



---

**KEENE MEDICAL PRODUCTS**

---

*“Bringing Healthcare Home Since 1975.”*

***A Clinician’s Guide  
to Prescribing  
Home Oxygen and  
Home Medical Equipment  
for the  
Medicare Beneficiary***



**Recipient of the HME Excellence Award for Best Respiratory Provider**

**INDEX**

Introduction..... 3

Reimbursement Categories ..... 4/5

Common Acronyms..... 6

Medical Record and Documentation ..... 7-15

Face-to-Face Requirements ..... 7-15

Proof of Delivery ..... 7-15

Equipment:

- Canes and Crutches (Retail Sale Only)..... 16
- Commodos (Retail Sale Only)..... 16
- Enteral and Parenteral Nutrition..... 17
- Enteral and Parenteral Nutrition (DME Information Form)..... 18-19
- Hospital Beds..... 20
- In-Exsufflation Device ..... 20
- Manual Wheelchairs ..... 21
- Nebulizer ..... 22
- Negative Pressure Wound Therapy Pumps..... 23-24
- Ostomy Supplies ..... 25
- Oxygen Guidelines..... 25-27
- Oxygen (Certificate of Medical Necessity) ..... 28-29
- Patient Lift..... 30
- Pneumatic Compression Device ..... 30-31
- Pneumatic Compression Device (Certificate of Medical Necessity)..... 32-33
- Positive Airway Pressure Devices (CPAP/BiLevel)..... 34-35
- Power Mobility Devices (Retail Sales Only)..... 36
- Respiratory Assist Device (BiLevel) ..... 37-39
- Seat Lift Chair Mechanism (Retail Sales Only)..... 40
- Seat Lift Mechanisms (Certificate of Medical Necessity)..... 41-42
- Support Surfaces ..... 43
- Surgical Dressings..... 44
- Therapeutic Shoes for Persons with Diabetes..... 45-46
- Trapeze ..... 47
- Urological Supplies..... 47
- Ventilator with Non-Invasive Interfaces..... 48
- Walkers (Retail Sales Only)..... 48

Non-Covered Items ..... 49

Summary ..... 49

## 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

#### *New Hampshire Branch Locations*

66 Airport Road  
**Concord, NH 03301**  
603-224-0135

275 Washington Street  
**Keene, NH 03431**  
603-357-3222

240 Meriden Road PO Box 439  
**Lebanon, NH 03766**  
603-448-5225

101 Elm Street  
**Nashua, NH 03060**  
603-595-2097  
(By appointment)

875 Greenland Road, Unit B12  
**Portsmouth, NH 03801**  
603-431-6006

#### *Vermont Branch Locations*

81 River Street  
Heritage 1 Building, Suite 104  
**Montpelier, VT 05602**  
802-223-0665

80 Commons Drive  
**Newport, VT 05855**  
802-334-5160

153 Allen Street  
**Rutland, VT 05701**  
802-773-4574

397 Railroad Street, Suite B  
**St. Johnsbury, VT 05819**  
802-748-4185  
(By Appointment)

296 Avenue D, Suite 15  
**Williston, VT 05495**  
802-863-2114

## **REIMBURSEMENT CATEGORIES**

### **1. Inexpensive or routinely purchased equipment**

Equipment 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.

### **7. Parenteral/Enteral Pump rental/purchase**

Parenteral/enteral pumps can be either rented or purchased. When rented, they are processed like capped rental items with two notable exceptions. First, they are not subject to the 25% reduction payment for the fourth rental month and after. Second, a beneficiary may elect to purchase a parenteral/enteral pump at any time. If the beneficiary decides to purchase the pump once rentals have been paid, the purchase allowance will consist of the used purchase allowance less the amount allowed to date for rentals.

Additional rental payments after the 15-month limit has been reached or after the pump has been purchased will only be considered if the attending physician changes the prescription between parenteral and enteral nutrients.

A change in suppliers during the 15-month rental period does not begin a new 15-month rental period. The new supplier is entitled to the balance remaining on the 15-month rental period. The

supplier that collects the last month of rental (i.e., the 15th month) is responsible for ensuring that the beneficiary has a pump for as long as it is medically necessary and for maintenance and servicing of the pump during the period of medical necessity.

## **8. Retail Items**

Keene Medical Products is not contracted with Medicare to bill for the following items:

- a. Canes and Crutches
- b. Commodes
- c. CPM Devices
- d. Heat and Cold Applications
- e. Scooters
- f. Transcutaneous Electrical Nerve Stimulators (TENS)
- g. Ultraviolet Lights
- h. Portable sleep therapy devices (I.e. Air Mini)
- i. So Clean sleep equipment sanitizer
- j. Any type Walker
- k. Stairway Lifts
- l. Seat Lift Chairs and Mechanisms

These items may be provided as a Retail Sale and paid out of pocket by the Medicare beneficiary.

## COMMON ACRONYMS

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

ABG	Arterial Blood Gas
ABN	Advanced Beneficiary Notice
ADL	Activities of Daily Living
AHI	Apnea Hypopnea Index
AOB	Assignment of Benefits
CMN	Certificate of Medical Necessity
CMS	Centers for Medicare and Medicaid Services (Formerly HCFA)
COPD	Chronic Obstructive Pulmonary Disease
CPAP	Continuous Positive Airway Pressure
CSA	Central Sleep Apnea
DIF	DME Information Form
DME	Durable Medical Equipment
DME MAC	Durable Medical Equipment Medicare Administrative Contractor
DME POS	Durable Medical Equipment, Prosthetics, Orthotics and Supplies
DME PSC	Durable Medical Equipment Program Safeguard Contractor
EOMB	Explanation of Medicare Benefits
HHA	Home Health Agency
HIPAA	Health Insurance Portability and Accountability Act
MRADL	Mobility Related Activities of Daily Living
NPI	National Provider Identifier
OSA	Obstructive Sleep Apnea
PAP	Positive Airway Pressure
PCP	Primary Care Physician
PMD	Power Mobility Device
POV	Power Operated Vehicle
RAD	Respiratory Assist Device
RDI	Respiratory Disturbance Index
SaO <sub>2</sub>	Oxygen Saturation Level by ABG
SpO <sub>2</sub>	Oxygen Saturation Level by Oximetry
WVO	Written Verbal Order
ZPIC	Zone Program Integrity Contractors

## 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).

### ORDERS

#### **GENERAL**

All claims for items billed to Medicare require a written order/prescription from the treating practitioner as a condition for payment.

