

Chapter 10: Durable Medical Equipment

Medical Overview

Medicare law limits Part B payment for durable medical equipment (DME) to items or supplies used (delivered) in the patient's home. The following sections provide an overview of the coverage issues and documentation requirements pertaining to DME claims processing.

Coverage

Expenses incurred by a beneficiary for the rental or purchase of durable medical equipment (DME) are reimbursable if the following three requirements are met (**Note: The decision whether to rent or purchase an item of equipment generally resides with the beneficiary, but the decision on how to pay rests with the Centers for Medicare & Medicaid Services (CMS)**):

1. Equipment meets the definition of DME (*see below*)
2. Equipment is necessary and reasonable for the treatment of the patient's illness or injury or to improve the functioning of his/her malformed body member (*see below*)
3. Equipment is used in the patient's home (*see below*)

Definition of DME - Durable medical equipment is equipment which (a) can withstand repeated use, (b) is primarily and customarily used to serve a medical purpose, (c) generally is not useful to a person in the absence of an illness or injury, and (d) is appropriate for use in the home. **All** requirements of the definition **must** be met before an item can be considered to be DME.

Necessary and Reasonable - Although an item may be classified as DME, it may **not** be covered in every instance. Coverage in a particular case is subject to the requirement that the equipment be necessary and reasonable for treatment of an illness or injury or to improve the functioning of a malformed body member. These considerations will bar payment for equipment which cannot reasonably be expected to perform a therapeutic function in an individual case or will permit only partial therapeutic function in an individual case or will permit only partial payment when the type of equipment furnished substantially exceeds that required for the treatment of the illness or injury involved.

Definition of Beneficiary's Home - For purposes of rental and purchase of DME, a beneficiary's home may be his/her own dwelling, an apartment, a relative's home, a home for the aged, or some other type of institution. However, an institution may **not** be considered a beneficiary's home if it:

- A. Meets at least the basic requirement in the definition of a hospital, i.e., it is primarily engaged in providing by or under the supervision of physicians to inpatients diagnostic and therapeutic services for medical diagnosis, treatment, and care of injured, disabled, and sick persons or rehabilitation services for the rehabilitation of injured, disabled, or sick persons; or
- B. Meets at least the basic requirement in the definition of a skilled nursing facility (SNF), i.e., it is primarily engaged in providing to inpatients skilled nursing care and related services for patients who require medical or nursing care or rehabilitation services for the rehabilitation of injured, disabled, or sick persons.

Thus, if an individual is a patient in an institution, or distinct part of an institution which provides the services described in A or B above, the individual is **not** entitled to have separate Part B payment made for rental or purchase of DME, because such an institution may **not** be considered the individual's home. The same concept applies even if the individual resides in a bed or portion of the institution not certified for Medicare. (**Note:** Orthotic and prosthetic devices are **not** subject to the "home use" requirement for coverage and payment purposes.)

Under the circumstances specified in Section 110.2 in Chapter 15 of Pub. 100-2, *Medicare Benefit Policy Manual*, <http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf>, payment may be made for repair, maintenance, replacement, and delivery of medically-required DME which the beneficiary owns or is purchasing, including equipment which had been in use before the user enrolled in Part B of the Medicare program. Payment may also be made for supplies (e.g., oxygen) that are necessary for the effective use of DME (see Section 110.3 for details). Payment can be made for the purchase of DME even though rental payments may have been made for prior months. This could occur where, because of a change in his/her condition, the beneficiary feels that it would be to his/her advantage to purchase the equipment rather than to continue to rent it (see Section 110.4 for details). Suppliers should refer to the individual medical policies for specific coverage and payment provisions. The medical policies for Jurisdiction A are available on the DME MAC A at: http://www.medicarenhic.com/dme/medical_review/mr_lcd_current.shtml. For additional information on DME billing and claims processing, suppliers should refer to Chapter 20 of Pub. 100-4, *Medicare Claims Processing Manual*, <http://www.cms.hhs.gov/manuals/downloads/clm104c20.pdf>.

