A Clinician’s Guide
To Prescribing
Home Oxygen and
Home Medical Equipment
for the
Medicare Beneficiary
# INDEX

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INTRODUCTION

This guide has been designed to provide physicians, nurses, discharge planners and other clinical personnel concise and convenient reference regarding reimbursement of durable medical equipment for the Medicare beneficiary. The information provided in this guide has been derived directly from the Medicare Part B Durable Medical Equipment Manual.

Please do not hesitate to call your local Keene Medical Products branch if you should require additional information and/or assistance. We are dedicated to serving all of your patient’s home medical equipment, respiratory services and medical supply needs.

Corporate Location
5 Landing Road, Enfield, NH 03748

<table>
<thead>
<tr>
<th>New Hampshire Branch Locations</th>
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<tbody>
<tr>
<td>240 Meriden Road</td>
</tr>
<tr>
<td>PO Box 439</td>
</tr>
<tr>
<td>Lebanon, NH 03766</td>
</tr>
<tr>
<td>603-448-5225</td>
</tr>
<tr>
<td>800-639-3305</td>
</tr>
<tr>
<td>603 Main Street</td>
</tr>
<tr>
<td>Gorham, NH 03581</td>
</tr>
<tr>
<td>603-752-7694</td>
</tr>
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<td>800-287-7698</td>
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<tr>
<td>160 Benmont Avenue, Suite 26</td>
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<tr>
<td>Bennington, VT 05201</td>
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<tr>
<td>802-447-7468</td>
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<tr>
<td>800-649-2577</td>
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<tr>
<td>802-773-4574</td>
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<tr>
<td>877-773-4574</td>
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<tr>
<td>153 Allen Street</td>
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<tr>
<td>Rutland, VT 05701</td>
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<tr>
<td>802-773-4574</td>
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<tr>
<td>877-773-4574</td>
</tr>
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</table>
1. **Inexpensive or routinely purchased equipment**
   Equipment for which the purchase price does not exceed $150.00 or which is normally purchased at least 75% of the time. Although equipment in this category is usually purchased, short-term rentals are allowed. Purchases will be reimbursed in a lump sum. Rentals will be paid up to the purchase price. Payment will be equal to the current fee schedule or the submitted charge, whichever is lower.

2. **Equipment requiring frequent and substantial servicing**
   Equipment that requires frequent and substantial servicing to ensure the health and safety of the patient. Items in this category will be paid as a rental until the medical need ends.

3. **Customized equipment**
   Equipment uniquely constructed or substantially modified to meet the specific needs of an individual patient. Payment will be made in a lump sum based upon carrier’s individual consideration.

4. **Prosthetic and Orthotic devices and other medical supplies**
   Includes all Prosthetic and Orthotic devices except items specifically listed in other categories such as TENS, urological supplies and dressings. Payment will be in a lump sum equal to the fee schedule purchase price or the submitted price, whichever is lower.

5. **Capped rental**
   All other equipment that meets the definition of DME is in this category. After 13 months of consecutive rental the equipment will meet the purchase price and be converted to a sale. The customer will retain ownership of the equipment and will be responsible for maintaining the equipment.

6. **Oxygen and oxygen equipment**
   Payment will be made at a monthly rate per beneficiary. The rate will be the same regardless of the type of oxygen delivery system used by the beneficiary, i.e., liquid, gas or concentrator. Payment will be made at the fee schedule rate for a medically necessary portable oxygen system used with the stationary oxygen system. Adjustments to the payment will be made on high or low liter flow. The fee schedule amount for a stationary oxygen system will be reduced by 50% if the prescription liter flow is less than one (1) liter per minute. The fee schedule amount for a stationary oxygen system will be increased by 50% if the prescribed liter flow is greater than four (4) liters per minute. However, if a portable unit is placed with the stationary system, the adjustment will be limited to the higher of either the 50% increase for the stationary system or the fee schedule amount for the portable equipment. The oxygen equipment will rent for 36 months and then billing will cease. Keene Medical Products will maintain ownership of the equipment and will be responsible for maintaining the equipment.
**COMMON ACRONYMS**

*Common acronyms* used by Medicare and throughout this guide.

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Description</th>
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<td>ABG</td>
<td>Arterial Blood Gas</td>
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<td>ABN</td>
<td>Advanced Beneficiary Notice</td>
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<td>ADL</td>
<td>Activities of Daily Living</td>
</tr>
<tr>
<td>AHI</td>
<td>Apnea Hypopnea Index</td>
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<td>AOB</td>
<td>Assignment of Benefits</td>
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<td>CMN</td>
<td>Certificate of Medical Necessity</td>
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<td>CMS</td>
<td>Centers for Medicare and Medicaid Services (Formerly HCFA)</td>
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<td>Chronic Obstructive Pulmonary Disease</td>
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<td>Continuous Positive Airway Pressure</td>
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<tr>
<td>CSA</td>
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<td>DME Information Form</td>
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<td>Durable Medical Equipment</td>
</tr>
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<td>Durable Medical Equipment Medicare Administrative Contractor</td>
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<tr>
<td>DMEPOS</td>
<td>Durable Medical Equipment, Prosthetics, Orthotics and Supplies</td>
</tr>
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<td>Durable Medical Equipment Program Safeguard Contractor</td>
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<td>Home Health Agency</td>
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<td>Mobility Related Activities of Daily Living</td>
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<tr>
<td>SpO₂</td>
<td>Oxygen Saturation Level by Oximetry</td>
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<td>WVO</td>
<td>Written Verbal Order</td>
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**MEDICAL RECORD AND DOCUMENTATION**

Suppliers are now required to show proof of medical necessity as indicated in the patient’s medical record. This is in addition to a written order (WVO) or certificate of medical necessity (CMN).

**Documentation in the Patient’s Medical Record**

*(Rev. 242: Issued: 02-22-08; Effective/Implementation Dates: 03-01-08)*

For any DMEPOS item to be covered by Medicare, the patient’s medical record must contain sufficient documentation of the patient’s medical condition to substantiate the necessity for the type and quantity of items ordered and for the frequency of use or replacement (if applicable). The information should include the patient’s diagnosis and other pertinent information including, but not limited to, duration of the patient’s condition, clinical course (worsening or improvement), prognosis, nature and extent of functional limitations, other therapeutic interventions and results, past experience with related items, etc. If an item requires a CMN or DIF, it is recommended that a copy of the completed
CMN or DIF be kept in the patient’s record. However, neither a physician’s order nor a CMN nor a DIF nor a supplier prepared statement nor a physician attestation by itself provides sufficient documentation of medical necessity, even though it is signed by the treating physician or supplier. There must be information in the patient’s medical record that supports the medical necessity for the item and substantiates the answers on the CMN (if applicable) or DIF (if applicable) or information on a supplier prepared statement or physician attestation (if applicable).

See PIM, chapter 3, section 3.4.1.1, for additional instructions regarding review of documentation during pre- and post-payment review.

The patient’s medical record is not limited to the physician’s office records. It may include hospital, nursing home, or HHA records and records from other health care professionals.

The documentation in the patient’s medical record does not have to be routinely sent to the supplier or to the DME MACs, DME PSCs, or ZPICs. However, the DME MACs, DME PSCs, or ZPICs may request this information in selected cases. If the DME, DME PSCs, or ZPICs do not receive the information when requested or if the information in the patient’s medical record does not adequately support the medical necessity for the item, then on assigned claims the supplier is liable for the dollar amount involved unless a properly executed advance beneficiary notice (ABN) of possible denial has been obtained.

Supplier Documentation

A. General
Before submitting a claim to the DME MAC the supplier must have on file a dispensing order, the detailed written order, the CMN (if applicable), the 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 as they determine they need 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 ABN of possible denial has been obtained.

Documentation must be maintained in the supplier’s files for seven (7) years from date of service. If the provider responds, in writing, that the Medicare qualifying supplier documentation is older than 7 years, and provides proof of continued use/continued need the contractors shall not deny the claim based solely on missing the supporting Medicare qualifying documentation that is over 7 years old.

For DME accessories and repairs, the contractor shall request the Medicare qualifying documentation as normal.

B. Proof of Delivery
Suppliers are required to maintain proof of delivery documentation in their files. For the purpose of the proof of delivery noted below, designee is defined as:

“Any person who can sign and accept the delivery of DMEPOS items on behalf of the beneficiary.”

Suppliers may deliver DMEPOS items directly to the beneficiary or the designee. The delivery ticket must be signed by the beneficiary or the designee upon delivery. The delivery ticket must also contain the date on which the DMEPOS item was delivered. The date of delivery may be entered by the beneficiary, designee, or supplier. The contractor shall not deny claims in which the date of delivery was completed by the supplier instead of the beneficiary or the designee. The date that the beneficiary received the DMEPOS supply shall be the date of service on the claim.
1. PRESCRIPTION

➢ Beneficiary’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
➢ The prescribing practitioner’s National Provider Identifier (NPI)
➢ The signature of the ordering practitioner
➢ Signature date

2. MEDICAL DOCUMENTATION

➢ Face-to-face examination with the beneficiary conducted within the six (6) months prior to the date of the prescription
➢ Face-to-face examination must document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered and must include:
   ○ Patient diagnosis
   ○ Duration of patient condition
   ○ Clinical course
   ○ Prognosis
   ○ Functional limitation
   ○ Therapeutic interventions and results
   ○ Past experience
➢ There must be sufficient medical information included in the medical record to demonstrate that the applicable coverage criteria are met (See Keene Medical Clinician Guide)

3. ALL RECORDS MUST BE SIGNED / PHYSICIAN AUTHENTICATION

Electronic Signatures
Medicare contractors recommend that an electronic signature be accompanied by a statement indicating that the signature was applied electronically. Some examples of electronic signature notations include (not all-inclusive):

➢ Electronically signed by
➢ Authenticated by
➢ Approved by
➢ Completed by
➢ Finalized by
➢ Signed by
➢ Validated by
➢ Sealed by
For all DMEPOS items, the initial justification for medical need is established at the time item(s) is first ordered; therefore, beneficiary 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 beneficiary’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 beneficiary’s medical record to support that the item continues to be used by the beneficiary and remains reasonable and necessary. Information used to justify continued medical need must be timely for the date of service (DOS) under review. Any of the following may serve as documentation justifying continued medical need:

1. A recent order by the treating physician for refills
2. A recent change in prescription
3. A properly completed CMN or DIF with an appropriate length of need specified
4. Timely documentation in the beneficiary’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 the policy.

Continued use describes the ongoing utilization of supplies or a rental item by a beneficiary. 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 Medicare when rental items or ongoing supply items are no longer being used by the beneficiary. Beneficiary medical records or supplier records may be used to confirm that a DMEPOS item continues to be used by the beneficiary. Any of the following may serve as documentation that an item submitted for reimbursement continues to be used by the beneficiary:

1. Timely documentation in the beneficiary’s medical record showing usage of the item, related option/accessories and supplies
2. 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)
3. Supplier records documenting beneficiary 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.