This written order/prescription is referred to as the Standard Written Order (SWO) (see below). "All claims" refers to all claims submitted for payment of purchases or rentals to Medicare Part B.

The term "treating practitioner" is used throughout this document and except where specifically noted, refers to physician, as defined in section 1861(r)(1) of the Act, or physician assistant, nurse practitioner, or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act.

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

Items dispensed and/or billed that do not meet these order/prescription requirements and those below must be submitted with an EY modifier added to each affected HCPCS code.

Certain items require an order based on statute (e.g., therapeutic shoes for diabetics, oral anticancer drugs, and oral antiemetic drugs which are a replacement for intravenous antiemetic drugs). In such instances, if statutory requirements related to the order are not met, the claim will be denied as not meeting the benefit category.

For DMEPOS items other than PMDs, someone other than the treating practitioner may complete certain required elements of the SWO; however, the SWO must be signed by the treating practitioner.

Prescribing of DMEPOS is limited by Medicare regulations and by the treating practitioner's respective scope of practice as determined by the state wherein they practice. Chiropractors are not permitted to prescribe DMEPOS items.

### **NEW ORDER REQUIREMENTS**

#### **A new order/prescription is required:**

- For all claims for purchases or initial rentals;
- If there is a change in the DMEPOS order/prescription e.g. quantity;
- On a regular basis (even if there is no change in the order/prescription) only if it is so specified in the documentation section of a particular medical policy;
- When an item is replaced;
- When there is a change in the supplier, and the new supplier is unable to obtain a copy of a valid order/prescription for the DMEPOS item from the transferring supplier.

## **STANDARD WRITTEN ORDER (SWO)**

A SWO must be communicated to the supplier prior to claim submission. For certain items of DMEPOS, a written order is required prior to delivery (WOPD) of the item(s) to the beneficiary (see below).

### **A SWO must contain all of the following elements:**

- Beneficiary's name or Medicare Beneficiary Identifier (MBI)
- Order Date
- General description of the item
- The description can be either a general description (e.g., wheelchair or hospital bed), a HCPCS code, a HCPCS code narrative, or a brand name/model number
- For equipment - In addition to the description of the base item, the SWO may include all concurrently ordered options, accessories or additional features that are separately billed or require an upgraded code (List each separately)
- For supplies – In addition to the description of the base item, the DMEPOS order/prescription may include all concurrently ordered supplies that are separately billed (List each separately)
- Quantity to be dispensed, if applicable
- Treating Practitioner Name or NPI
- Treating practitioner's signature

Signatures must comply with the CMS signature requirements outlined in CMS Internet-Only Manuals 100-08, Program Integrity Manual (PIM), Chapter 3, Section 3.3.2.4. Signature and date stamps are not allowed.

Upon request by a contractor, DMEPOS suppliers must provide documentation of the completed SWO.

In those limited instances in which the treating practitioner is also the supplier and is permitted to furnish specific items of DMEPOS and fulfill the role of the supplier in accordance with any applicable laws and policies, a SWO is not required. However, the medical record must still contain all of the required SWO elements.

## **WRITTEN ORDERS PRIOR TO DELIVERY (WOPD)**

A WOPD is a completed SWO that is communicated to the DMEPOS supplier before delivery of the item(s).

Pursuant to Final Rule 1713 (84 Fed. Reg Vol 217), CMS may select DMEPOS items appearing on the Master List of DMEPOS Items potentially subject to a Face-to-Face Encounter and WOPD requirement and include them on a Required List.

### **The Required List will be comprised of:**

- Statutorily required DMEPOS items such as Power Mobility Devices (PMDs); and
- Additional DMEPOS items selected by CMS appearing on the Required List.

Items appearing on the Required List are subject to the face-to-face encounter and WOPD requirements.

CMS and the DME MACs will post on their websites the Required List of the selected HCPCS codes, once published through the Federal Register Notice, and the Required List will be periodically updated.

Note that the face-to-face encounter and WOPD requirements are statutorily required for PMDs, and in accordance with this statutory obligation, both will continue to be required, and will be included in any future publications of the Required List.

The date of the WOPD shall be on or before the date of delivery.

A WOPD must be completed within six (6) months after the required face-to-face encounter.

For PMDs, following the face-to-face encounter, the treating practitioner must complete the WOPD of the item pursuant to 1834(a)(1)(E)(iv).

Upon request by a contractor, DMEPOS suppliers must provide documentation of the completed WOPD.

## **DOCUMENTATION REQUIREMENTS**

### **GENERAL**

There are numerous CMS manual requirements, reasonable and necessary (R&N) requirements, benefit category, and other statutory and regulatory requirements that must be met in order for payment to be justified. In the event of a claim review, a DMEPOS supplier must provide sufficient information to demonstrate that the applicable criteria have been met thus justifying payment.