Suppliers should also refer to Section 280.1 in Chapter 1, Part 4 of Pub. 100-3, *Medicare National Coverage Determinations Manual*, http://www.cms.hhs.gov/manuals/downloads/ncd103c1_Part4.pdf, for the current "Durable Medical Equipment Reference List." This list is designed to be used as a quick reference tool for determining the coverage status of certain pieces of DME and especially, for those items which are commonly referred to by both brand and generic names. Further coverage requirements are in Chapter 15 of Pub. 100-2, *Medicare Benefit Policy Manual*, <http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf>, and in Pub. 100-3, *Medicare National Coverage Determinations Manual*, Chapter 1:

- Part 1 (http://www.cms.hhs.gov/manuals/downloads/ncd103c1_Part1.pdf)
- Part 3 (http://www.cms.hhs.gov/manuals/downloads/ncd103c1_Part3.pdf)
- Part 4 (http://www.cms.hhs.gov/manuals/downloads/ncd103c1_Part4.pdf)

Continuous Use

Recent legislative changes mandated by sections 5101(a) and 5101(b) of the Deficit Reduction Act (DRA) of 2005 mandate changes in the way Medicare makes payment for certain items of DME.

Section 5101(a) revises the payment rules for capped rental DME. After 13 months, the beneficiary owns the capped rental DME item. and after that time, Medicare pays for reasonable and necessary repairs and servicing (i.e., parts and labor not covered by a supplier's or manufacturer's warranty) of the item. Payment will no longer be made every 6 months for Maintenance and Servicing (M&S) for capped rental items. The provision applies to beneficiaries renting an item for which the first rental month occurs on or after January 1, 2006.

Capped rental items furnished to beneficiaries prior to January 1, 2006 will continue to be paid under the payment rules in effect prior to the DRA changes.

The DRA limited monthly payments for oxygen and oxygen equipment to 36 months of continuous use after which the equipment title transferred to the beneficiary. Section 144(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) repealed the transfer of ownership provision and permits suppliers to retain ownership of the oxygen equipment following the 36-month rental cap.

For gaseous or liquid oxygen systems, Medicare will continue to pay for the oxygen contents after the 36 month cap. In addition, Medicare will allow a general maintenance-and-servicing visit for concentrators or transfilling equipment, which must take place 6 months after the end of the 36-month rental period.

The 36 month cap provision was effective January 1, 2006. For beneficiaries receiving oxygen equipment on December 31, 2005, the 36-month rental period began on January 1, 2006.

Updates to the *Medicare Claims Processing Manual*, Publication 100-04 and the *Benefit Policy Manual*, Publication 100-02, will follow at a later date.

Homebound

Definition of Homebound Patient - This definition applies to homebound for purposes of the Medicare home health benefits. An individual does **not** have to be bedridden to be considered as confined to home. However, the condition of these patients should be such that there exists a normal inability to leave home and consequently, leaving their home would require a considerable and taxing effort. If the patient does in fact leave the home, the patient may nevertheless be considered homebound if the absences from the home are infrequent or for periods of relatively short duration. It is expected that in most instances, absences from the home will be for the purpose of receiving medical treatment. However, occasional absences from the home for non-medical purposes, e.g., an

occasional trip to the barber, a walk around the block, or a drive to attend an infrequent or unique event (i.e., funeral), would **not** necessitate a finding that the individual is not homebound if absences are undertaken on an infrequent basis or are of relatively short duration and do not indicate that the patient has the capacity to obtain the healthcare provided outside rather than in the home. These examples are **not** all-inclusive and are meant to be illustrative of the kinds of infrequent or unique events a patient may attend.