Suppliers are required to maintain proof of delivery documentation in their files. The proof of delivery requirements is outlined below according to the method of delivery. The three methods of delivery are:

- Supplier delivering directly to the beneficiary or authorized representative;
- Supplier utilizing a delivery/shipping service to deliver items; and
- Delivery of items to a nursing facility on behalf of the beneficiary.

Proof of delivery documentation must be available to the DME PSC on request. All services that do not have appropriate proof of delivery from the supplier will be denied and overpayments will be requested. Suppliers who consistently do not provide documentation to support their services may be referred to the OIG for imposition of CMPs or Administrative Sanctions.
**CANES AND CRUTCHES**

**DOCUMENTATION REQUIREMENTS:**

CANES (E0100, E0105) and CRUTCHES (E0110 - E0116) are covered if the following criteria are documented in the patient’s medical record.

1) The patient has a mobility limitation that significantly impairs his/her ability to participate in one or more mobility-related activities of daily living (MRADL) in the home.
   - A mobility limitation is one that:
     a) Prevents the patient from accomplishing the MRADL entirely, or
     b) Places the patient at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform an MRADL, or
     c) Prevents the patient from completing the MRADL within a reasonable time frame;
   And,

2) The patient is able to safely use the cane or crutch; and,

3) The functional mobility deficit can be sufficiently resolved by use of a cane or crutch.

**WALKERS**

A standard walker (E0130, E0135, E0141, E0143) and related accessories are covered if the following criteria are documented in the patient’s medical record.

1) The patient has a mobility limitation that significantly impairs his/her ability to participate in one or more mobility-related activities of daily living (MRADL) in the home.
   - A mobility limitation is one that:
     a) Prevents the patient from accomplishing the MRADL entirely, or
     b) Places the patient at reasonably determined heightened risk of morbidity or mortality secondary to the attempts to perform the MRADL, or
     c) Prevents the patient from completing the MRADL within a reasonable time frame;
   and

2) The patient is able to safely use the walker; and

3) The functional mobility deficit can be sufficiently resolved by use of a walker.

A heavy-duty walker (E0148, E0149): is covered for patients who meet coverage criteria for a standard walker and who weigh more than 300 pounds.
**COMMODES**

A commode is covered when the patient is physically incapable of utilizing regular toilet facilities and the following criteria are documented in the patient’s medical record. This would occur in the following situations:

1) The patient is confined to a single room, or

2) The patient is confined to one level of the home environment and there is no toilet on that level, or

3) The patient is confined to the home and there are no toilet facilities in the home.

**An extra wide/heavy duty commode chair (E0168):** is covered for a patient who weighs 300 pounds or more.

**A commode chair with detachable arms (E0165):** is covered if the detachable arms feature is necessary to facilitate transferring the patient or if the patient has a body configuration that requires extra width.

**Commode chair with seat lift mechanism (E0170, E0171):** is covered if the patient has medical necessity for a commode and meets the coverage criteria for a seat lift mechanism. However, a commode with seat lift mechanism is intended to allow the patient to walk after standing. If the patient can ambulate, he/she would rarely meet the coverage criteria for a commode.

**MANUAL WHEELCHAIRS**

A manual wheelchair is covered for use inside the home if the following criteria are documented in the patient’s medical record:

- **Criteria A, B, C, D and E** are met; and
- **Criteria F or G** are met
  
  A) The patient has a mobility limitation that significantly impairs his/her ability to participate in one or more mobility-related activities of daily living (MRADLs).
  
  B) The patient’s mobility limitation cannot be sufficiently resolved by the use of an appropriately fitted cane or walker.
  
  C) The patient’s home provides adequate access between rooms, maneuvering space and surfaces for use of the manual wheelchair that is provided.
  
  D) Use of a manual wheelchair will significantly improve the patient’s ability to participate in MRADLs and the patient will use it on a regular basis in the home.
  
  E) The patient has not expressed an unwillingness to use the manual wheelchair that is provided in the home.
  
  F) The patient has sufficient upper extremity function and other physical and mental capabilities needed to safely self-propel the manual wheelchair that is provided in the home during a typical day or the patient has a caregiver who is available, willing and able to provide assistance with the wheelchair.
  
  G) The beneficiary has a caregiver who is available, willing and able to provide assistance with the wheelchair.

**STANDARD HEMI WHEELCHAIR (K0002):** covered when the patient requires a lower seat height (17” to 18 “) because of short stature or to enable the patient to place his/her feet on the ground for propulsion.
LIGHTWEIGHT WHEELCHAIR (K0003): covered when a patient:
a) Cannot self-propel in a standard wheelchair in the home; and
b) The patient can and does self-propel in a lightweight wheelchair.

HIGH STRENGTH LIGHTWEIGHT WHEELCHAIR (K0004): covered when a patient meets the criteria in (1) and/or (2):
1) The patient self-propels the wheelchair while engaging in frequent activities in the home that cannot be performed in a standard or lightweight wheelchair.
2) The patient requires a seat width, depth, or height that cannot be accommodated in a standard, lightweight or hemi wheelchair, and spends at least two hours per day in the wheelchair.

HEAVY DUTY WHEELCHAIR (K0006): covered if the patient weighs more than 250 pounds or the patient has severe spasticity.

EXTRA HEAVY DUTY WHEELCHAIR (K0007): covered if the patient weighs more than 300 pounds.

FOLLOW FACE-TO-FACE REQUIREMENTS (See Page 6)
POWER MOBILITY DEVICES
(Power Wheelchair and Power Operated Vehicle)

**DOCUMENTATION REQUIREMENTS:**

Power wheelchairs and power-operated vehicles are covered if the following criteria are documented in the patient’s medical record:

**ORDER:** must be received within 45 days after completion of the face-to-face examination and must contain all of the following elements:
1) Beneficiary’s name
2) Description of the item that is ordered
3) Date of the face-to-face examination
4) Pertinent diagnoses/conditions
5) Length of need
6. Physician’s signature
7. Date of physician’s signature

**FACE-TO-FACE EXAMINATION:** must be done for each Power Mobility Device and should include the following:

<table>
<thead>
<tr>
<th>For POVs and PWCs</th>
<th>What is this patient’s mobility limitation and how does it interfere with the performance of activities of daily living?</th>
</tr>
</thead>
<tbody>
<tr>
<td>For POVs and PWCs</td>
<td>Why can’t cane or walker meet this patient’s mobility needs in the home?</td>
</tr>
<tr>
<td>For POVs and PWCs</td>
<td>Why can’t a manual wheelchair meet this patient’s mobility needs in the home?</td>
</tr>
<tr>
<td>For POVs</td>
<td>Does this patient have the physical and mental abilities to transfer into a POV and to operate it safely in the home?</td>
</tr>
<tr>
<td>For PWCs</td>
<td>Why can’t a POV (scooter) meet this patient’s mobility needs in the home?</td>
</tr>
<tr>
<td>For PWCs</td>
<td>Does this patient have the physical and mental abilities to operate a power wheelchair safely in the home?</td>
</tr>
</tbody>
</table>

The report should also provide the following documentation:

- Related diagnosis
- History
- Physical Exam
- Functional assessment

**HOME ASSESSMENT:** It must be verified that the patient can adequately maneuver the device that is provided considering physical layout, doorway width, doorway thresholds, and surfaces. There must be a written report of this evaluation available on request.

**FOLLOW FACE-TO-FACE REQUIREMENTS (See Page 6)**
**HOSPITAL BEDS**

**FIXED HEIGHT HOSPITAL BED (E0250, E0251, E0290, E0291, and E0328):** covered if one or more of the following criteria are documented in the patient’s medical record:

1) The patient has a medical condition which requires positioning of the body in ways not feasible with an ordinary bed. Elevation of the head/upper body less than 30 degrees does not usually require the use of a hospital bed, or

2) The patient requires positioning of the body in ways not feasible with an ordinary bed in order to alleviate pain, or

3) The patient requires the head of the bed to be elevated more than 30 degrees most of the time due to congestive heart failure, chronic pulmonary disease or problems with aspiration, or

4) The patient requires traction equipment which can only be attached to a hospital bed.

**VARIABLE HEIGHT HOSPITAL BED (E0255, E0256, E0292, E0293):** covered if the patient meets one of the criteria for a fixed height hospital bed and requires a bed height different than a fixed height hospital bed to permit transfers to chair, wheelchair or standing position.

**SEMI-ELECTRIC HOSPITAL BED (E0260, E0261, E0294, E0295 and E0329):** covered if the patient meets one of the criteria for a fixed height bed and requires frequent changes in body position and/or has an immediate need for a change in body position.

**HEAVY DUTY EXTRA WIDE HOSPITAL BED (E0301, E0303):** covered if the patient meets one of the criteria for a fixed height hospital bed and the patient’s weight is more than 350 pounds, but does not exceed 600 pounds.

**EXTRA HEAVY DUTY HOSPITAL BED (E0302, E0304):** covered if the patient meets one of the criteria for a hospital bed and the patient’s weight exceeds 600 pounds.

**TOTAL ELECTRIC HOSPITAL BED (E0265, E0266, E0296, and E0297):** not covered; the height adjustment feature is a convenience feature.

**FOLLOW FACE-TO-FACE REQUIREMENTS (See Page 6)**
**TRAPEZE**

**DOCUMENTATION REQUIREMENTS:**

Trapeze equipment (E0910, E0940) is covered if the beneficiary needs this device to sit up because of a respiratory condition, to change body position for other medical reasons, or to get in or out of bed.

Heavy duty trapeze equipment (E0911, E0912) is covered if the beneficiary meets the criteria for regular trapeze equipment and the beneficiary’s weight is more than 250 pounds.

**FOLLOW FACE-TO-FACE REQUIREMENTS (See Page 6)**

---

**PATIENT LIFT**

**DOCUMENTATION REQUIREMENTS:**

A patient lift is covered if transfer between bed and a chair, wheelchair, or commode is required and, without the use of a lift, the beneficiary would be bed confined.

A patient lift described by codes E0630, E0635, E0639, or E0640 is covered if the basic coverage criteria are met.

If the coverage criteria are not met, the lift will be denied as not reasonable and necessary.

A multi-positional patient transfer system (E0636, E1035, E1036) is covered if both of the following criteria 1 and 2 are met:

1) The basic coverage criteria for a lift are met; and
2) The beneficiary requires supine positioning for transfers

If either criterion 1 or 2 is not met, codes E0636, E1035, and E1036 will be denied as not reasonable and necessary.

**FOLLOW FACE-TO-FACE REQUIREMENTS (See Page 6)**
POSITIVE AIRWAY PRESSURE DEVICES FOR THE TREATMENT OF SLEEP APNEA (PAP)

INITIAL COVERAGE: (First Three Months):
1) The patient has a face to face clinical evaluation by the treating physician (PCP or Sleep doctor) prior to the sleep test
   Physicians shall document the face-to-face clinical evaluations and re-evaluations in a detailed narrative note in their charts in the format that they use for other entries. For the initial evaluation, the report would commonly document pertinent information about the following elements, but may include other details. Each element would not have to be addressed in every evaluation.