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

CMS requires that in the event of an audit, the MACs, CERT, SMRC, Recovery Auditors, and UPICs shall determine that an item/service is correctly coded. The supplier must have on file a description of items provided to the beneficiary in sufficient detail to determine the accuracy of claims coding including a description of the item(s) delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number.

Reimbursement shall be based on the specific utilization amount that is supported by contemporaneous medical records.

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

If the Medicare qualifying supplier documentation is older than 7 years, proof of continued *medical necessity of the item or necessity of the repair* can be used as the supporting Medicare qualifying documentation.

## **REASONABLE AND NECESSARY CRITERIA (R&N)**

CMS National Coverage Determinations (NCDs) and contractor Local Coverage Determinations (LCDs) describe the requirements that must be met for an item to be considered R&N. These R&N criteria are often referred to as medical necessity.

### **MEDICAL RECORD DOCUMENTATION**

In the event of a claim review, information contained directly in the contemporaneous medical record is the source required to justify payment except as noted elsewhere for prescriptions and CMNs. The medical record is not limited to treating practitioner's office records but may include records from hospitals, nursing facilities, home health agencies, other healthcare professionals, etc. (not all-inclusive). Records from suppliers or healthcare professionals with a financial interest in the claim outcome are not considered sufficient by themselves for determining that an item is reasonable and necessary. DMEPOS suppliers are reminded that:

- Supplier-produced records, even if signed by the treating practitioner, and attestation letters (e.g. letters of medical necessity) are deemed not to be part of a medical record for Medicare payment purposes.
- Templates and forms, including CMS CMNs, are subject to corroboration with information in the medical record.
- A prescription is not considered to be part of the medical record. Medical information intended to demonstrate compliance with coverage criteria may be included on the prescription but must be corroborated by information contained in the medical record.

In addition to the general requirements discussed above, certain DMEPOS items may have specific documentation requirements. Details regarding these policy specific requirements are contained in the applicable LCD-related Policy Article.

### **CONTINUED MEDICAL NEED**

For all DMEPOS items, the initial justification for medical need is established at the time the item(s) is first ordered; therefore, 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 timeframe. 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 rented 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 remain reasonable and necessary. Information used to justify continued medical need must be timely for the DOS under review. Any of the following may serve as documentation justifying continued medical need:

- A recent order/prescription by the treating practitioner for refills;
- A recent change in an order/prescription;
- A properly completed CMN or DIF with an appropriate length of need specified;

- 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**

Continued use describes the ongoing utilization of supplies or a rented 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:

- Timely documentation in the beneficiary's medical record showing usage of the item, related option/accessories and supplies;
- Supplier records documenting the request for refill/replacement of supplies in compliance with the REFILL DOCUMENTATION REQUIREMENTS section. This is deemed sufficient to document continued use for the base item, as well;
- 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.

### **REFILL DOCUMENTATION REQUIREMENTS**

This section contains general refill requirements that pertain to all policies. Refer to the applicable LCD for policy specific refill requirements.

A routine prescription for refills is not needed.

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

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

The refill record must include:

- Beneficiary's name or authorized representative if different from the beneficiary
- A description of each item that is being requested
- Date of refill request
- For consumable supplies i.e., those that are used up (e.g., ostomy or urological supplies, surgical dressings, etc.) the supplier must assess the quantity of each item that the beneficiary still has remaining to document that the amount remaining will be nearly exhausted on or about the supply anniversary date.
- For non-consumable supplies i.e., those more durable items that are not used up but may need periodic replacement (e.g., PAP and RAD supplies) the supplier must assess whether the supplies remain functional, providing replacement (a refill) only when the supply item(s) is no longer able to function. The supplier must document the functional condition of the item(s) being refilled in sufficient detail to demonstrate the cause of the dysfunction that necessitates replacement (refill).

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

### **PROOF OF DELIVERY (POD)**

42 CFR 424.57(c)(12) requires suppliers to maintain POD documentation in their files.

POD documentation, as well as claims documentation, must be maintained in the supplier's files for 7 years (starting from the DOS).

No billing may be made for any DMEPOS to the DME MAC prior to the date of discharge from an inpatient facility. A supplier may deliver a DME, prosthetics, or orthotics item (but not supplies) to a beneficiary in an inpatient facility that does not qualify as the beneficiary's home, for the purpose of fitting or training the beneficiary in the proper use of the item. This delivery may be done up to two (2) days prior to the beneficiary's anticipated discharge to their home. The supplier must bill the date of service on the claim as the date of discharge and the supplier must ensure that the beneficiary takes the item home, or the supplier picks up the item at the facility and delivers it to the beneficiary's home on the date of discharge. Any attempt by the supplier and/or facility to substitute an item that is payable to the supplier for an item that, under statute, should be provided by the facility, may be considered fraudulent.

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

For the purpose of the delivery methods noted below, designee is defined as any person who can sign and accept the delivery of DMEPOS on behalf of the beneficiary.

The supplier should also have on file any documentation containing a description of the item delivered to the beneficiary to determine the accuracy of claims coding including, but not limited to, a voucher, invoice or statement in the supplier records. A description of the item(s) delivered must be noted on the POD. The description can be

either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number.