Generally speaking, a beneficiary will be considered to be homebound if the beneficiary has a condition due to an illness or injury which restricts ability to leave the residence except with the aid of supportive devices such as crutches, canes, wheelchairs, and walkers, the use of special transportation, or the assistance of another person or if the beneficiary has a condition which is such that leaving home is medically contraindicated. In determining whether the patient has the general inability to leave the home and leaves the home only infrequently or for periods of short duration, it is necessary (as is the case in determining whether skilled nursing services are intermittent) to look at the patient's condition over a period of time rather than for short periods within the home health stay.

The aged person who does not often travel from home because of feebleness and insecurity brought on by advanced age is **not** considered confined to home for purposes of this reimbursement, unless the person's condition is comparable to those above. If for any reason a question is raised as to whether an individual is confined to home, request the physician to furnish the information necessary to establish if the beneficiary is homebound, as defined above. For more information on homebound, refer to Chapter 15 of Pub. 100-2, *Medical Benefit Policy Manual*, <http://www.cms.hhs.gov/manuals/Downloads/bp102c15.pdf>

Services Not Provided Within the United States

Items and services furnished outside the United States are **excluded from coverage**, except for the following Canadian and Mexican services and certain services rendered on board a ship:

- Emergency inpatient hospital services where the emergency occurred:
 1. While the beneficiary was physically present in the United States; or
 2. In Canada while the beneficiary was traveling without unreasonable delay and by the most direct route between Alaska and another state.
- Emergency or non-emergency inpatient hospital services furnished in a Canadian or Mexican hospital closer to, or substantially more accessible from, the beneficiary's United States residence than the nearest participating United States hospital which was adequately equipped to deal with and available to provide treatment of the illness or injury.
- Physician and ambulance services furnished in connection with, and during a period of, covered foreign hospitalization. Program payment may **not** be made for any other Part B

medical and other health services, including outpatient services furnished outside the United States.

- Services furnished on board a ship in a United States port, or within six (6) hours of when the ship arrived at or departed from a United States port, are considered to have been furnished in United States territorial waters. Services not furnished in a United States port, or within six hours of when the ship arrived at or departed from a United States port, are considered to have been furnished outside United States territorial waters, even if the ship is of United States registry.

The term “United States” means the 50 states, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, American Samoa, and for purposes of services rendered on a ship, includes the territorial waters adjoining the land areas of the United States. A hospital that is **not** physically situated in one of the above named jurisdictions is considered to be outside the United States, even if it is owned or operated by the United States government.

Payment is **not** made for any item or service provided or delivered to a beneficiary outside the United States, even though the beneficiary may have contracted to purchase the item or service while they were within the United States or purchased the item from an American firm. *Payment may not be made for a medical service (or a portion of it) that was subcontracted to another provider or supplier located outside the United States.*

For more information, refer to Chapter 16 of Pub. 100-2, *Medicare Benefit Policy Manual*, <http://www.cms.hhs.gov/manuals/Downloads/bp102c16.pdf>

Advance Determination of Medicare Coverage

Section 1834(a)(15)(C) of the Social Security Act (the Act) provides that contractors shall, at the request of a supplier or beneficiary, determine **in advance of delivery** of an item whether payment for the item may **not** be made because the item is **not** covered if:

- The item is a customized item,
- The patient to whom the item is to be furnished, or the supplier, requests that such advance determination be made, and
- The item is not an inexpensive item, as specified by the Secretary.

Section 1834(a)(4) of the Act and 42 CFR 414.224 define customized DME as being items of DME which have been **uniquely constructed or substantially modified** for a specific beneficiary according to the description and orders of the beneficiary’s treating physician.

It is important to note that Advance Determinations of Medicare Coverage (ADMCs) are **not** initial determinations, as defined at 42 CFR 405.801(a), because **no** request for payment is being made. As

such, an ADMC **cannot** be appealed. This is a **voluntary** program, therefore, beneficiaries and suppliers are **not** required to submit ADMC requests in order to submit claims for items.

Submitting ADMC Requests

Suppliers or beneficiaries may submit, **in hard copy**, requests for ADMC. Requests **must** contain adequate information from the patient's medical record to identify the patient for whom the item is intended, the intended use of the item, and the medical condition of the patient that necessitates the use of a customized item.