   History
   - Signs and symptoms of sleep disordered breathing including snoring, daytime sleepiness, observed apneas, choking or gasping during sleep, morning headaches
   - Duration of symptoms
   - Validated sleep hygiene inventory such as the Epworth Sleepiness Scale (see Appendices)

   Physical Exam
   - Focused cardiopulmonary and upper airway system evaluation
   - Neck circumference
   - Body mass index (BMI)

2) Equipment is covered if the patient has a diagnosis of obstructive sleep apnea (OSA) documented by an attended, facility-based polysomnogram and meets either of the following criteria (a or b):
   a) The AHI is greater than or equal to 15 events per hour, or
   b) The AHI is from 5 to 14 events per hour with documented symptoms of:
      1) excessive daytime sleepiness
      2) impaired cognition
      3) mood disorders
      4) insomnia
      5) hypertension
      6) ischemic heart disease
      7) history of stroke.

3) The patient and/or their caregiver has received instruction from the supplier of the CPAP device and accessories in the proper use and care of the equipment.

*If the AHI or RDI is calculated based on less than 2 hours of sleep or recording time, the total number of recorded events used to calculate the AHI or RDI (respectively) must be at least the number of events that would have been required in a 2 hour period (i.e., must reach ≥30 events without symptoms or ≥10 events with symptoms).*
Sleep Test
Coverage of a PAP device for the treatment of OSA is limited to claims where the diagnosis of OSA is based upon a Medicare-covered sleep test (Type I, II, III, IV). A Medicare-covered sleep test must be either a polysomnogram performed in a facility-based laboratory (Type I study) or a home sleep test (HST) (Types II, III, or IV). The test must be ordered by the beneficiary’s treating physician and conducted by an entity that qualifies as a Medicare provider of sleep tests and is in compliance with all applicable state regulatory requirements.

CPAP Found Ineffective:
For beneficiaries changing from an E0601 to E0470 due to ineffective therapy while on E0601 (either during a facility-based titration or in the home setting), the treating physician must document:
1. Interface fit and comfort. An appropriate interface has been properly fit and the beneficiary is using it without difficulty. This properly fit interface will be used with the E0470 device; and,
2. E0601 pressure settings. The current pressure setting of the E0601 prevents the beneficiary from tolerating the therapy and lower pressure settings of the E0601 were tried but failed to:
   A. Adequately control the symptoms of OSA; or,
   B. Improve sleep quality; or,
   C. Reduce the AHI/RDI to acceptable levels.

Sleep Test must be interpreted by a physician who holds either:
1. Current certification in Sleep Medicine by the American Board of Sleep Medicine (ABSM); or,
2. Current subspecialty certification in Sleep Medicine by a member board of the American Board of Medical Specialties (ABMS); or,
3. Has completed residency or fellowship training by an ABMS member board and has completed all the requirements for subspecialty certification in sleep medicine except the examination itself and only until the time of reporting of the first examination for which the physician is eligible; or,
4. Has active staff membership at a sleep center or laboratory accredited by the American Academy of Sleep Medicine (AASM) or The Joint Commission (formerly the Joint Commission on Accreditation of Healthcare Organizations - JCAHO).

CONTINUED COVERAGE BEYOND THE FIRST THREE MONTHS OF THERAPY
Continued coverage of a PAP device (E0470 or E0601) beyond the first three months of therapy requires that, no sooner than the 31st day but no later than the 91st day after initiating therapy, the treating physician (primary care physician or sleep certified physician) must conduct a clinical re-evaluation and document that the beneficiary is benefiting from PAP therapy.
For PAP devices with initial dates of service on or after November 1, 2008, documentation of clinical benefit is demonstrated by:
1. Face-to-face clinical re-evaluation by the treating physician with documentation that symptoms of obstructive sleep apnea are improved; and,
2. Objective evidence of adherence to use of the PAP device, reviewed by the treating physician.
Adherence to therapy is defined as use of PAP ≥4 hours per night on 70% of nights during a consecutive thirty (30) day period anytime during the first three (3) months of initial usage.

Beneficiaries who fail the initial 12-week trial are eligible to requalify for a PAP device but must have both:

1. Face-to-face clinical re-evaluation by the treating physician to determine the etiology of the failure to respond to PAP therapy; and,

2. Repeat sleep test in a facility-based setting (Type 1 study).

FOLLOW FACE-TO-FACE REQUIREMENTS (See Page 6)
E0470 - RESPIRATORY ASSIST DEVICE, BI-LEVEL PRESSURE CAPABILITY, WITHOUT BACKUP RATE FEATURE,
E0471 - RESPIRATORY ASSIST DEVICE, BI-LEVEL PRESSURE CAPABILITY, WITH BACKUP RATE FEATURE,

INITIAL COVERAGE: (First Three Months):
The treating physician must fully document in the patient’s medical record symptoms characteristic of sleep-associated hypoventilation, such as daytime hypersomnolence, excessive fatigue, morning headache, cognitive dysfunction, dyspnea, etc.

A respiratory assist device (RAD) is covered for those patients with clinical disorder groups characterized as (I) restrictive thoracic disorders, (II) severe chronic obstructive pulmonary disease (COPD), (III) central sleep apnea (CSA), or (IV) obstructive sleep apnea (OSA) (E0470 only) and who also meet the following criteria:

I) Restrictive Thoracic Disorders:
   A) There is documentation in the patient’s medical record of a progressive neuromuscular disease (for example, amyotrophic lateral sclerosis) or a severe thoracic cage abnormality (for example, postthoracoplasty for TB), and
      a. An arterial blood gas PaCO2, done while awake and breathing the patient’s prescribed FIO2, is greater than or equal to 45 mm Hg, or
      b. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours), or
      c. For a progressive neuromuscular disease (only), maximal inspiratory pressure is less than 60 cm H2O or forced vital capacity is less than 50% predicted.
   B) And, Chronic obstructive pulmonary disease does not contribute significantly to the patient’s pulmonary limitation.

II) Severe COPD:
   A) An arterial blood gas PaCO2, done while awake and breathing then patient’s prescribed FIO2, is greater than or equal to 52 mm Hg, and
   B) Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the patient’s prescribed FIO2 (whichever is higher), and
   C) Prior to initiating therapy, OSA (and treatment with CPAP) has been considered and ruled out.

If all of the above criteria for patients with COPD are met, an E0470 device will be covered for the first three months of therapy.

An E0471 device will be covered for a patient with COPD in either of the two situations below, depending on the testing performed to demonstrate the need.
Situation 1 - For Group II patients (COPD) who qualified for an E0470 device, an E0471 started any time after a period of initial use of an E0470 device is covered if both criteria A and B are met.

A.) An arterial blood gas PaCO2, done while awake and breathing the patient’s prescribed FIO2, shows that the beneficiary’s PaCO2 worsens less than or equal to 7mm HG compared to the original result from criterion A, (above).

B.) A facility-based PSG demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) while using an E0470 device that is not caused by obstructive upper airway events - i.e. AHI less than 5.

Situation 2 - For Group II patients (COPD) who qualified for an E0470 device, an E0471 device will be covered if, at a time no sooner than 61 days after initial issue of the E0470 device, both of the following criteria A and B are met:

A.) An arterial blood gas PaCO2 is done while awake and breathing the patient’s prescribed FIO2, still remains greater than or equal to 52 mm Hg.

B.) Sleep oximetry while breathing with the E0470 device, demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours), done while breathing oxygen at 2 LPM or the patient’s prescribed FIO2 (whichever is higher).

III) Central Sleep Apnea or Complex Sleep Apnea:

A) The diagnosis of central sleep apnea (CSA) or complex sleep apnea (CompSA) and

B) Significant improvement of the sleep-associated hypoventilation with the use of an E0470 or E0471 device on the settings that will be prescribed for initial use at home, while breathing the patient’s usual FIO2.

- Central Sleep Apnea (CSA) is defined by all of the following:
  1. An apnea-hypopnea index (AHI) greater than or equal to 5; and
  2. The sum total of central apneas plus central hypopneas is greater than 50% of the total apneas and hypopneas; and
  3. A central apnea-central hypopnea index (CAHI) is greater than or equal 0.5 per hour; and
  4. The presence of at least one of the following:
     • Sleepiness
     • Difficulty initiating or maintaining sleep, frequent awakenings, or non-restorative sleep
     • Awakening short of breath
     • Snoring
     • Witnessed apneas
  5. There is no evidence of daytime or nocturnal hypoventilation

IV) Hypoventilation Syndrome:

An E0470 device is covered if ...

A) An initial arterial blood gas PaCO2, done while awake and breathing the patient’s prescribed FIO2, is greater than or equal to 45 mm Hg, and

B) Spirometry shows an FEV1/FVC greater than or equal to 70%, and
C) An arterial blood gas PaCO2, done during sleep or immediately upon awakening, and breathing the patient’s prescribed FiO2, shows the beneficiary’s PaCO2 worsened greater than or equal to 7 mm HG compared to the original result in criterion 1, or
D) A facility-based PSG demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events - i.e., AHI less than 5.

An E0471 device is covered if . . .
   A) A covered E0470 device is being used, and
   B)Spirometry shows an FEV1/FVC greater than or equal to 70%, and
   C) An arterial blood gas PaCO2, done while awake, and breathing the patient’s prescribed FiO2, shows that the beneficiary’s PaCO2 worsens greater than or equal to 7 mm HG compared to the ABG result performed to qualify the patient for the E0470 device, or
   D) A facility-based PSG demonstrates oxygen saturation less than or equal to 88% for greater than or equal to 5 minutes of nocturnal recording time (minimum recording time of 2 hours) that is not caused by obstructive upper airway events - i.e., AHI less than 5 while using an E0470 device.

CONTINUED COVERAGE BEYOND THE FIRST THREE MONTHS OF THERAPY:
Patients covered for the first 3 months of a BI-LEVEL unit device must be re-evaluated to establish the medical necessity of continued coverage by Medicare beyond the first three months. While the patient may certainly need to be evaluated at earlier intervals after this therapy is initiated, the re-evaluation upon which Medicare will base a decision to continue coverage beyond this time must occur no sooner than 61 days after initiating therapy by the treating physician. Medicare will not continue coverage for the 4th and succeeding months of therapy until this re-evaluation has been completed.

There must be documentation in the patient’s medical record about the progress of relevant symptoms and patient usage of the device up to that time. Failure of the patient to be consistently using the E0470 or E0471 device for an average of 4 hours per 24 hour period by the time of the re-evaluation (on or after 61 days after initiation of therapy) would represent non-compliant utilization for the intended purposes and expectations of benefit of this therapy.

The following item of documentation must be obtained by the supplier of the device for continuation of coverage beyond three months:
   A signed and dated statement completed by the treating physician no sooner than 61 days after initiating use of the device, declaring that the patient is compliantly using the device (an average of 4 hours per 24 hour period) and that the patient is benefiting from its use.