POD documentation must be available to the Medicare contractor on request. All services that do not have appropriate POD from the supplier will be denied and overpayments will be requested. Suppliers who consistently fail to provide documentation to support their services may be referred to the Office of Inspector General (OIG) or the National Supplier Clearinghouse for investigation and/or imposition of sanctions. As a general Medicare rule, the date of service shall be the date of delivery. There are three methods of delivery. Regardless of the method of delivery, the contractor must be able to determine that the item(s) delivered are the same item(s) submitted for Medicare reimbursement and that the item(s) were received by a specific beneficiary:

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

### **Method 1—Direct Delivery to the Beneficiary by the Supplier**

Suppliers may deliver directly to the beneficiary or the designee. In this case, POD to a beneficiary must be a signed and dated delivery document. The POD document must include:

- Beneficiary's name
- Delivery address
- A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number
- Quantity delivered
- Date delivered
- Beneficiary (or designee) signature

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

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

### **Method 2—Delivery via Shipping or Delivery Service directly to a Beneficiary**

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

- Beneficiary's name

- Delivery address
- Delivery service's package identification number, supplier invoice number, or alternative method that links the supplier's delivery documents with the delivery service's records
- A description of the item(s) being delivered. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number
- Quantity delivered
- Date delivered
- Evidence of delivery

If a supplier utilizes a shipping service or mail order, suppliers have two options for the DOS to use on the claim:

1. Suppliers may use the shipping date as the DOS. The shipping date is defined as the date the delivery/shipping service label is created or the date the item is retrieved by the shipping service for delivery. However, such dates should not demonstrate significant variation.
2. Suppliers may use the date of delivery as the DOS on the claim.

Suppliers may also utilize a return postage-paid delivery invoice from the beneficiary or designee as POD. This type of POD document must contain the information specified above.

### **Method 3—Delivery to Nursing Facility on behalf of a Beneficiary**

For items directly delivered by the supplier to a nursing facility or when a delivery service or mail order is used to deliver the item(s) to a nursing facility, the supplier must have:

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

**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's 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

## **CANES AND CRUTCHES**

*(Retail Sale Only)*

### **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.

## **COMMODES**

*(Retail Sale Only)*

**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.

## ENTERAL NUTRITION

***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 (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

DME 10.03

All INFORMATION ON THIS FORM MAY BE COMPLETED BY THE SUPPLIER		
Certification Type/Date: INITIAL ___/___/___ REVISED ___/___/___ RECERTIFICATION ___/___/___		
PATIENT NAME, ADDRESS, TELEPHONE and MEDICARE ID  (____) _____ - _____ Medicare ID	SUPPLIER NAME, ADDRESS, TELEPHONE and NSC or applicable NPI NUMBER/LEGACY NUMBER  (____) _____ - _____ 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 # _____	
EST. 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 (Check Y for Yes, N for No, Unless Otherwise Noted)	
<input type="checkbox"/> Y <input type="checkbox"/> N	1. 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?	
<input type="checkbox"/> Y <input type="checkbox"/> N	2. Is the enteral nutrition being provided for administration via tube? (i.e., gastrostomy tube, jejunostomy tube, nasogastric tube)	
A) _____ B) _____	3. Print Supply Item/Service Procedure Code(s) of product.	
A) _____ B) _____	4. Calories per day for each corresponding Supply Item/Service Procedure Code(s).	
<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4	5. Check 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)	
<input type="checkbox"/> Y <input type="checkbox"/> N	7. 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?	
<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	8. Formula components: Amino Acid _____ (ml/day) _____ concentration % _____ gms protein/day Dextrose _____ (ml/day) _____ concentration % Lipids _____ (ml/day) _____ days/week _____ concentration %	
<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	9. Check the number for the route of administration. 1 – Central Line (Including PICC) 2 – Hemodialysis Access Line 3 – Peritoneal Catheter	
<b>Supplier Attestation and Signature/Date</b>		
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)

---

<b>CERTIFICATION TYPE/DATE:</b>	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.
<b>PATIENT INFORMATION:</b>	Indicate the patient's name, permanent legal address, telephone number and his/her Medicare ID as it appears on his/her Medicare card and on the claim form.
<b>SUPPLIER INFORMATION:</b>	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)
<b>PLACE OF SERVICE:</b>	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.
<b>FACILITY NAME:</b>	If the place of service is a facility, indicate the name and complete address of the facility.
<b>SUPPLY ITEM/SERVICE PROCEDURE CODE(S):</b>	List all 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.
<b>PATIENT DOB, HEIGHT, WEIGHT AND SEX:</b>	Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if required.
<b>PHYSICIAN NAME, ADDRESS:</b>	Indicate the physician's name and complete mailing address.
<b>PHYSICIAN INFORMATION:</b>	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)
<b>PHYSICIAN'S TELEPHONE NO.:</b>	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.
<b>QUESTION SECTION:</b>	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.
<b>SUPPLIER ATTESTATION:</b>	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.
<b>SUPPLIER SIGNATURE AND DATE:</b>	After completion, supplier must sign and date the DME Information Form, verifying the Attestation.

---

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-10126 (06/19) INSTRUCTIONS

## **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 8)**

## **IN-EXSUFFLATION 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 8)**

## 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 8)**

## **NEBULIZER**

***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 8)**

## **NEGATIVE PRESSURE WOUND THERAPY PUMPS**

***A NEGATIVE PRESSURE WOUND THERAPY PUMP (E2402) AND SUPPLIES (A6550 AND A7000): covered if either criteria A or B are met and documented in the patient's medical record:***

### **A. Ulcers and Wounds in the Home Setting:**

The beneficiary has a chronic Stage III or IV pressure ulcer, neuropathic ulcer, venous or arterial insufficiency ulcer, or a chronic ulcer of mixed etiology. A complete wound therapy program as applicable depending on the type of wound, must have been tried or considered and ruled out prior to application of NPWT.