Currently for Jurisdiction A, the following Healthcare Common Procedure Coding System (HCPCS) codes are eligible for ADMC:

- Manual wheelchairs described by codes **E1161, E1231-E1234, K0005, and K0009**
- Group 2, 3, 4 or 5 Single Power Option or Multiple Power Options wheelchair (**K0835-K0843, K0856-K0864, K0877-K0891**) - whether or not a power seating system will be provided at the time of initial issue.
- Group 3 or 4 No Power Option wheelchair (**K0848-K0855, K0868-K0871**) that will be provided with an alternative drive control interface at the time of initial issue.

(**Note:** When a particular item is eligible for ADMC, **all** options and accessories ordered by the physician for that patient, along with the base HCPCS code, are eligible for ADMC.)

Effective April 1, 2006 Certificates of Medical Necessity (CMNs) for Manual and Power Wheelchair Bases were discontinued. As a result, CMNs are no longer required to accompany ADMC requests. Refer to the DME MAC Medical Review July 2006 Bulletin article, "*Advance Determination of Medicare Coverage - Wheelchairs*", for proper completion of the ADMC form. See the end of this section for information on how to access this article. Furthermore, refer to the individual medical policies for additional specific documentation requirements.

ADMC requests may either be mailed or be sent via fax (refer to Chapter 1 of this manual for the mailing address and fax number). An "ADMC Request" form is available for use at http://www.medicarenhic.com/dme/dme_forms.shtml. ADMC requests **cannot** be submitted electronically at this time.

Notice of Determination

Once a request is received, the DME MAC shall determine if there is sufficient medical documentation that supports whether the item is reasonable and necessary. In addition, a review of the beneficiary's claims history shall be conducted in order to determine whether any other reason exists to cause the claim to be denied, e.g., whether the same or similar equipment has already been provided (i.e., POV).

Upon receipt of a request, the DME MAC will make a determination within thirty (30) calendar days. The requestor will be sent a letter with a decision, either affirmative or negative, in writing. If requests are received for the wrong item(s), the request will be rejected. Requests for appropriate items received without documentation to support coverage will be denied as not meeting the medical necessity requirements Medicare has established for the item.

An affirmative ADMC decision will provide the supplier and beneficiary assurance that the beneficiary, based on the information submitted with the request, will meet the medical necessity requirements Medicare has established for the item. An affirmative determination does **not** provide assurance that the beneficiary meets Medicare eligibility requirements, nor does it assure that any other Medicare requirements (e.g., place of service, Medicare Secondary Payer, etc.) have been met. Only upon submission of a **complete** claim can the DME MAC make a full and complete determination. An affirmative determination does **not** extend to the price that Medicare will pay for the item. Finally, the DME MAC reserves the right to review claims on a prepayment or post-payment basis and may deny a claim, or request an overpayment, if it determines that an affirmative determination was made based on incorrect information.

A negative ADMC decision communicates to the supplier and beneficiary that, based on the information submitted with the request, the beneficiary does **not** meet the medical necessity requirements Medicare has established for the item. The negative determination should indicate why the request was denied. A beneficiary or supplier can **resubmit** an ADMC request if additional medical documentation is obtained that could affect the prior negative ADMC decision. However, requests may **only be re-submitted once** during a **six-month** period.

Duration of ADMC Determinations

An affirmative ADMC decision is **only** valid for a period of **six (6) months** from the date the decision is rendered. Oftentimes, beneficiaries who require customized DME are subject to rapid changes in medical conditions. These changes may preclude the need for a particular item, either because the beneficiary's condition improved or deteriorated. For this reason, the date the item is provided to the beneficiary **cannot** be more than six (6) months after the date the ADMC decision was made.