***The AHI is equal to the average number of episodes of apnea and hypopnea per hour and must be based on a minimum of 2 hours of recording time without the use of the device. The AHI may not be extrapolated or projected.

*** Apnea is defined as a cessation of airflow for at least 10 seconds.
Hypopnea is defined as an abnormal respiratory event lasting at least 10 seconds with at least 30% reduction in thoracoabdominal movement or airflow as compared to the baseline and with at least a 4% oxygen desaturation.

The polysomnography must be performed in a facility based sleep study laboratory and not in the home or in a mobile facility.

An E0471 device (BI-LEVEL ST) is not medically necessary if the primary diagnosis is OSA.

**FOLLOW FACE-TO-FACE REQUIREMENTS (See Page 6)**

**VENTILATOR WITH NON-INVASIVE INTERFACES**

Ventilators are covered for the following conditions:

1. Neuromuscular diseases
2. Thoracic Restrictive diseases
3. Chronic Respiratory failure consequent to chronic obstructive pulmonary disease

Each of these disease categories are comprised of conditions that can vary from severe and life threatening to less serious forms. These disease groups may appear to overlap conditions described in the Respiratory Assist Devices LCD but they are not overlapping.

Choice of an appropriate device i.e., a ventilator versus a bi-level PAP device is made based upon the severity of the condition. CMS distinguished the use of respiratory product types in a National Coverage Analysis Decision Memo (CAG-00052N) in June 2001 saying that RAD is “distinguished from ventilation in a patient for whom interruption or failure of respiratory support leads to death.” The conditions described in the Respiratory Assistance Devices (RAD) local coverage determination are not life-threatening conditions where interruption of respiratory support would quickly lead to serious harm or death. These policies describe clinical conditions that require intermittent and relatively short durations of respiratory support. Thus, any type ventilator would not be eligible for reimbursement for any of the conditions described in the RAD LCD even though the ventilator equipment may have the capability of operating in a bi-level PAP mode. Bi-level PAP devices are considered as reasonable and necessary in those clinical scenarios. Claims for ventilators used for the treatment of conditions described in the RAD LCD will be denied as not reasonable and necessary.

**SEAT LIFT CHAIR MECHANISM**

A seat lift chair is covered if ALL of the following are met and the following criteria are documented in the patient’s medical record:

1. Patient must have severe arthritis of the hip and/or knee, or have a severe neuromuscular disease.
2. The seat lift mechanism must be a part of the physician’s course of treatment and be prescribed to effect improvement, or arrest or retard deterioration of the patient’s condition.
3. The patient must be completely incapable of standing up from any chair.
4. Once standing, the beneficiary must have the ability to ambulate.

**FOLLOW FACE-TO-FACE REQUIREMENTS (See Page 6)**
**CERTIFICATE OF MEDICAL NECESSITY**

**CMS-849 — SEAT LIFT MECHANISMS**

**SECTION A: Certification Type/Date:** INITIAL ___/___/___  REVISED ___/___/___  RECERTIFICATION ___/___/___

<table>
<thead>
<tr>
<th>PATIENT NAME, ADDRESS, TELEPHONE and HICN</th>
<th>SUPPLIER NAME, ADDRESS, TELEPHONE and NSC or NPI #</th>
</tr>
</thead>
<tbody>
<tr>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>PLACE OF SERVICE</th>
<th>Supply Item/Service Procedure Code(s)</th>
<th>PT DOB <em><strong>/</strong></em>/____</th>
<th>Sex (M/F)</th>
<th>Ht. ___(in)</th>
<th>Wt. ___(lbs.)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>NAME and ADDRESS of FACILITY if applicable (see reverse)</th>
<th>PHYSICIAN NAME, ADDRESS, TELEPHONE and UPIN or NPI #</th>
</tr>
</thead>
<tbody>
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</tbody>
</table>

**SECTION B: Information in this Section May Not Be Completed by the Supplier of the Items/Supplies.**

<table>
<thead>
<tr>
<th>EST. LENGTH OF NEED (# OF MONTHS): 1-99 (99=LIFETIME)</th>
<th>DIAGNOSIS CODES: ______  ______  ______  ______</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>ANSWERS</th>
<th>ANSWER QUESTIONS 1-5 FOR SEAT LIFT MECHANISM (Circle Y for Yes, N for No, or D for Does Not Apply)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>1. Does the patient have severe arthritis of the hip or knee?</td>
<td>Y</td>
</tr>
<tr>
<td>N</td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>D</td>
<td></td>
<td>D</td>
</tr>
<tr>
<td>Y</td>
<td>2. Does the patient have a severe neuromuscular disease?</td>
<td>Y</td>
</tr>
<tr>
<td>N</td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>D</td>
<td></td>
<td>D</td>
</tr>
<tr>
<td>Y</td>
<td>3. Is the patient completely incapable of standing up from a regular armchair or any chair in his/her home?</td>
<td>Y</td>
</tr>
<tr>
<td>N</td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>D</td>
<td></td>
<td>D</td>
</tr>
<tr>
<td>Y</td>
<td>4. Once standing, does the patient have the ability to ambulate?</td>
<td>Y</td>
</tr>
<tr>
<td>N</td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>D</td>
<td></td>
<td>D</td>
</tr>
<tr>
<td>Y</td>
<td>5. Have all appropriate therapeutic modalities to enable the patient to transfer from a chair to a standing position (e.g., medication, physical therapy) been tried and failed? If YES, this is documented in the patient’s medical records.</td>
<td>Y</td>
</tr>
<tr>
<td>N</td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>D</td>
<td></td>
<td>D</td>
</tr>
</tbody>
</table>

| NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print): | |
| NAME: ____________________________________________ | |
| TITLE: ___________________________________________ | |
| EMPLOYER: _______________________________________ | |

**SECTION C: Narrative Description of Equipment and Cost**

(1) Narrative description of all items, accessories and options ordered; (2) Supplier's charge; and (3) Medicare Fee Schedule Allowance for each item, accessory, and option. (see instructions on back)

**SECTION D: PHYSICIAN Attestation and Signature/Date**

I certify that I am the treating physician identified in Section A of this form. I have received Sections A, B and C of the Certificate of Medical Necessity (including charges for items ordered). Any statement on my letterhead attached hereto, has been reviewed and signed by me. I certify that the medical necessity information in Section B is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact in that section may subject me to civil or criminal liability.

PHYSICIAN’S SIGNATURE ___________________________________________ DATE ___/___/____

Signature and Date Stamp Are Not Acceptable.
INSTRUCTIONS FOR COMPLETING THE CERTIFICATE OF MEDICAL NECESSITY FOR SEAT LIFT MECHANISMS (CMS-849)

SECTION A: (May be completed by the supplier)

CERTIFICATION TYPE/DATE: If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked “INITIAL.” If this is a revised certification (to be completed when the physician changes the order, based on the patient’s changing clinical needs), indicate the initial date needed in the space marked “INITIAL,” and indicate the recertification date in the space marked “REVISED.” If this is a recertification, indicate the initial date needed in the space marked “INITIAL,” and indicate the recertification date in the space marked “RECERTIFICATION.” Whether submitting a REVISED or a RECERTIFIED CMN, be sure to always furnish the INITIAL date as well as the REVISED or RECERTIFICATION date.

PATIENT INFORMATION: Indicate the patient’s name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on his/her Medicare card and on the claim form.

SUPPLIER INFORMATION: Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC) or applicable National Provider Identifier (NPI). If using the NPI Number, indicate this by using the qualifier XX followed by the 10-digit number. If using a legacy number, e.g. NSC number, use the qualifier 1C followed by the 10-digit number. (For example, 1Cxxxxxxxxxx)

PLACE OF SERVICE: Indicate the place in which the item is being used, i.e., patient’s home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMERC supplier manual for a complete list.

FACILITY NAME: If the place of service is a facility, indicate the name and complete address of the facility.

HCPCS CODES: List all HCPCS procedure codes for items ordered. Procedure codes that do not require certification should not be listed on the CMN.

PATIENT DOB, HEIGHT, WEIGHT AND SEX: Indicate patient’s date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if requested.

PHYSICIAN NAME, ADDRESS: Indicate the PHYSICIAN’S name and complete mailing address.

PHYSICIAN INFORMATION: Accurately indicate the treating physician’s Unique Physician Identification Number (UPIN) or applicable National Provider Identifier (NPI). If using the NPI Number, indicate this by using the qualifier XX followed by the 10-digit number. If using UPIN number, use the qualifier 1G followed by the 6-digit number. (For example, 1Gxxxxxxx)

PHYSICIAN’S TELEPHONE NO: Indicate the telephone number where the physician can be contacted (preferably where records would be accessible pertaining to this patient) if more information is needed.

SECTION B: (May not be completed by the supplier. While this section may be completed by a non-physician clinician, or a Physician employee, it must be reviewed, and the CMN signed (in Section D) by the treating practitioner.)

EST. LENGTH OF NEED: Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the patient will require the item for the duration of his/her life, then enter “99”.

DIAGNOSIS CODES: In the first space, list the ICD9 code that represents the primary reason for ordering this item. List any additional ICD9 codes that would further describe the medical need for the item (up to 4 codes).

QUESTION SECTION: This section is used to gather clinical information to help Medicare determine the medical necessity for the item(s) being ordered. Answer each question which applies to the items ordered, circling “Y” for yes, “N” for no, or “D” for does not apply.

NAME OF PERSON ANSWERING SECTION B QUESTIONS: If a clinical professional other than the treating physician (e.g., home health nurse, physical therapist, dietician) or a physician employee answers the questions of Section B, he/she must print his/her name, give his/her professional title and the name of his/her employer where indicated. If the physician is answering the questions, this space may be left blank.

SECTION C: (To be completed by the supplier)

NARRATIVE DESCRIPTION OF EQUIPMENT & COST: Supplier gives (1) a narrative description of the item(s) ordered, as well as all options, accessories, supplies and drugs; (2) the supplier’s charge for each item(s), options, accessories, supplies and drugs; and (3) the Medicare fee schedule allowance for each item(s), options, accessories, supplies and drugs, if applicable.

SECTION D: (To be completed by the physician)

PHYSICIAN ATTESTATION: The physician’s signature certifies (1) the CMN which he/she is reviewing includes Sections A, B, C and D; (2) the answers in Section B are correct; and (3) the self-identifying information in Section A is correct.

PHYSICIAN SIGNATURE AND DATE: After completion and/or review by the physician of Sections A, B and C, the physician’s must sign and date the CMN in Section D, verifying the Attestation appearing in this Section. The physician’s signature also certifies the items ordered are medically necessary for this patient.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0679. The time required to complete this information collection is estimated to average 12 minutes per response, including the time to review instructions, search existing resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security Blvd. Baltimore, Maryland 21244.

DO NOT SUBMIT CLAIMS TO THIS ADDRESS. Please see http://www.medicare.gov/ for information on claim filing.