1. **For all ulcers or wounds**, the following components of a wound therapy program must include a minimum of all of the following general measures, which should either be addressed, applied, or considered and ruled out prior to application of NPWT:

- a. Documentation in the beneficiary's medical record of evaluation, care, **and** wound measurements by a licensed medical professional, **and**
- b. Application of dressings to maintain a moist wound environment, **and**
- c. Debridement of necrotic tissue if present, **and**
- d. Evaluation of and provision for adequate nutritional status

2. **For Stage III or IV pressure ulcers:**

- a. The beneficiary has been appropriately turned and positioned, **and**
- b. The beneficiary has used a group 2 or 3 support surface for pressure ulcers on the posterior trunk or pelvis, **and**
- c. The beneficiary's moisture and incontinence have been appropriately managed

3. **For neuropathic (for example, diabetic) ulcers:**

- a. The beneficiary has been on a comprehensive diabetic management program, **and**
- b. Reduction in pressure on a foot ulcer has been accomplished with appropriate modalities

4. **For venous insufficiency ulcers:**

- a. Compression bandages and/or garments have been consistently applied, **and**
- b. Leg elevation and ambulation have been encouraged

### **B. Ulcers and Wounds Encountered in an Inpatient Setting"**

1. An ulcer or wound (described under A above) is encountered in the inpatient setting and, after wound treatments described under A-1 through A-4 have been tried or considered and ruled out, NPWT is initiated because it is considered in the judgment of the treating physician, the best available treatment option.

The beneficiary has complications of a surgically created wound (for example, dehiscence) or a traumatic wound (for example, pre-operative flap or graft) where there is documentation of the medical necessity for accelerated formation of granulation tissue which cannot be achieved by other available topical wound

treatments (for example, other conditions of the beneficiary that will not allow for healing times achievable with other topical wound treatments)

**a. For all ulcers or wounds**, the following components of a wound therapy program must include a minimum of all of the following general measures, which should either be addressed, applied, or considered and ruled out prior to application of NPWT:

- a. Documentation in the beneficiary's medical record of evaluation, care, **and** wound measurements by a licensed medical professional, **and**
- b. Application of dressings to maintain a moist wound environment, **and**
- c. Debridement of necrotic tissue if present, **and**
- d. Evaluation of and provision for adequate nutritional status

**An NPWT pump and supplies will be denied at any time as not reasonable and necessary if one or more of the following are present:**

- 1. The presence in the wound of necrotic tissue with eschar if debridement is not attempted;
- 2. Osteomyelitis within the vicinity of the wound that is not concurrently being treated with intent to cure;
- 3. Cancer present in the wound;
- 4. The presence of an open fistula to an organ or body cavity within the vicinity of the wound.

**Continued Coverage:**

In order for coverage to continue, a licensed medical professional must do the following:

- 1. On a regular basis
  - a. Directly assess the wound(s) being treated with the NPWT pump, and
  - b. Supervise or directly perform the NPWT dressing changes, and
- 2. On at least a monthly basis, document changes in the ulcer's dimensions and characteristics.

**Coverage Ends:**

For wounds and ulcers an NPWT pump and supplies will be denied as not reasonable and necessary with any of the following, whichever occurs earliest:

- 1. The continued coverage guidelines cease to occur
- 2. In the judgement of the treating physician, adequate wound healing has occurred to the degree that NPWT may be discontinued
- 3. Any measurable degree of wound healing has failed to occur over the prior month. Wound healing is defined as improvement occurring in either surface area (length times width) or depth of the wound
- 4. 4 months (including the time NPWT was applied in an inpatient setting prior to discharge to the home) have elapsed using an NPWT pump in the treatment of the most recent wound
- 5. Once equipment or supplies are no longer being used for the beneficiary, whether or not by the physician's order

## 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.

## OXYGEN GUIDELINES

### 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. PO<sub>2</sub> 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 PO<sub>2</sub> or 89% O<sub>2</sub> Sat.):
  - a. Dependent edema suggesting CHF
  - b. Pulmonary hypertension or cor pulmonale
  - c. Erythrocythemia with a hematocrit greater than 56%
4. For PO<sub>2</sub> levels at or above 60 or O<sub>2</sub> SAT at or above 90%, oxygen is not medically necessary

### TESTING SPECIFICATIONS:

#### **General**

For purposes of this policy:

- “Blood gas study” shall refer to both gas (ABG) studies and pulse oximetry
- “Oximetry” shall refer to routine or “Spot” pulse oximetry
- **“Overnight oximetry” shall refer to stand-alone pulse oximetry continuously recorded overnight. It does not include oximetry results done as part of other overnight testing such as polysomnography or home sleep testing.**

### 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 PO<sub>2</sub> 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 PO<sub>2</sub> at or above 56 mm Hg or an arterial oxygen saturation at or above 89 percent while awake, or

2. A decrease in arterial PO<sub>2</sub> 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 PO<sub>2</sub> or 89% O<sub>2</sub> Sat.) must be retested between the 61<sup>st</sup> and 90<sup>th</sup> day of home oxygen therapy.

1. This is to establish long term need
2. Recertification is required after 12 months of therapy (by the 13<sup>th</sup> 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.
  - a. No more CMNs will be required (routinely)
  - b. Patients with borderline blood gas results (56-59 PO<sub>2</sub> or 89% Sat.) require renewal CMN with the 4<sup>th</sup> 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.

### **OBSTRUCTIVE SLEEP APNEA TESTING**

For beneficiaries with OSA, a qualifying oxygen saturation test may only occur during a titration polysomnographic study (either split night or stand-alone). Nocturnal oximetry conducted for the purpose for oxygen reimbursement qualification may only be performed after optimal PAP settings have been determined and the beneficiary is using the PAP device at those settings.

The nocturnal oximetry conducted during the PSG demonstrates an oxygen saturation  $\leq$  88% for 5 minutes total (which need not be continuous).