For more information, refer to Section 5.16 in Chapter 5 of Pub. 100-8, *Medicare Program Integrity Manual*, <http://www.cms.hhs.gov/manuals/downloads/pim83c05.pdf>, and to the DME MAC Medical Review Bulletins Web page, http://www.medicarenhic.com/dme/medical_review/mr_bulletin_current.shtml

Limitation of Liability/Advance Beneficiary Notice

Section 1879(a)-(g) of the Act provides financial relief to beneficiaries, providers, practitioners, physicians, and other suppliers by permitting Medicare payment to be made, or requiring refunds to be made, for certain services and items for which Medicare payment would otherwise be denied. This section of the Act is referred to as “the limitation of liability provision”. The basic purpose of this provision is to protect beneficiaries and other claimants from liability in denial cases under certain conditions when services they received are found to be excluded from coverage for one of the reasons specified in Section 20.1 in Chapter 30 of Pub. 100-4, *Medicare Claims Processing Manual*.

Where items or services are denied for one of the reasons specified in Section 20.1 and the other conditions described above are met, the Medicare program makes payment when neither the beneficiary nor the provider, practitioner, or supplier knew, and could not reasonably be expected to have known, that the items or services were **not** covered. When the beneficiary did **not** have such knowledge, but the provider, practitioner, or supplier knew, or could have been expected to know, of the exclusion of the items or services, the liability for the charges for the denied items or services rests with the provider, practitioner, or supplier. When the beneficiary knew, or could have been reasonably expected, to know that the items or services were not covered, the liability for the charges rests with the beneficiary; i.e., the beneficiary is responsible for making payment to the provider, practitioner, or supplier.

In deciding whether the beneficiary or his/her representative knew, or could reasonably have been expected to know, that payment would **not** be made for items or services he/she received, the beneficiary’s allegation that he/she did **not** know, in the absence of evidence to the contrary, will be acceptable evidence for limitation of liability purposes. However, it does **not** hold a provider, practitioner, or supplier liable under Section 1879 where the provider, practitioner, or supplier indicates on the claim (via use of HCPCS code modifier **GA**) that they have given the beneficiary, **before furnishing the items or services**, an Advance Beneficiary Notice (ABN). In such a case, Medicare holds the beneficiary, **not** the provider, practitioner, or supplier, liable for denied charges.

The purpose of the ABN is to inform a Medicare beneficiary, **before he or she receives specified items or services that otherwise might be paid for**, that Medicare certainly or probably will **not** pay for them on that particular occasion. The ABN also allows the beneficiary to make an informed consumer decision whether or not to receive the items or services, for which he or she may have to pay out-of-pocket or through other insurance. In addition, the ABN allows the beneficiary to better participate in his/her own healthcare treatment decisions by making informed consumer decisions.

.ABN delivery is considered to be effective when the notice is:

- Delivered by a suitable notifier to a capable recipient and comprehended by that recipient
- Provided using the correct OMB approved notice with all required blanks completed
- Failure to use the correct notice may lead to notifiers being found liable since the burden of proof is on the notifier to show knowledge was conveyed to the beneficiary according to CMS instructions

- Delivered to the beneficiary in person if possible
- Provided far enough in advance of delivering potentially noncovered items or services to allow sufficient time for the beneficiary to consider all available options
- Explained in its entirety, and all of the beneficiary's related questions are answered timely, accurately, and completely to the best of the notifier's ability
- Signed by the beneficiary or his or her representative

An ABN can remain effective for up to one year. ABNs may describe treatment of up to a year's duration, as long as no other triggering event occurs. If a new triggering event occurs within the 1-year period, a new ABN must be given.