Form CMS-849 (09/05) INSTRUCTIONS EF 08/2006
**ENTERAL NUTRITION** is covered for a patient if the following criteria are documented in the patient’s medical record:

- (a) Permanent non-function or disease of the structures that normally permit food to reach the small bowel or
- (b) Disease of the small bowel, which impairs digestion, and absorption of an oral diet, either of which requires tube feedings to provide sufficient nutrients to maintain weight and strength commensurate with the patient’s overall health status.

The patient must have a permanent impairment (at least 3 months).

The patient’s condition could be either anatomic (e.g., obstruction due to head and neck cancer or reconstructive surgery, etc.) or due to a motility disorder (e.g., severe dysphagia following a stroke, etc.).

**NUTRIENTS:**

**Enteral formulae consisting of semi-synthetic intact protein/protein isolates (B4150 or B4152):**

Are appropriate for the majority of patients requiring enteral nutrition.

**Special enteral formulae (B4149, B4153-B4157, B4161, and B4162):**

Need to be justified in each patient

**EQUIPMENT AND SUPPLIES:**

**Feeding Pump (B9000-B9002):** there must be documentation in the patient’s medical record to justify its use (e.g., gravity feeding is not satisfactory due to reflux and/or aspiration, severe diarrhea, dumping syndrome, administration rate less than 100 ml/hr, blood glucose fluctuations, circulatory overload, gastrostomy/jejunostomy tube used for feeding).

**Feeding supply kit (B4034-B4036):** must correspond to the method of administration.

**Supplies included, but not limited to, in the kit billing:**

- (a) Feeding bag/container
- (b) Flushing solution bag/container
- (c) Administration set tubing
- (d) Extension tubing
- (e) Feeding/flushing syringes
- (f) Gastrostomy tube holder
- (g) Dressings used for gastrostomy tube site
- (h) Y Connector, adapter, pressure relieve valve

**Nasogastric tubes (B4081-B4083):** 3 allowed per month

**Gastrostomy/jejunostomy tube (B4087 and B4088):** 1 allowed every 3 months
**DME INFORMATION FORM**

**CMS-10126 — ENTERAL AND PARENTERAL NUTRITION**

All information on this form may be completed by the supplier.

<table>
<thead>
<tr>
<th>Certification Type/Date: INITIAL <em><strong>/</strong></em>/___</th>
<th>REVISED <em><strong>/</strong></em>/___</th>
<th>RECERTIFICATION <em><strong>/</strong></em>/___</th>
</tr>
</thead>
</table>

**Patient Information**

- **Patient Name, Address, Telephone and HIC Number**
  - (____ _) __ __ __ - __ __ __ __
  - HICN _______________________

- **Place of Service**
  - ____________________________
  - Supply Item/Service Procedure Code(s)

- **Physician Name, Address, Telephone and UPIN or NPI Number**
  - (____ _) __ __ __ - __ __ __ __
  - UPIN or NPI #_________________

**Supplier Information**

- **Supplier Name, Address, Telephone and NSC or Applicable NPI Number/Legacy Number**
  - (____ _) __ __ __ - __ __ __ __
  - NSC or NPI #_________________

**Additional Information**

- **Name and Address of Facility**
  - If applicable (see reverse)

- **Place of Service**
  - ____________________________

- **PT DOB ____/____/____**
  - Sex ____ (M/F)
  - Ht. ____(in)
  - Wt. ____(lbs.)

**Estimated Length of Need (# of Months):**

- 1-99 (99=LIFETIME)

**Diagnosis Codes:**

- ____________________________

**Answers**

**Answer Questions 1-6 for Enteral Nutrition, and 6-9 for Parenteral Nutrition** (Circle Y for Yes, N for No, Unless Otherwise Noted)

1. **Y**  
   Is there documentation in the medical record that supports the patient having a permanent non-function or disease of the structures that normally permit food to reach or be absorbed from the small bowel?

2. **Y**  
   Is the enteral nutrition being provided for administration via tube? (i.e., gastrostomy tube, jejunostomy tube, nasogastric tube)

3. **A)________________ B)________________**  
   Print Supply Item/Service Procedure Code(s) of product.

4. **A)________________ B)________________**  
   Calories per day for each corresponding Supply Item/Service Procedure Code(s).

5. **1 2 3 4**  
   Circle the number for method of administration?  
   - 1 – Syringe  
   - 2 – Gravity  
   - 3 – Pump  
   - 4 – Oral (i.e. drinking)

6. **______**  
   Days per week administered or infused (Enter 1 – 7)

7. **Y**  
   Is there documentation in the medical record that supports the patient having permanent disease of the gastrointestinal tract causing malabsorption severe enough to prevent maintenance of weight and strength commensurate with the patient’s overall health status?

8. **Formula components:**
   - Amino Acid ___________(ml/day) _____________concentration % _______gms protein/day
   - Dextrose_____________(ml/day) _____________concentration %
   - Lipids _______________(ml/day) _____________days/week ___________concentration %

9. **1 2 3**  
   Circle the number for the route of administration.  
   - 1 – Central Line (Including PICC)  
   - 2 – Hemodialysis Access Line  
   - 3 – Peritoneal Catheter

**Supplier Attestation and Signature/Date**

I certify that I am the supplier identified on this DME Information Form and that the information provided is true, accurate and complete, to the best of my knowledge. I understand that any falsification, omission, or concealment of material fact associated with billing this service may subject me to civil or criminal liability.

**Supplier Signature_________________________________________**  
**Date _____/____/_____**
INSTRUCTIONS FOR COMPLETING DME INFORMATION FORM
FOR ENTERAL AND PARENTERAL NUTRITION (CMS-10126)

CERTIFICATION TYPE/DATE: If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked “INITIAL.” If this is a revised certification (to be completed when the physician changes the order, based on the patient’s changing clinical needs), indicate the initial date needed in the space marked “INITIAL,” and also indicate the revision date in the space marked “REVISED.” If this is a recertification, indicate the initial date needed in the space marked “INITIAL,” and also indicate the recertification date in the space marked “RECERTIFICATION.” Whether submitting a REVISED or a RECERTIFICATION DIF, be sure to always furnish the INITIAL date as well as the REVISED or RECERTIFICATION date.

PATIENT INFORMATION: Indicate the patient's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on his/her Medicare card and on the claim form.

SUPPLIER INFORMATION: Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC) or applicable National Provider Identifier (NPI). If using the NPI Number, indicate this by using the qualifier XX followed by the 10-digit number. If using a legacy number, e.g. NSC number, use the qualifier 1C followed by the 10-digit number. (For example: 1Cxxxxxxxxxx)

PLACE OF SERVICE: Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMERC supplier manual for a complete list.

FACILITY NAME: If the place of service is a facility, indicate the name and complete address of the facility.

SUPPLY ITEM/SERVICE PROCEDURE CODE(S): List all HCPCS procedure codes for items ordered that require a DIF. Procedure codes that do not require certification should not be listed in this section of the DIF.

PATIENT DOB, HEIGHT, WEIGHT AND SEX: Indicate patient’s date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if required.

PHYSICIAN NAME, ADDRESS: Indicate the physician’s name and complete mailing address.

PHYSICIAN INFORMATION: Accurately indicate the treating physician’s Unique Physician Identification Number (UPIN) or applicable National Provider Identifier (NPI). If using the NPI Number, indicate this by using the qualifier XX followed by the 10-digit number. If using UPIN number, use the qualifier 1G followed by the 6-digit number. (For example: 1Gxxxxxxxx)

PHYSICIAN’S TELEPHONE NO.: Indicate the telephone number where the physician can be contacted (preferably where records would be accessible pertaining to this patient) if more information is needed.

QUESTION SECTION: This section is used to gather clinical information about the item or service billed. Answer each question which applies to the items ordered, checking “Y” for yes, “N” for no, a number if this is offered as an answer option, or fill in the blank if other information is requested.

SUPPLIER ATTESTATION: The supplier’s signature certifies that the information on the form is an accurate representation of the situation(s) under which the item or service is billed.

SUPPLIER SIGNATURE AND DATE: After completion, supplier must sign and date the DME Information Form, verifying the Attestation.
REQUIREMENTS FOR MEDICARE COVERAGE:
1. Patients with significant, chronic hypoxemia or severe lung disease
2. Qualifying blood study results
3. Diagnosis warranting need
4. Alternative treatments have been tried
5. Testing within 30 days prior to set-up

QUALIFYING BLOOD GAS STUDIES:
1. PO2 at or below 55
2. Oxygen saturation at or below 88%
3. Anything above these figures requires a “group II” diagnosis (for results between 56-59 PO2 or 89% O2 Sat.):
   a. Dependent edema suggesting CHF
   b. Pulmonary hypertension or cor pulmonale
   c. Erythrocytemia with a hematocrit greater than 56%
4. For PO2 levels at or above 60 or O2 SAT at or above 90%, oxygen is not medically necessary

TESTING DURING EXERCISE:
When oxygen is covered based on an oxygen study obtained during exercise, there must be Documentation of three (3) oxygen studies in the patient’s medical record
1. Oxygen test results at Rest
2. Oxygen test results during exercise without Oxygen
3. Oxygen test results during exercise with Oxygen

TESTING DURING SLEEP:
1. An arterial PO2 at or below 55 mm Hg, or an arterial oxygen saturation at or below 88 percent, for at least 5 minutes taken during sleep for a beneficiary who demonstrates an arterial PO2 at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent while awake, or
2. A decrease in arterial PO2 more than .10 mm Hg, or a decrease in arterial oxygen saturation more than 5 percent from baseline saturation, for at least 5 minutes taken during sleep associated with symptoms (e.g., impairment of cognitive processes and [nocturnal restlessness or insomnia]) or signs (e.g., cor pulmonale, “P” pulmonale on EKG, documented pulmonary hypertension and erythrocytosis) reasonably attributable to hypoxemia

RETESTING:
Patients whose results are borderline (56-59 PO2 or 89% O2 Sat.) must be retested between the 61st and 90th day of home oxygen therapy.
1. This is to establish long term need
2. Recertification is required after 12 months of therapy (by the 13th month claim). No retest is required if the initial CMN was prescribed for a lifetime. If the initial CMN was prescribed for at least 12 months but less than lifetime, testing must be redone within 30 days prior to the renewal date.

FOLLOW FACE-TO-FACE REQUIREMENTS (See Page 6)
a. No more CMNs will be required (routinely)
b. Patients with borderline blood gas results (56-59 PO2 or 89% Sat.) require renewal CMN with the 4th month’s claim. This includes a recertification CMN and blood gas retest.
3. If initial CMN is for less than 12 months, patient will need to be retested within 30 days prior to the revised date to complete the first year and again within 30 days prior to the one year recertification.
4. A revised CMN form must be submitted when changes occur.
   a. E.g. increase or decrease in oxygen flow rate, change in attending physician.