### **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. Extenuating 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 8)**

**CERTIFICATE OF MEDICAL NECESSITY  
CMS-484— OXYGEN**

**DME 484.3**

**SECTION A: Certification Type/Date: INITIAL** \_\_\_/\_\_\_/\_\_\_ **REVISED** \_\_\_/\_\_\_/\_\_\_ **RECERTIFICATION** \_\_\_/\_\_\_/\_\_\_

PATIENT NAME, ADDRESS, TELEPHONE and MEDICARE ID  (____) _____ Medicare ID		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. _____	
NAME and ADDRESS of FACILITY if applicable (see reverse)		PHYSICIAN NAME, ADDRESS, TELEPHONE and UPIN or NIP #  (____) _____ UPIN or NPI # _____	

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

EST. LENGTH OF NEED (# OF MONTHS): \_\_\_\_\_ 1–99 (99=LIFETIME) | DIAGNOSIS CODES: \_\_\_\_\_

ANSWERS	ANSWER QUESTIONS 1–9. (Check Y for Yes, N for No, or D for Does Not Apply, unless otherwise noted.)
a) _____ mm Hg b) _____ % c) ___/___/___	1. Enter the result of recent test taken on or before the certification date listed in Section A. Enter (a) arterial blood gas PO2 and/or (b) oxygen saturation test; (c) date of test.
<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	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?
<input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3	3. Check the one number for the condition of the test in Question 1: (1) At Rest; (2) During Exercise; (3) During Sleep
<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> D	4. If you are ordering portable oxygen, is the patient mobile within the home? If you are not ordering portable oxygen, check D.
_____ LPM	5. Enter the highest oxygen flow rate ordered for this patient in liters per minute. If less than 1 LPM, enter an "X".
a) _____ mm Hg b) _____ % c) ___/___/___	6. If greater than 4 LPM is prescribed, enter results of 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).

**ANSWER QUESTIONS 7-9 ONLY IF PO2 = 56–59 OR OXYGEN SATURATION = 89 IN QUESTION 1**

<input type="checkbox"/> Y <input type="checkbox"/> N	7. Does the patient have dependent edema due to congestive heart failure?
<input type="checkbox"/> Y <input type="checkbox"/> N	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.
<input type="checkbox"/> Y <input type="checkbox"/> N	9. Does the patient have a hematocrit greater than 56%?

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 option ordered; (2) Suppliers 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 OXYGEN

---

<b>SECTION A:</b>	<b>(May be completed by the supplier)</b>
<b>CERTIFICATION DATE:</b>	If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space 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.
<b>PATIENT INFORMATION:</b>	Indicate the patient's name, permanent legal address, telephone number and his/her Medicare ID as it appears on his/her Medicare card and on the claim form.
<b>SUPPLIER INFORMATION:</b>	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. 1Cxxxxxxxx)
<b>PLACE OF SERVICE:</b>	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.
<b>FACILITY NAME:</b>	If the place of service is a facility, indicate the name and complete address of the facility.
<b>SUPPLY ITEM/SERVICE PROCEDURE CODE(S):</b>	List all procedure codes for items ordered. Procedure codes that do not require certification should not be listed on the CMN.
<b>PATIENT DOB, HEIGHT, WEIGHT AND SEX:</b>	Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if requested.
<b>PHYSICIAN NAME, ADDRESS:</b>	Indicate the PHYSICIAN'S name and complete mailing address.
<b>PHYSICIAN INFORMATION:</b>	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)
<b>PHYSICIAN'S TELEPHONE NO:</b>	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.
<b>SECTION B:</b>	<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.)</b>
<b>EST. LENGTH OF NEED:</b>	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".
<b>DIAGNOSIS CODES:</b>	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).
<b>QUESTION SECTION:</b>	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.
<b>NAME OF PERSON ANSWERING SECTION B QUESTIONS:</b>	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.
<b>SECTION C: NARRATIVE DESCRIPTION OF EQUIPMENT &amp; COST:</b>	<b>(To be completed by the supplier)</b> 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.
<b>SECTION D: PHYSICIAN ATTESTATION:</b>	<b>(To be completed by the physician)</b> 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.
<b>PHYSICIAN SIGNATURE AND DATE:</b>	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.**

## **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 8)**

## **PNEUMATIC COMPRESSION DEVICE**

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.

## Four-Week Trial for Lymphedema

A four-week trial of conservative therapy demonstrating failed response to treatment is required. The four-week trial of conservative therapy must include all of the following:

- Regular and compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
  - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement, and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point.
  - The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally.
  - Regular exercise
  - Elevation of the limb

When available, manual lymphatic drainage is a key component of conservative treatment as is appropriate medication treatment when there is concurrent congestive failure.

At the end of the four-week trial, if there has been improvement, then reimbursement for a PCD is not justified. Where improvement has occurred, the trial of conservative therapy must be continued with subsequent reassessment at intervals at least a week apart. Only when no significant improvement has occurred in the most recent four weeks and the coverage criteria above are still met, may the lymphedema be considered unresponsive to conservative therapy, and coverage for a PCD considered.

The medical necessity determination for a PCD by the treating practitioner must include symptoms and objective findings, including measurements, to establish the severity of the condition.

The documentation by the treating practitioner of the medical necessity of a pneumatic compression device must include:

- The patient's diagnosis and prognosis.
- Symptoms and objective findings, including measurements which establish the severity of the condition.
- The reason the device is required, including the treatments which have been tried and failed; and
- The clinical response to an initial treatment with the device

At a minimum, re-assessments conducted for a trial must include detailed measurements, obtained in the same manner and with reference to the same anatomic landmarks, prior to and at the conclusion of the various trials and therapy, with bilateral comparisons where appropriate.