For more information about Financial Liability Protections, refer to Chapter 30 of Pub. 100-4, *Medicare Claims Processing Manual*, <http://www.cms.hhs.gov/manuals/downloads/clm104c30.pdf>

Upgrades

An upgrade is an item with features that go **beyond** what the is medically necessary. An upgrade may include an excess component. An excess component may be an item feature or service, which is in addition to, or is more extensive and/or more expensive than the item that is reasonable and necessary under Medicare's coverage requirements. When a DMEPOS supplier knows or believes that the DMEPOS item does or may not meet Medicare's reasonable and necessary rules under specific circumstances, it is the responsibility of the supplier to notify the beneficiary in writing via an ABN if the supplier wants to collect money from a beneficiary if an item is denied. When a supplier furnishes an upgraded item of DMEPOS and the supplier expects Medicare to reduce the level of payment based on a medical necessity partial denial of coverage for additional expenses attributable to the upgrade, the supplier must give an ABN to the beneficiary for signature for holding the beneficiary responsible for the additional expense. ABN forms are available at http://www.cms.hhs.gov/BNI/01_overview.asp.

Suppliers **are permitted to** furnish upgraded DMEPOS items and to charge the same price to Medicare and the beneficiary that they would charge for a non-upgraded item. This policy allows suppliers to furnish to beneficiaries, at no extra costs to the Medicare program or the beneficiary, a DMEPOS item that exceeds what the non-upgraded item that Medicare considers to be medically necessary. Therefore, even though the beneficiary received an upgraded DMEPOS item, Medicare's payment and the beneficiary's coinsurance would be based on the Medicare allowed amount for a non-upgraded item that does not include features that exceed the beneficiary's medical needs.

For more information on upgrades, refer to Section 120 of Chapter 20 of Pub. 100-4, *Medicare Claims Processing Manual*, <http://www.cms.hhs.gov/manuals/downloads/clm104c20.pdf>

See also the online ABN resources on the CMS Beneficiary Notices Initiative (BNI) Web page at <http://www.cms.hhs.gov/BNI/>

For the online replicable copies of CMS-R-131 form, in Portable Document Format (PDF) or Microsoft Word format, go to <http://www.cms.hhs.gov/BNI/Downloads/ABNFormInstructions.zip>

Documentation

The supplier for all durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) is required to keep on file a physician prescription (order). The treating physician **must** sign and date the order. A supplier **must** have an order from the treating physician **before** dispensing any DMEPOS items to a beneficiary.

Orders

Except for items requiring a written order prior to delivery, suppliers may dispense most items of DMEPOS based on a verbal order. This verbal dispensing order **must** include:

- Description of the item
- Beneficiary's name
- Physician's name
- Start date of the order

Suppliers **must** maintain **written** documentation of the verbal order, and this documentation **must** be available to the DME MAC upon request. If the supplier does **not** have an order from the treating physician **before** dispensing an item, the item is non-covered, and the supplier **must not** submit a claim for the item to the DME MAC. (**Note:** If a claim is submitted to the DME MAC, it may be denied or returned as unprocessable.) For items that are dispensed based on a verbal order, the supplier **must** obtain a **written** order that meets the requirements of this section.

Written Orders

Written orders are acceptable for all transactions involving DMEPOS. Written orders may take the form of a photocopy, facsimile image, electronically maintained, or original “pen-and-ink” document.

All orders must clearly specify the start date of the order.

If the written order is for supplies that will be provided on a periodic basis, the written order should include appropriate information on the quantity used, frequency of change, and duration of need. The written order **must be sufficiently detailed**, including **all** options or additional features that will

be separately billed or that will require an upgraded code. The description can be either a narrative description (e.g., lightweight wheelchair base) or a brand name/model number. If the order is for a rented item, or if the coverage criteria in a medical policy specify length of need, the order **must** include the length of need. If the supply is a drug, the order **must** specify the name of the drug, concentration (if applicable), dosage, frequency of administration, and duration of infusion (if applicable).

Someone other than the physician may complete the detailed description of the item. However, the treating physician **must** review the detailed description **and** personally sign **and** date the order to indicate agreement. Signature stamps are not acceptable on orders.