**COMMON ISSUES**
1. Testing on room air versus on oxygen
   a. Patient must be tested in a chronic stable state or 2 days prior to hospital discharge
   b. Exhustuating conditions must be documented to justify testing done on oxygen
2. “PRN” liter flow is not covered
3. Doctor’s original signature required on 484.03 form
4. Greater than 4 LPM requires tests to be conducted on oxygen at 4 LPM showing desaturation of 88 or below.

**REIMBURSEMENT:**
1. Oxygen is paid for in one rental payment amount (MPA), regardless of oxygen type, and payment includes the following:
   a. The oxygen
   b. The cannulas, tubing, masks and other supplies (including transtracheal catheters for patients renting oxygen equipment)
   c. All required oxygen equipment

**PORTABLE OXYGEN:**
1. Portable oxygen used as stationary backup is not reimbursed
2. Patient must have need to ambulate beyond stationary system (in the home) for personal needs
3. Portable oxygen is reimbursed as one monthly payment amount. If assignment is accepted, supplier may NOT charge beneficiary in excess of allowable for portable system. Oxygen refills cannot be billed separately.
4. If the only qualifying blood gas study was performed during sleep, portable oxygen will be denied as not medically necessary.
5. Portable oxygen clients may be candidates for portable transfilling systems or portable oxygen concentrators (POC).

**CHRONIC STABLE STATE**
Coverage of home oxygen therapy requires that the beneficiary be tested in the “chronic stable state.” Chronic Stable State is defined as “...not during a period of an acute illness or an exacerbation of their underlying disease.” All co-existing diseases or conditions that can cause hypoxia must be treated and the beneficiary must be in a chronic stable state before oxygen therapy is considered eligible for payment.

In addition, the beneficiary 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 beneficiary is in the chronic stable state before oxygen saturation results obtained during sleep testing are considered qualifying for oxygen therapy.

**FOLLOW FACE-TO-FACE REQUIREMENTS (See Page 6)**
# Certificate of Medical Necessity

## CMS-484 — Oxygen

### SECTION A: Certification Type/Date

<table>
<thead>
<tr>
<th>Certification Type/Date</th>
<th>INITIAL <em><strong>/</strong></em>/___</th>
<th>REVISED <em><strong>/</strong></em>/___</th>
<th>RECERTIFICATION <em><strong>/</strong></em>/___</th>
</tr>
</thead>
</table>

#### PATIENT

- **Name:** [Patient Name]
- **Address:** [Patient Address]
- **Telephone:** [Patient Telephone]
- **HICN:** [Patient HICN]

#### SUPPLIER

- **Name:** [Supplier Name]
- **Address:** [Supplier Address]
- **Telephone:** [Supplier Telephone]
- **NSC or NPI #:** [Supplier NSC or NPI #]

#### PLACE OF SERVICE

- **PT DOB:** [Patient Date of Birth]
- **Sex:** [Patient Sex (M/F)]
- **Ht:** [Patient Height (in)]
- **Wt:** [Patient Weight]

#### EST. LENGTH OF NEED

- **(1-99) 1-99 (99=LIFETIME)]: [Estimated Length of Need]

#### DIAGNOSIS CODES

- [List of Diagnosis Codes]

### SECTION B: Information in This Section May Not Be Completed by the Supplier of the Items/Supplies.

#### EST. LENGTH OF NEED (# OF MONTHS)

- **1-99 (99=LIFETIME): [Estimated Length of Need] (99=LIFETIME)**

#### DIAGNOSIS CODES

- [List of Diagnosis Codes]

#### ANSWERS

1. **Enter the result of most recent test taken on or before the certification date listed in Section A.**
   - a) [Arterial Blood Gas PO2]
   - b) [Oxygen Saturation]
   - c) [Date of Test]

2. **Was the test in Question 1 performed (1) with the patient in a chronic stable state as an outpatient, (2) within two days prior to discharge from an inpatient facility to home, or (3) under other circumstances?**

3. **Check the one number for the condition of the test in Question 1:**
   - (1) At Rest
   - (2) During Exercise
   - (3) During Sleep

4. **If you are ordering portable oxygen, is the patient mobile within the home? If you are not ordering portable oxygen, check D.**

5. **Enter the highest oxygen flow rate ordered for this patient in liters per minute. If less than 1 LPM, enter a "X".**
   - a) [Arterial Blood Gas PO2]
   - b) [Oxygen Saturation]
   - c) [Date of Test]

6. **If greater than 4 LPM is prescribed, enter results of most recent test taken on 4 LPM. This may be an (a) arterial blood gas PO2 and/or (b) oxygen saturation test with patient in a chronic stable state. Enter date of test (c).**

7. **Does the patient have dependent edema due to congestive heart failure?**

8. **Does the patient have cor pulmonale or pulmonary hypertension documented by P pulmonale on an EKG or by an echocardiogram, gated blood pool scan or direct pulmonary artery pressure measurement?**

9. **Does the patient have a hematocrit greater than 56%?**

#### NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print):

- **Name:** [Person's Name]
- **Title:** [Person's Title]
- **Employer:** [Person's Employer]

### SECTION C: Narrative Description of Equipment and Cost

(1) Narrative description of all items, accessories and options ordered; (2) Supplier’s charge and (3) Medicare Fee Schedule Allowance for each item, accessory and option. (See instructions on back.)

### SECTION D: Physician Attestation and Signature/Date

I certify that I am the treating physician identified in Section A of this form. I have received Sections A, B and C of the Certificate of Medical Necessity (including charges for items ordered). Any statement on my letterhead attached hereto, has been reviewed and signed by me. I certify that the medical necessity information in Section B is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact in that section may subject me to civil or criminal liability.

- **Physician's Signature:** [Signature]
- **Date:** [Date]

Form CMS-484 (11/11)
INSTRUCTIONS FOR COMPLETING THE CERTIFICATE OF MEDICAL NECESSITY FOR OXYGEN

SECTION A: (May be completed by the supplier)

CERTIFICATION DATE: If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked "TYPE"/marked "INITIAL." If this is a revised certification (to be completed when the physician changes the order, based on the patient’s changing clinical needs), indicate the initial date needed in the space marked "INITIAL," and indicate the recertification date in the space marked “REVISED.” If this is a recertification, indicate the initial date needed in the space marked “INITIAL,” and indicate the recertification date in the space marked “RECERTIFICATION.” Whether submitting a REVISED or a RECERTIFIED CMN, be sure to always furnish the INITIAL date as well as the REVISED or RECERTIFICATION date.

PATIENT INFORMATION: Indicate the patient’s name, permanent legal address, telephone number and his/her health insurance claim number (HCN) as it appears on his/her Medicare card and on the claim form.

SUPPLIER INFORMATION: Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC) or applicable National Provider Identifier (NPI). If using the NPI Number, indicate this by using the qualifier XX followed by the 10-digit number. If using a legacy number, e.g. NSC number, use the qualifier 1C followed by the 10-digit number. (For example. 1Cxxxxxxxxx)

PLACE OF SERVICE: Indicate the place in which the item is being used, i.e., patient’s home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMERC supplier manual for a complete list.

FACILITY NAME: If the place of service is a facility, indicate the name and complete address of the facility.

SUPPLY ITEM/SERVICE PROCEDURE CODE(S) List all procedure codes for items ordered. Procedure codes that do not require certification should not be listed on the CMN.

PATIENT DOB, HEIGHT, WEIGHT AND SEX: Indicate patient’s date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if requested.

PHYSICIAN NAME, ADDRESS: Indicate the PHYSICIAN’S name and complete mailing address.

PHYSICIAN INFORMATION: Accurately indicate the treating physician’s Unique Physician Identification Number (UPIN) or applicable National Provider Identifier (NPI). If using the NPI Number, indicate this by using the qualifier XX followed by the 10-digit number. If using UPIN number, use the qualifier 1G followed by the 6-digit number. (For example. 1Gxxxxxxx)

PHYSICIAN’S TELEPHONE NO: Indicate the telephone number where the physician can be contacted (preferably where records would be accessible pertaining to this patient) if more information is needed.

SECTION B: (May not be completed by the supplier. While this section may be completed by a non-physician clinician, or a Physician employee, it must be reviewed, and the CMN signed (in Section D) by the treating practitioner.)

EST. LENGTH OF NEED: Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the patient will require the item for the duration of his/her life, then enter “99”.

DIAGNOSIS CODES: In the first space, list the diagnosis code that represents the primary reason for ordering this item. List any additional diagnosis codes that would further describe the medical need for the item (up to 4 codes).

QUESTION SECTION: This section is used to gather clinical information to help Medicare determine the medical necessity for the item(s) being ordered. Answer each question which applies to the items ordered, checking “Y” for yes, “N” for no, or “D” for does not apply.

NAME OF PERSON ANSWERING SECTION B QUESTIONS: If a clinical professional other than the treating physician (e.g., home health nurse, physical therapist, dietician) or a physician employee answers the questions of Section B, he/she must print his/her name, give his/her professional title and the name of his/her employer where indicated. If the physician is answering the questions, this space may be left blank.

SECTION C: (To be completed by the supplier)

NARRATIVE DESCRIPTION OF EQUIPMENT & COST: Supplier gives (1) a narrative description of the item(s) ordered, as well as all options, accessories, supplies and drugs; (2) the supplier’s charge for each item(s), options, accessories, supplies and drugs; and (3) the Medicare fee schedule allowance for each item(s), options, accessories, supplies and drugs, if applicable.

SECTION D: (To be completed by the physician)

PHYSICIAN ATTESTATION: The physician’s signature certifies (1) the CMN which he/she is reviewing includes Sections A, B, C and D; (2) the answers in Section B are correct; and (3) the self-identifying information in Section A is correct.

PHYSICIAN SIGNATURE AND DATE: After completion and/or review by the physician of Sections A, B and C, the physician’s must sign and date the CMN in Section D, verifying the Attestation appearing in this Section. The physician’s signature also certifies the items ordered are medically necessary for this patient.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0534. The time required to complete this information collection is estimated to average 12 minutes per response, including the time to review instructions, search existing resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security Blvd. Baltimore, Maryland 21244.

DO NOT SUBMIT CLAIMS TO THIS ADDRESS. Please see http://www.medicare.gov/ for information on claim filing.

Form CMS-484 (11/11) INSTRUCTIONS
A SMALL VOLUME NEBULIZER (A7003, A7004, A7005) and related COMPRESSOR (E0570, E0571) are covered when the following criteria are documented in the patient’s medical record:

a) It is medically necessary to administer albuterol (J7611, J7613), budesonide (J7626), cromolyn (J7631), ipratropium (J7644), levalbuterol (J7612, J7614), or metaproterenol (J7669) for the management of obstructive pulmonary disease (ICD-10 diagnosis codes J41.0-J70.9), or

b) It is medically necessary to administer dornase alpha (J7639) to a patient with cystic fibrosis (ICD-10 diagnosis code E84.0) or

c) It is medically necessary to administer tobramycin (J7682) to a patient with cystic fibrosis or bronchiectasis (ICD-10 diagnosis code A15.0, E84.0, J47.0, J47.1, J47.9, Q33.4) or

d) It is medically necessary to administer pentamidine (J2545) to a patient with HIV (ICD-10 diagnosis code B20), pneumocystosis (ICD-10 diagnosis code B59), or complications of organ transplants (ICD-10 diagnosis codes T86.00-T86.99) or

e) It is medically necessary to administer acetylcysteine (J7608) for persistent thick or tenacious pulmonary secretions (ICD-10, A22.1, A37.01- A37.91, A48.1, B25.0, B44.0, B77.81, J09.X1-J63.3 diagnosis codes 480.0-508.9, 786.4).