The trial of conservative therapy must be documented in the beneficiary's medical record before prescribing any type of pneumatic compression device (E0650, E0651, E0652). This assessment may be performed by the treating practitioner or any other licensed/certified medical professional (LCMP) directly involved in the beneficiary's lymphedema treatment. The LCMP may not have any financial relationship with the DMEPOS supplier providing the device. If the assessment is performed by an LCMP, the treating practitioner must receive and review the report of the evaluation. In addition, the treating practitioner must sign and date the report, and state concurrence or disagreement with the assessment. The signature date must be on or before the prescription date.



---

## INSTRUCTIONS FOR COMPLETING THE CERTIFICATE OF MEDICAL NECESSITY FOR PNEUMATIC COMPRESSION DEVICES (CMS-846)

---

<b>SECTION A:</b>	<b>(May be completed by the supplier)</b>
<b>CERTIFICATION TYPE/DATE:</b>	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.
<b>PATIENT INFORMATION:</b>	Indicate the patient's name, permanent legal address, telephone number and his/her Medicare ID as it appears on his/her Medicare card and on the claim form.
<b>SUPPLIER INFORMATION:</b>	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. 1Cxxxxxxxx)
<b>PLACE OF SERVICE:</b>	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.
<b>FACILITY NAME:</b>	If the place of service is a facility, indicate the name and complete address of the facility.
<b>SUPPLY ITEM/SERVICE PROCEDURE CODE(S):</b>	List all procedure codes for items ordered. Procedure codes that do not require certification should not be listed on the CMN.
<b>PATIENT DOB, HEIGHT, WEIGHT AND SEX:</b>	Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if requested.
<b>PHYSICIAN NAME, ADDRESS:</b>	Indicate the PHYSICIAN'S name and complete mailing address.
<b>PHYSICIAN INFORMATION:</b>	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)
<b>PHYSICIAN'S TELEPHONE NO:</b>	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.
<b>SECTION B:</b>	<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.)</b>
<b>EST. LENGTH OF NEED:</b>	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".
<b>DIAGNOSIS CODES:</b>	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).
<b>QUESTION SECTION:</b>	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.
<b>NAME OF PERSON ANSWERING SECTION B QUESTIONS:</b>	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.
<b>SECTION C:</b>	<b>(To be completed by the supplier)</b>
<b>NARRATIVE DESCRIPTION OF EQUIPMENT &amp; COST:</b>	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.
<b>SECTION D:</b>	<b>(To be completed by the physician)</b>
<b>PHYSICIAN ATTESTATION:</b>	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.
<b>PHYSICIAN SIGNATURE AND DATE:</b>	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.**

---

## ***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 sub-specialty certification in Sleep Medicine by a board member of the American Board of Medical Specialties (ABMS); or,
3. Has completed residency or fellowship training by an ABSM member board and has completed all the requirements for sub-specialty 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 31<sup>st</sup> day but no later than the 91<sup>st</sup> 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  $\geq$  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 8)**

## **POWER MOBILITY DEVICES**

(Power Wheelchair and Power Operated Vehicle - Retail Sale Only)

### 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:

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

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 8)**

## **RESPIRATORY ASSIST DEVICE (BI-LEVEL)**

**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, post thoracoplasty for TB), and
  - a. An arterial blood gas PaCO<sub>2</sub>, done while awake and breathing the patient's prescribed FIO<sub>2</sub>, is greater than or equal to 45 mm Hg, or
  - b. Sleep oximetry demonstrates oxygen saturation less than or equal to 88% for great 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 H<sub>2</sub>O 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 PaCO<sub>2</sub>, done while awake and breathing then patient's prescribed FI<sub>02</sub>, is greater than or equal to 52 mm Hg, and
- B) Sleep oximetry demonstrates oxygen saturation less than or equal to 88% or 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 FIO<sub>2</sub> (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 PaCO<sub>2</sub>, done while awake and breathing the patient's prescribed FIO<sub>2</sub>, shows that the beneficiary's PaCO<sub>2</sub> 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 PaCO<sub>2</sub> is done while awake and breathing the patient's prescribed FIO<sub>2</sub>, 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 FIO<sub>2</sub> (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 FIO<sub>2</sub>.
- C) 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 to 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 PaCO<sub>2</sub>, done while awake and breathing the patient's prescribed FIO<sub>2</sub>, 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 PaCO<sub>2</sub>, done during sleep or immediately upon awakening, and breathing the patient's prescribed FI<sub>O2</sub>, shows the beneficiary's PaCO<sub>2</sub> 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 PaCO<sub>2</sub>, done while awake, and breathing the patient's prescribed FIO<sub>2</sub>, shows that the beneficiary's PaCO<sub>2</sub> 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 4<sup>th</sup> 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 8)**

**SEAT LIFT CHAIR MECHANISM**

**(Retail Sale Only)**

**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 8)**

## CERTIFICATE OF MEDICAL NECESSITY CMS-849 — SEAT LIFT MECHANISMS

DME 07.03A

<b>SECTION A: Certification Type/Date: INITIAL</b> ___/___/___ <b>REVISED</b> ___/___/___ <b>RECERTIFICATION</b> ___/___/___		
PATIENT NAME, ADDRESS, TELEPHONE and MEDICARE ID  ( ___ ) ___ - ___ Medicare ID _____	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. ___
NAME and ADDRESS of FACILITY <i>if applicable (see reverse)</i>  _____ _____ _____	PHYSICIAN NAME, ADDRESS, TELEPHONE and UPIN or NPI #  ( ___ ) ___ - ___ UPIN or NPI # _____	
<b>SECTION B: Information in this Section May Not Be Completed by the Supplier of the Items/Supplies.</b>		
EST. LENGTH OF NEED (# OF MONTHS): _____ 1-99 (99=LIFETIME)		DIAGNOSIS CODES: _____
ANSWERS	ANSWER QUESTIONS 1-5 FOR SEAT LIFT MECHANISM (Check Y for Yes, N for No, or D for Does Not Apply)	
<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> D	1. Does the patient have severe arthritis of the hip or knee?	
<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> D	2. Does the patient have a severe neuromuscular disease?	
<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> D	3. Is the patient completely incapable of standing up from a regular armchair or any chair in his/her home?	
<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> D	4. Once standing, does the patient have the ability to ambulate?	
<input type="checkbox"/> Y <input type="checkbox"/> N <input type="checkbox"/> D	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.	
NAME OF PERSON ANSWERING SECTION B QUESTIONS, IF OTHER THAN PHYSICIAN (Please Print): NAME: _____ TITLE: _____ EMPLOYER: _____		
<b>SECTION C: Narrative Description of Equipment and Cost</b>		
(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)		
<b>SECTION D: PHYSICIAN Attestation and Signature/Date</b>		
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 ___/___/___		
<b>Signature and Date Stamps Are Not Acceptable.</b>		

