **Patient tested during exercise on room air:**
  - Patient demonstrates an arterial PO2 ≥ 56 mm Hg or arterial oxygen saturation ≥ 89 percent, during the day at rest; and
  - Demonstrates a decrease with exercise in arterial PO2 ≤ 55 mm Hg or an arterial oxygen saturation ≤ 88 percent; and
  - Documented evidence of improvement of hypoxemia during exercise with application of supplemental oxygen.

- The patient qualifies for a portable oxygen systems because he/she is mobile within the home and the qualifying blood gas test result(s) was/were performed, (at rest while
awake and/or during exercise), meeting the above coverage criteria.

**NOTE:** Initial coverage of Group I home oxygen therapy is limited to 12 months or the treating physician-specified length of need for oxygen, whichever is shorter.

**Group II Criteria:**

- Medicare coverage is available, (except for patients with variable factors affecting blood gas values as listed below), for patients whose arterial PO2 is 56-59 mm Hg or whose arterial blood oxygen saturation is 89 percent at rest while awake, during sleep for at least 5 minutes in total, or during exercise provided 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 percent.
  - The patient qualifies for a portable oxygen systems because he/she is mobile within the home and the qualifying blood gas test result(s) was/were performed, (at rest while awake and/or during exercise), meeting the above coverage criteria.

**NOTE:** Initial coverage of Group II home oxygen therapy is limited to 3 months or the treating physician-specified length of need for oxygen, whichever is shorter.

**Variable Factors That May Affect Blood Gas Values:**

- The following variations in the patient’s oxygen measurements are documented in the medical record and may support consideration of coverage secondary to:
  
  - The patient’s age;
  - The altitude level; or
  - The patient’s decreased oxygen carrying capacity
HOME OXYGEN THERAPY

PHYSICIAN/NON-PHYSICIAN PRACTITIONER (NPP) DOCUMENTATION CHECKLIST

The Centers for Medicare & Medicaid Services (CMS) issues this checklist solely for educational purposes and as a helpful resource for physicians and NPPs to ensure their orders and medical record documentation include all relevant information required to support Medicare coverage of home oxygen therapy.

The use of this checklist is voluntary and does not ensure Medicare reimbursement of home oxygen therapy equipment or supplies.

All of the following, as applicable, must be available in the patient’s medical record(s):

Written Order Prior To Delivery (WOPD):

The following items of home oxygen therapy equipment require a WOPD: Healthcare Common Procedure Coding System (HCPCS) codes E0424, E0431, E0433, E0434, E0439, E0441, E0442, E0443, or E0444. The WOPD provided to the supplier for the above type of oxygen equipment prescribed contains the following required elements:

- Beneficiary’s name
- Item of DME ordered
- National Provider Identifier (NPI) of the prescribing practitioner;
- Signature of the prescribing practitioner; and
- Date of the order

NOTE: The supplier must have evidence that the order was written prior to delivery to meet this requirement.

Physician Evaluation for Home Oxygen Equipment not requiring a Face-to-Face Encounter: (E1390, E1391, E1392, and K0738)

- Documentation demonstrates the beneficiary was seen and evaluated by the treating physician within 30 days prior to the date of Initial Certification.


Initial Coverage: Certification:

- The medical record, (e.g., progress note, hospital discharge summary) documents the patient had an in-person visit or face to face (F2F) encounter addressing the patient’s underlying condition requiring supplemental oxygen

- The F2F encounter was conducted within 6 months as required and prior to the date of the order for home oxygen equipment for the above listed HCPCS codes
The patient was seen and evaluated within 30 days prior to the start of home oxygen therapy.

The patient has severe lung disease or hypoxia-related symptoms that is/are expected to benefit from oxygen therapy.

Oxygen testing was ordered, performed, and evaluated within 30 days prior to date of

Initial Certification and meets the criteria for home oxygen therapy (see the reference for Covered Blood Gas Values in Appendix C)

The patient was in a chronic stable state at the time of the test if tested as an outpatient.

If testing was performed when the patient was an inpatient, it was performed within 2 days prior to discharge from the hospital.

The patient requires an oxygen flow greater than 4 liters per minute (LPM).

Oxygen testing results confirm low blood oxygen levels at qualifying levels while breathing.

The patient is mobile within the home, which supports the use of a portable oxygen system.

Alternative treatment measures have been tried or considered and deemed clinically ineffective, for example:

- Medical and physical therapy directed at secretions;
- Medical management of bronchospasm;
- Medical management of infection has been tried, has not been sufficiently successful, and oxygen therapy is still required; or
- Optimum therapy received prior to the order for long-term home oxygen therapy.

**Continued Coverage: Recertification:**

A Recertification is required as follows:

**For the patient that meets Group I criteria (see Appendix C):**

- Twelve months after initial CMN;
- Most recent blood gas study is prior to the 13th month of therapy;
- Beneficiary was seen and reevaluated by the treating physician within 90 days prior to the Recertification date; and
- There is documentation, including a copy of the most recent qualifying arterial blood gas study.

**For the patient that meets Group II criteria (see Appendix C):**

- Three months after initial CMN;
- The documentation substantiates the patient was seen and re-evaluated by the treating physician within 90 days prior to the Recertification date; and
- There is documentation and a copy of a repeat blood gas study performed between days 61–90 following the Initial Certification.