If a supplier does **not** have a faxed, photocopied, electronic, or pen-and-ink signed order in their records **before** they can submit a claim for payment to Medicare (i.e., if there is no order or only a verbal order), the claim will be denied. If the claim is for an item for which an order is required by statute, the claim will be denied as **not** meeting the benefit category and is therefore **not** appealable by the supplier. For all other items, if the supplier does **not** have an order that has been both signed **and** dated by the treating physician **before** billing the Medicare program, the item will be denied as **not** reasonable and necessary. These claims must be submitted with an **EY** modifier and a properly executed ABN is recommended.

If an item requires a CMN and the supplier does **not** have a faxed, photocopied, electronic, or pen-and-ink signed CMN in their records **before** they submit a claim to Medicare, the claim will be denied. If the CMN is used to verify that statutory benefit requirements have been met, then the claim will be denied as **not** meeting the benefit category. If the CMN is used to verify that medical necessity criteria have been met, the claim will be denied as **not** reasonable and necessary.

Medical necessity information (e.g., an ICD-9-CM diagnosis code, narrative description of the patient's condition, abilities, limitations, etc.) is NOT in itself considered to be part of the order, although it may be put on the same document as the order. Refer to individual medical policies for specific requirements.

Written Orders Prior to Delivery

A written order prior to delivery is required for: pressure reducing pads, mattress overlays, mattresses, and beds; seat lift mechanisms; transcutaneous electrical nerve stimulator (TENS) units; and power mobility devices (PMDs). DME MACs may identify other items for which they will require a written order prior to delivery. For these items, the supplier **must** have received a written order that has been both signed **and** dated by the treating physician, and meets the requirements for written orders, **before** dispensing the item. If a supplier bills for an item without a written order, when the supplier is required to have a written order prior to delivery, the item will be denied as **not** meeting the benefit category and is therefore **not** appealable by the supplier.

Refer to the Documentation section of individual medical policies for those items requiring a written order prior to delivery. The medical policies for Jurisdiction A are available on the DME MAC A Web site at: http://www.medicarenhic.com/dme/medical_review/mr_lcd_current.shtml

Requirement of New Orders

A new order is required in the following situations:

- There is a change in the order for the accessory, supply, drug, etc.
- On a regular basis (even if there is no change in the order) **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
- In cases where two or more suppliers merge, the resultant supplier should make **all** reasonable attempts to secure copies of **all** active CMNs from the supplier(s) purchased. This document should be kept on file by the resultant supplier for future presentation to the DME MAC.

Nurse Practitioner or Clinical Nurse Specialist Rules Concerning Orders

A nurse practitioner or clinical nurse specialist may give the dispensing order and sign the written order in the following situations:

- They are treating the beneficiary for the condition for which the item is needed
- They are practicing independently of a physician
- They bill Medicare for other covered services using their **own** provider number
- They are permitted to do all of the above in the state in which the services are rendered

A nurse practitioner or clinical nurse specialist may complete Section B and sign Section D of a CMN if they meet **all** the criteria described above for signing orders.

Physician Assistant Rules Concerning Orders and CMNs

Physician assistants may provide the dispensing order and write and sign the written order if they satisfy **all** the following requirements:

- They meet the definition of physician assistant found in Section 1861(aa)(5)(A) of the *Social Security Act*

- They are treating the beneficiary for the condition for which the item is needed
- They are practicing under the supervision of a Doctor of Medicine or Doctor of Osteopathy
- They have their **own** National Provider Identifier (NPI)
- They are permitted to perform services in accordance with state law

Physician assistants may complete Section B and sign Section D of a CMN if they meet **all** the criteria described above for signing orders.

Evidence of Medical Necessity

If replacement supplies are needed for the therapeutic use of **purchased** DMEPOS, the treating physician **must** specify on the prescription, or on the CMN, the type of supplies needed **and** the frequency with which they must be replaced, used, or consumed. DME MACs evaluate supply utilization information as part of the medical necessity determination for DMEPOS. “PRN” or “as needed” utilization estimates for supply replacement, use, or consumption are not acceptable.