# INSTRUCTIONS FOR COMPLETING THE CERTIFICATE OF MEDICAL NECESSITY FOR SEAT LIFT MECHANISMS (CMS-849)

<b>SECTION A:</b>	<b>(May be completed by the supplier)</b>
<b>CERTIFICATION DATE:</b>	If this is an initial certification for this patient, indicate this by placing date (MM/DD/YY) needed initially in the space 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.
<b>PATIENT INFORMATION:</b>	Indicate the patient's name, permanent legal address, telephone number and his/her Medicare ID as it appears on his/her Medicare card and on the claim form.
<b>SUPPLIER INFORMATION:</b>	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)
<b>PLACE OF SERVICE:</b>	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.
<b>FACILITY NAME:</b>	If the place of service is a facility, indicate the name and complete address of the facility.
<b>SUPPLY ITEM/SERVICE PROCEDURE CODE(S):</b>	List all procedure codes for items ordered. Procedure codes that do not require certification should not be listed on the CMN.
<b>PATIENT DOB, HEIGHT, WEIGHT AND SEX:</b>	Indicate patient's date of birth (MM/DD/YY) and sex (male or female); height in inches and weight in pounds, if requested.
<b>PHYSICIAN NAME, ADDRESS:</b>	Indicate the PHYSICIAN'S name and complete mailing address.
<b>PHYSICIAN INFORMATION:</b>	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)
<b>PHYSICIAN'S TELEPHONE NO.:</b>	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.
<b>SECTION B:</b>	<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.)</b>
<b>EST. LENGTH OF NEED:</b>	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".
<b>DIAGNOSIS CODES:</b>	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).
<b>QUESTION SECTION:</b>	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.
<b>NAME OF PERSON ANSWERING SECTION B QUESTIONS:</b>	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.
<b>SECTION C:</b>	<b>(To be completed by the supplier)</b>
<b>NARRATIVE DESCRIPTION OF EQUIPMENT &amp; COST:</b>	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.
<b>SECTION D:</b>	<b>(To be completed by the physician)</b>
<b>PHYSICIAN ATTESTATION:</b>	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.
<b>PHYSICIAN SIGNATURE AND DATE:</b>	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 (06/19) INSTRUCTIONS

## **SUPPORT SURFACES**

**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 8)**

**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.

## *THERAPEUTIC SHOES FOR PERSONS WITH DIABETES*

- 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.



# KEENE MEDICAL PRODUCTS

Central Intake Phone: 1-855-622-5556 Fax: 1-603-727-0996

<b>Concord, NH</b> P: 1-603-224-0135 F: 1-603-228-4311	<b>Keene, NH</b> P: 1-603-357-3222 F: 1-603-357-9469	<b>Lebanon, NH</b> P: 1-603-448-5225 F: 1-603-448-5671	<b>Nashua, NH</b> P: 1-603-595-2097 F: 1-603-595-2098	<b>Portsmouth, NH</b> P: 1-603-431-6006 F: 1-603-431-9080
<b>Williston, VT</b> P: 1-802-863-2114 F: 1-802-660-9237	<b>Montpelier, VT</b> P: 1-802-223-0665 F: 1-802-223-0760	<b>Newport, VT</b> P: 1-802-334-5160 F: 1-802-334-8852	<b>Rutland, VT</b> P: 1-802-773-4574 F: 1-802-773-8077	<b>St. Johnsbury, VT</b> P: 1-802-748-4185 F: 1-802-748-4187

*"Bringing Healthcare Home Since 1975."*

## Physician's Order for Diabetic Footwear

Patient: \_\_\_\_\_

Patient Date of Birth: \_\_\_\_\_ Patient Phone: \_\_\_\_\_

### 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:

- Regular Depth (A5500) - 1 pair, unless otherwise noted.  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: \_\_\_\_\_

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

MRKT - 052  
REV/TL - 11/17

**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 8)**

**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.

## 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

These ventilator-related disease groups overlap conditions described in the Respiratory Assist Devices LCD used to determine coverage for bi-level PAP devices. Each of these disease categories are conditions where the specific presentation of the disease can vary from patient to patient. For conditions, such as these, the specific treatment plan for any individual patient will vary as well. Choice of an appropriate treatment plan, including the determination to use a ventilator vs. a bi-level PAP device, is made based upon the specifics of each individual beneficiary's medical condition. In the event of a claim review, there must be sufficient detailed information in the medical record to justify the treatment selected.

## WALKERS

**(Retail Sale Only)**

**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.

## **NON-COVERED ITEMS**

**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  
Bathtub Rail  
Bathtub Wall Rail (Grab Bar)  
Bed Board  
Biofeedback Therapy for the Treatment of Urinary Incontinence  
Breast Pumps  
Diapers  
Disposable Sheets  
Disposable Under pads  
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

## **SUMMARY**

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.