**Detailed Written Order (DWO):**

A DWO is required for oxygen equipment and supplies that do not require a WOPD.
A DWO for the oxygen equipment prescribed contains the following elements:

- Beneficiary’s name;
- Item of DME ordered*
- Physician or NPP signature and signature date; and
- Start date of the order or date the order was written

*The detailed item description can be either a narrative description or a brand name/model number and must include all options or additional features that will be separately billed or that will require an upgraded code.

For home oxygen therapy supplies provided on a periodic basis, these ADDITIONAL elements are required in the DWO:

- Duration of need;
- Flow rate and/or oxygen percent; and
- Frequency of use
APPENDIX: E

HOME OXYGEN THERAPY
SUPPLIER DOCUMENTATION CHECKLIST

The Centers for Medicare & Medicaid Services (CMS) issues this checklist solely for educational purposes and as a helpful resource for suppliers to ensure their orders and medical record documentation include all relevant information required to support Medicare coverage of home oxygen therapy.

The use of this checklist is voluntary and does not ensure Medicare reimbursement of home oxygen therapy equipment or supplies.

**Written Order Prior To Delivery (WOPD):**

The following items of home oxygen therapy equipment require a WOPD: Healthcare Common Procedure Coding System (HCPCS) codes E0424, E0431, E0433, E0434, E0439, E0441, E0442, E0443, or E0444. The WOPD provided to the supplier for the above type of oxygen equipment prescribed contains the following required elements:

- Beneficiary’s name
- Item of DME ordered
- National Provider Identifier (NPI) of the prescribing practitioner
- Signature of the prescribing practitioner
- Date of the order

**NOTE:** The supplier must have evidence that the order was written prior to delivery to meet this requirement.

**Physician Evaluation for Home Oxygen Equipment not requiring a Face-to-Face Encounter (E1390, E1391, E1392, and K0738):**

- Documentation demonstrates the beneficiary was seen and evaluated by the treating physician within 30 days prior to the date of Initial Certification

**Initial Coverage: Certification:**

- The medical record (e.g. physician progress note, hospital discharge summary) documents the patient had an in-person visit or face to face (F2F) encounter within 6 months as required and prior to the date of the order for home oxygen equipment
- The F2F encounter addressed the patient’s underlying condition requiring supplemental oxygen
- The patient was seen and evaluated by a physician within 30 days of the start of home oxygen therapy
- The patient has severe lung disease or hypoxia-related symptoms that is/are expected to benefit from oxygen therapy
- Oxygen testing was ordered and performed within 30 days prior to date of Initial Certification and meets the criteria for home oxygen therapy (see the reference for Covered Blood Gas Values below)
The patient was in a chronic stable state at the time of the test
If the test was performed when the patient was an inpatient, it was performed within 2 days prior to discharge from the hospital
The patient requires an oxygen flow greater than 4 liters per minute (LPM)
Oxygen testing results confirm low blood oxygen levels at qualifying levels while breathing oxygen at a flow rate of 4 LPM or greater
The patient is mobile within the home, which supports the use of a portable oxygen system
Alternative treatment measures have been tried or considered and deemed clinically ineffective, for example:
- Medical and physical therapy directed at secretions;
- Medical management of bronchospasm;
- Medical management of infection has been tried, has not been sufficiently successful, and oxygen therapy is still required; or
- Optimum therapy received prior to the order for long-term home oxygen therapy

**Continued Coverage: Recertification:**
A Recertification CMN is required as follows:

For the patient that meets Group I criteria (see Appendix C):
- Current date is twelve months after initial CMN;
- Most recent blood gas study is prior to the 13th month of therapy;
- Beneficiary was seen and reevaluated by the treating physician within 90 days prior to the Recertification date; and
- There is documentation, including a copy of the most recent qualifying arterial blood gas study

For the patient that meets Group II criteria (see Appendix C):
- Current date is three months after initial CMN;
- The documentation substantiates the patient was seen and re-evaluated by the treating physician within 90 days prior to the Recertification date; and
- There is documentation and a copy of a repeat blood gas study performed between days 61–90 following the Initial Certification

**Detailed Written Order (DWO):**
The following items of home oxygen therapy equipment require a DWO: Healthcare Common Procedure Coding System (HCPCS) codes E0424, E0431, E0433, E0434, E0439, E0441, E0442, E0443, or E0444. A DWO is required before you can bill for oxygen and oxygen equipment and accessories. The DWO provided to the supplier for the above type of oxygen equipment prescribed contains the following required elements:
- A DWO was received from prescribing practitioner prior claim submission
- A DWO for the oxygen equipment prescribed contains the following:
  - Beneficiary’s name;
  - Item of DME ordered*
Physician or NPP signature and signature date; and
Start date of the order or the date the order was written

*The detailed item description can be either a narrative description or a brand name/model number and must include all options or additional features that will be separately billed or that will require an upgraded code.

For home oxygen supplies provided on a periodic basis, these ADDITIONAL elements are required in the DWO:
- Duration of need;
- Flow rate and/or oxygen percent; and
- Frequency of use