A LARGE VOLUME NEBULIZER (A7007, A7017), related COMPRESSOR (E0565 or E0572), and WATER or SALINE (A4217 or A7018) are covered when:

a) It is medically necessary to deliver humidity to a patient with thick, tenacious secretions, who has cystic fibrosis, bronchiectasis, a tracheostomy or a tracheobronchial stent (ICD-10) diagnosis codes A15.0, E84.0, J39.8, J47.0, J47.1, J47.9, J98.09, Q33.4, Z43.0, Z93.0). Combination code E0585 will be covered for the same indications.

An E0565 or E0572 COMPRESSOR and FILTERED NEBULIZER (A 7006) are covered when.

a) It is medically necessary to administer pentamidine to patients with HIV (ICD-10 diagnosis code B20) pneumocystosis (ICD-10 diagnosis code B59) and complications of organ transplants (ICD-9 diagnosis codes T86.00-T86.99)

FOLLOW FACE-TO-FACE REQUIREMENTS (See Page 6)
Group 1 mattress overlay or mattress (E0180-E0189, E0196-E0199, A4640) is covered if the patient meets:

a) Criterion 1, or
b) Criteria 2 or 3 and at least one of criteria 4-7.

1) Completely immobile - i.e., patient cannot make changes in body position without assistance.

2) Limited mobility - i.e., patient cannot independently make changes in body position significant enough to alleviate pressure.

3) Any stage pressure ulcer on the trunk or pelvis.

4) Impaired nutritional status.

5) Fecal or urinary incontinence.

6) Altered sensory perception.

7) Compromised circulatory status.

A group 2 support surface is covered if the beneficiary meets at least one of the following three Criteria (1, 2 or 3):

1) The beneficiary has multiple stage II pressure ulcers located on the trunk or pelvis which have failed to improve over the past month, during which time the beneficiary has been on a comprehensive ulcer treatment program including each of the following:
   a. Use of an appropriate group 1 support surface, and
   b. Regular assessment by a nurse, physician, or other licensed healthcare practitioner, and
   c. Appropriate turning and positioning, and
   d. Appropriate wound care, and
   e. Appropriate management of moisture/incontinence, and
   f. Nutritional assessment and intervention consistent with the overall plan of care

2) The beneficiary has large or multiple stage III or IV pressure ulcer(s) on the trunk or pelvis.

3) The beneficiary had a myocutaneous flap or skin graft for a pressure ulcer on the trunk or pelvis within the past 60 days, and has been on a group 2 or 3 support surface immediately prior to discharge from a hospital or nursing facility within the past 30 days.

FOLLOW FACE-TO-FACE REQUIREMENTS (See Page 6)
Surgical dressings are covered when either of the following criteria are met:

1. They are required for the treatment of a wound caused by, or treated by, a surgical procedure; or
2. They are required after debridement of a wound.

There must be a physician’s order on file that contains the following (per wound):

(a) The type of dressing (e.g., hydrocolloid wound cover, hydrogel wound filler, etc.),
(b) The size of the dressing (if appropriate)
(c) The number/amount to be used at one time (if more than one)
(d) The frequency of dressing change
(e) The expected duration of need.

There must be documentation in the medical record containing:

(a) Information defining the number and size of surgical/debrided wounds being treated with a dressing and the reason for dressing use (e.g., surgical wound, debrided wound, etc.),
(b) Whether the dressing is being used as a primary or secondary dressing or for some non-covered use (e.g., wound cleansing)
(c) Clinical information, which supports the reasonableness and necessity of the type and, quantity of surgical dressings provided
(d) Evaluation of a patient’s wound(s) must be performed at least on a monthly basis unless there is documentation in the medical record which justifies why an evaluation could not be done within this time frame and what other monitoring methods were used to evaluate the patient’s need for dressings
(e) Evaluation is expected on a more frequent basis (e.g., weekly) in patients in a nursing facility or in patients with heavily draining or infected wounds.

Evaluation: a nurse, physician or other health care professional may perform this. This evaluation must include the type of each wound (e.g., surgical wound, pressure ulcer, burn, etc), its location, its size (length x width in cm) and depth, the amount of drainage and any other relevant information.

Examples of situations in which dressings are non-covered under the Surgical Dressings benefit are:

(a) Drainage from a cutaneous fistula which has not been caused by or treated by a surgical procedure; or
(b) A Stage 1 pressure ulcer; or
(c) A first degree burn; or
(d) Wounds caused by trauma which do not require surgical closure or debridement - e.g., skin tear or abrasion; or
(e) A venipuncture or arterial puncture site (e.g., blood sample) other than the site of an indwelling catheter or needle.
**IN-EXSUFLATION DEVICE**

Mechanical in-exsufflation devices (ICD10, diagnostic codes B91, G12.0-G12.9, G14, G35, G71.0-G71.2, G72.41, G82.50-G82.54) are covered if the following criteria are documented in the patient's medical record:

1. They have a neuromuscular disease, and
2. This condition is causing a significant impairment of chest wall and/or diaphragmatic movement, such that it results in an inability to clear retained secretions.

**FOLLOW FACE-TO-FACE REQUIREMENTS (See Page 6)**

**UROLOGICAL SUPPLIES**

Urinary catheters and external urinary collection devices are covered to drain or collect urine for a beneficiary who has the following:

1. permanent urinary incontinence
2. permanent urinary retention

Permanent urinary retention is defined as retention that is not expected to be medically or surgically corrected in that beneficiary in 3 months.

If the catheter or the external urinary collection device meets the coverage criteria then the related supplies that are necessary for their effective use are also covered.

Urological supplies that are used for purposes not related to the covered use of catheters or external urinary collection devices (i.e., drainage and/or collection of urine from the bladder) are non-covered.

The beneficiary must have a permanent impairment of urination. This does not require a determination that there is no possibility that the beneficiary’s condition may improve sometime in the future. If the medical record, including the judgment of the attending physician, indicates the condition is of long and indefinite duration (ordinarily at least 3 months), the test of permanence is considered met.

Catheters and related supplies will be denied as non-covered in situations in which it is expected that the condition will be temporary.

The use of urological supply for the treatment of chronic urinary tract infection or other bladder condition in the absence of permanent urinary incontinence or retention is non-covered.

Since the beneficiary’s urinary system is functioning, the criteria for coverage under the prosthetic benefit provision are not met.

**OSTOMY SUPPLIES**

Ostomy supplies are covered on a beneficiary with a surgically created opening (stoma) to divert urine, or fecal contents outside the body.

Ostomy supplies are appropriately used for colostomies ileostomies, or urinary ostomies.

The quantity of ostomy supplies needed by a beneficiary is determined by the type of ostomy, its location, its construction, and the condition of the skin surface surrounding the stoma. There will be variation according to individual beneficiary need and their needs may vary over time.
A PCD coded as E0650 or E0651 is covered for both primary and secondary lymphedema in beneficiaries with chronic and severe lymphedema when all of the following three requirements are met:

1. The beneficiary has a diagnosis of lymphedema as defined above, and
2. The beneficiary has persistence of chronic and severe lymphedema as identified by the documented presence of at least one of the following clinical findings:
   - Marked hyperkeratosis with hyperplasia and hyperpigmentation
   - Papillomatosis cutis lymphostatica,
   - Deformity of elephantiasis,
   - Detailed measurements over time confirming the persistence of the lymphedema with a history evidencing a likely etiology, and
3. In addition to this documented persistence, the lymphedema is then documented to be unresponsive to other clinical treatment over the course of a required four-week trial (see below for trial guidelines)

Instructions as to the pressure to be used and the frequency and duration of use must be prescribed by the physician.

Pneumatic compression devices are only covered as a treatment of last resort, i.e., other treatments should have been tried and failed which include extremity elevation and custom fabricated gradient pressure stockings or sleeves.

For patients with lymphedema as the result of refractory edema from venous insufficiency causing scarring of the lymphatic channels, a pump will only be covered if ALL of the following criteria have been met:

   a. Ulceration of lower extremity(ies) and,
   b. Standard treatment such as compression bandages have been tried and failed, and
   c. The ulcer(s) have failed to heal after 6 months of continuous treatment.
### SECTION A: Certification Type/Date
- Certification Type/Date: INITIAL / / REVISED / / RECERTIFICATION / /

**PATIENT NAME, ADDRESS, TELEPHONE and HICN**
- (___ ___) ___ ___ - ___ ___ HICN

**SUPPLIER NAME, ADDRESS, TELEPHONE and NSC or NPI #**
- (___ ___) ___ ___ - ___ ___ NSC or NPI #

**PLACE OF SERVICE**

**Supply Item/Service Procedure Code(s):**
- PT DOB ___/___/___ Sex (M/F) Ht. (in) Wt. (lbs.)

**NAME and ADDRESS of FACILITY if applicable (see reverse)**

**PHYSICIAN NAME, ADDRESS, TELEPHONE and UPIN or NPI #**
- (___ ___) ___ ___ - ___ ___ UPIN or NPI #

### SECTION B: Information in this Section May Not Be Completed by the Supplier of the Items/Supplies.

**EST. LENGTH OF NEED (# OF MONTHS):** 1-99 (99=LIFETIME)

**DIAGNOSIS CODE(S):**

<table>
<thead>
<tr>
<th>ANSWERS</th>
<th>ANSWER QUESTIONS 1-5 FOR PNEUMATIC COMPRESSION DEVICES (Check Y for Yes, N for No, Unless Otherwise Noted)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>1. Does the patient have chronic venous insufficiency with venous stasis ulcers?</td>
</tr>
<tr>
<td>Y</td>
<td>2. If the patient has venous stasis ulcers, have you seen the patient regularly over the past six months and treated the ulcers with a compression bandage system or compression garment?</td>
</tr>
<tr>
<td>Y</td>
<td>3. Has the patient had radical cancer surgery or radiation for cancer that interrupted normal lymphatic drainage of the extremity?</td>
</tr>
<tr>
<td>Y</td>
<td>4. Does the patient have a malignant tumor with obstruction of the lymphatic drainage of an extremity?</td>
</tr>
<tr>
<td>Y</td>
<td>5. Has the patient had lymphedema since childhood or adolescence?</td>
</tr>
</tbody>
</table>

**NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print):**
- NAME: ____________________________ TITLE: ______________________ EMPLOYER: ____________________________

### SECTION C: Narrative Description of Equipment and Cost

1. Narrative description of all items, accessories and options ordered; (2) Supplier’s charge; and (3) Medicare Fee Schedule Allowance for each item, accessory, and option. (see instructions on back)

### SECTION D: PHYSICIAN Attestation and Signature/Date

I certify that I am the treating physician identified in Section A of this form. I have received Sections A, B and C of the Certificate of Medical Necessity (including charges for items ordered). Any statement on my letterhead attached hereto, has been reviewed and signed by me. I certify that the medical necessity information in Section B is true, accurate and complete, to the best of my knowledge, and I understand that any falsification, omission, or concealment of material fact in that section may subject me to civil or criminal liability.

**PHYSICIAN’S SIGNATURE:** ____________________________

**DATE:** ___/___/____

**Signature and Date Stamps Are Not Acceptable.**
INSTRUCTIONS FOR COMPLETING THE CERTIFICATE OF MEDICAL NECESSITY FOR PNEUMATIC COMPRESSION DEVICES (CMS-846)

SECTION A: (May be completed by the supplier)
CERTIFICATION TYPE/DATE: If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space marked "INITIAL." If this is a revised certification (to be completed when the physician changes the order, based on the patient's changing clinical needs), indicate the initial date needed in the space marked "INITIAL," and indicate the recertification date in the space marked "REVISED." If this is a recertification, indicate the initial date needed in the space marked "INITIAL," and indicate the recertification date in the space marked "RECERTIFICATION." Whether submitting a REVISED or a RECERTIFIED CMN, be sure to always furnish the INITIAL date as well as the REVISED or RECERTIFICATION date.

PATIENT INFORMATION: Indicate the patient's name, permanent legal address, telephone number and his/her health insurance claim number (HICN) as it appears on his/her Medicare card and on the claim form.

SUPPLIER INFORMATION: Indicate the name of your company (supplier name), address and telephone number along with the Medicare Supplier Number assigned to you by the National Supplier Clearinghouse (NSC) or applicable National Provider Identifier (NPI). If using the NPI Number, indicate this by using the qualifier XX followed by the 10-digit number. If using a legacy number, e.g., NSC number, use the qualifier 1G followed by the 10-digit number. (For example. 1Gxxxxxx)

PLACE OF SERVICE: Indicate the place in which the item is being used, i.e., patient's home is 12, skilled nursing facility (SNF) is 31, End Stage Renal Disease (ESRD) facility is 65, etc. Refer to the DMERC supplier manual for a complete list.

FACILITY NAME: If the place of service is a facility, indicate the name and complete address of the facility.

SUPPLY ITEM/SERVICE PROCEDURE CODE(S): List all procedure codes for items ordered. Procedure codes that do not require certification should not be listed on the CMN.

PATIENT DOB, HEIGHT, WEIGHT AND SEX: Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if requested.

PHYSICIAN NAME, ADDRESS: Indicate the PHYSICIAN'S name and complete mailing address.

PHYSICIAN INFORMATION: Accurately indicate the treating physician's Unique Physician Identification Number (UPIN) or applicable National Provider Identifier (NPI). If using the NPI Number, indicate this by using the qualifier XX followed by the 10-digit number. If using UPIN number, use the qualifier 1G followed by the 6-digit number. (For example. 1Gxxxxxx)

PHYSICIAN'S TELEPHONE NO: Indicate the telephone number where the physician can be contacted (preferably where records would be accessible pertaining to this patient) if more information is needed.

SECTION B: (May not be completed by the supplier. While this section may be completed by a non-physician clinician, or a Physician employee, it must be reviewed, and the CMN signed (in Section D) by the treating practitioner.)

EST. LENGTH OF NEED: Indicate the estimated length of need (the length of time the physician expects the patient to require use of the ordered item) by filling in the appropriate number of months. If the patient will require the Item for the duration of his/her life, then enter "99".

DIAGNOSIS CODES: In the first space, list the diagnosis code that represents the primary reason for ordering this item. List any additional diagnosis codes that would further describe the medical need for the item (up to 4 codes).

QUESTION SECTION: This section is used to gather clinical information to help Medicare determine the medical necessity for the item(s) being ordered. Answer each question which applies to the items ordered, checking "Y" for yes, "N" for no, or "D" for does not apply.

NAME OF PERSON ANSWERING SECTION B QUESTIONS: If a clinical professional other than the treating physician (e.g., home health nurse, physical therapist, dietician) or a physician employee answers the questions of Section B, he/she must print his/her name, give his/her professional title and the name of his/her employer where Indicated. If the physician is answering the questions, this space may be left blank.

SECTION C: (To be completed by the supplier)

NARRATIVE DESCRIPTION OF EQUIPMENT & COST: Supplier gives (1) a narrative description of the item(s) ordered, as well as all options, accessories, supplies and drugs; (2) the supplier's charge for each item(s), options, accessories, supplies and drugs; and (3) the Medicare fee schedule allowance for each item, options, accessories, supplies and drugs, if applicable.

SECTION D: (To be completed by the physician)

PHYSICIAN ATTESTATION: The physician's signature certifies (1) the CMN which he/she is reviewing includes Sections A, B, C and D; (2) the answers in Section B are correct; and (3) the self-identifying information in Section A is correct.

PHYSICIAN SIGNATURE AND DATE: After completion and/or review by the physician of Sections A, B and C, the physician's must sign and date the CMN in Section D, verifying the Attestation appearing in this Section. The physician's signature also certifies the items ordered are medically necessary for this patient.

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this Information collection is: 0938-0679. The time required to complete this Information collection is estimated to average 12 minutes per response, including the time to review Instructions, search existing resources, gather the data needed, and complete and review the Information collection. If you have any comments concerning the accuracy of the time estimate or suggestions for improving this form, please write to: CMS, Attn: PRA Reports Clearance Officer, 7500 Security Blvd., Baltimore, Maryland 21244.

DO NOT SUBMIT CLAIMS TO THIS ADDRESS. Please see http://www.medicare.gov/ for information on claim filing.

Form CMS-846 (11/11) INSTRUCTIONS
A. The patient must have Diabetes Mellitus.

B. The patient has to have one or more of the following conditions:
   1. History of partial or complete amputation of foot
   2. History of previous foot ulceration
   3. Peripheral neuropathy with evidence of callous formation
   4. History of pre-ulcerative callous
   5. Foot deformity
   6. Poor circulation

C. Patient must have a documented comprehensive Plan of Care.

D. There must be medical documentation in the medical record that documents Diabetes Mellitus as well as one of the conditions above.

E. A written prescription order is required up front for diabetic/therapeutic shoes. The written order form may be used for this purpose or a written prescription containing this required information.

F. A “statement of certification for therapeutic shoe and inserts” is also required

G. A new order (medical statement) will be required for replacement shoes and inserts annually.

H. The prescribing physician must be an MD or DO and may NOT be a Podiatrist, PA, Nurse Practitioner or clinical nurse specialist.
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**Physician’s Order for Diabetic Footwear**

**Patient:**

**Patient Date of Birth:** ____________  
**Patient Phone:** __________________________________________

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**Statement of Certifying Physician**

1. The patient has diabetes mellitus:  
   - Type 1  
   - Type 2

2. **QUALIFYING CONDITIONS:**
   - I have diagnoses and am including my notes showing that this patient has one or more of the following:
     - History of partial or complete amputation of the foot.
     - History of previous foot ulceration.
     - History of pre-ulcerative callus.
     - Peripheral neuropathy with evidence of callus formation.
     - Foot deformity.
     - Poor circulation.

3. I am treating this patient under a comprehensive plan for care of their diabetes.

4. This patient needs special shoes (Extra depth or custom molded) because of their diabetes.

5. This patient needs shoe inserts (Heat molded or custom fabricated) because of their diabetes.

---

**Physician Signature:** ___________________________  
**Signature Date:** ____________

Must be an M.D. or D.O.

**Physician Name:** ___________________________  
**NPI:** ___________________________

**Physician Address:** ___________________________  
**Physician Phone:** ___________________________

---

**Prescription for Diabetic Shoes and Inserts**

1. **Type of shoes prescribed:**
   - ☐ Extra Depth (A5500) - 1 pair, unless otherwise noted.

2. **Type of inserts prescribed:**
   - ☐ Heat Moldable (A5512) - 3 pairs, unless otherwise noted.
   - ☐ Custom Fabricated (A5513) - 3 pairs, unless otherwise noted.

**ICD Notes and/or Special Instructions:**

---

**Physician Signature:** ___________________________  
**Signature Date:** ____________

**Physician Name:** ___________________________  
**NPI:** ___________________________  
**Order Date:** ____________

**Physician Address:** ___________________________  
**Physician Phone:** ___________________________

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Please sign and fax along with your **PATIENT NOTES.**

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MRKT - 052  
REV/CF - 12/15
The following is a partial listing of products that are considered not medically necessary by Medicare and are therefore non-covered.

- Automatic Blood Pressure Monitor
- Bath Tub Rail
- Bath Tub Wall Rail (Grab Bar)
- Bed Board
- Biofeedback Therapy for the Treatment of Urinary Incontinence
- Breast Pumps
- Diapers
- Disposable Sheets
- Disposable Underpads
- Exercise Equipment
- Heel or Elbow Protector
- Hot Water Bottle
- Joint Supportive Device/Garment, Elastic or Equal, Each
- Non-Electric Heat Pad, Moist
- Over-Bed Table
- Raised Toilet Seat
- Safety Equipment (E.G., Belt, Harness or Vest)
- Slings
- Stairway or Platform Lifts
- Stand Rack (Prone Stander)
- Surgical Stockings
- Toilet Rail
- Transfer Tub Rail Attachment
- Tub Stool or Bench
- Wheelchair Ramps
- Whirlpool Baths
It should be noted that Medicare considers the following pieces of equipment contraindicated.

- Commode
- Walker (or any walking aid)
- Wheelchair

As a general rule, a claim for any combination of these pieces of equipment simultaneously will result in partial or complete denial of the claim. There are, however, some exceptions to the rule. They are as follows:

1. If the patient requires a wheelchair, and his/her physician’s medical documentation states that he/she is undergoing rehabilitation and ambulation is a short-term goal, the reimbursement may be granted for a wheelchair and walking aid.
2. If the patient requires a walking aid, or is wheelchair confined, and therefore restricted to floor of his/her home, reimbursement may be made for a commode if there is no bathroom located on that floor.
3. If a patient is wheelchair confined, and the wheelchair is too wide to pass through the bathroom door, a commode may be reimbursed.

Criterion 1, 2 or 3 must be clearly documented in the patient’s medical record.
As the future of home health care evolves, Keene Medical Products remains committed to helping our customers recuperate in the comfort of their homes.

Our health care reimbursement system continues to change at both a federal government level and in the private sector. Keene Medical Products strives to offer updated reimbursement information to our customers and referral sources.

We hope you find this guide helpful and we look forward to working with you to meet the healthcare challenges of today and into the future.