Absent a state law to the contrary or a supply utilization problem, the prescription or physician’s certification submitted for the DMEPOS may also serve as medical evidence for supply replacement claims. However, when a prescription for DMEPOS is renewed or revised, supply utilization information **must** be specified or updated by the physician on the CMN. Based upon this information, DME MACs assess the continuing medical necessity.

Suppliers need to submit updated medical information if the patient’s condition materially changes the equipment, device, or supply utilization requirements. Absent such notification, DME MACs do **not** allow claims for unexplained increases in supply utilization above the usage level they previously determined as medically necessary. Suppliers **must** provide this information with the claim, where indicated in published medical policy, or make it available to the DME MAC on request.

If necessary or appropriate for a medical necessity determination, the DME MAC will ask the supplier to obtain documentation from the treating physician, establishing the severity of the patient’s condition and the immediate and long-term need for the equipment and the therapeutic benefits the patient is expected to realize from its use. A claim of therapeutic effectiveness or benefit based on speculation or theory alone **cannot** be accepted. When restoration of function is cited as a reason for use of DMEPOS, the **exact** nature of the deformity or medical problem should be clear from the medical evidence submitted. Also, the manner in which the equipment or device will restore or improve the bodily function should be explained by the treating physician.

If the DME MAC is unsuccessful in obtaining medical information from the supplier for non-assigned claims, it gives the beneficiary the opportunity to obtain the desired information from the supplier. If, after obtaining the requested information, a question of medical necessity remains, the DME MAC medical review staff must resolve the issue.

Certificates of Medical Necessity and DME MAC Information Forms

Certificates of Medical Necessity (CMN) and DME Information Forms (DIF) are forms required to help document the medical necessity and other coverage criteria for selected DMEPOS items. CMNs contain sections A through D. Section A and C are completed by the supplier and Section B and D are completed by the physician. A DIF is completed and signed by the supplier. It does not require a narrative description of equipment and cost or a physician signature.

For items that require a certificate of medical necessity (CMN), and for accessories, supplies, and drugs related to an item requiring a CMN, the CMN may serve as the written order if the narrative description in Section C is sufficiently detailed. This applies to both hard copy and electronic orders and CMNs.

A supplier **must** have a hard copied, faxed, or electronic order CMN or DIF in their records **before** they can submit a claim for payment to Medicare. Suppliers **must** ensure the security and integrity of electronically maintained CMNs are in accordance with any regulations published by CMS. The following is a list of the currently approved CMNs and DIFs [for hard copy and electronic submission in the American National Standards Institute (ANSI) format]:

Certificates of Medical Necessity		
DME Form	CMS Form	Items Addressed
484.03	484	Home Oxygen Therapy
04.04B	846	Lymphedema Pumps (Pneumatic Compression Devices)
04.04C	847	Osteogenesis Stimulators
06.03B	848	Transcutaneous Electrical Nerve Stimulators (TENS)
07.03A	849	Seat Lift Mechanisms
11.02	854	Section C Continuation (Manual/Motorized Wheelchairs-ONLY)

DME Information Forms		
DME Form	CMS Form	Items Addressed
9.03	10125	External Infusion Pumps
10.03	10126	Enteral and Parenteral Nutrition

Cover Letters for CMNs

Cover letters can be used by a supplier as a method of communication between the supplier and the physician. Suppliers should remind physicians of their responsibility in completing and signing the CMN. It is the physician's responsibility to determine both the medical need for, and the utilization of, all healthcare services. The physician should ensure that information relating to the beneficiary's condition is correct.

Completing a CMN

The "Initial Date," found in Section A of the CMN, should be either the specific date that the physician gives as the start of the medical necessity or, if the physician does not give a specific start date, the "Initial Date" would be the date of the order.

The "Signature Date" is the date the physician signed and dated Section D of the CMN. This date might not be the same as the "Initial Date," since the "Signature Date" **must** indicate when the physician signed Section D of the CMN. The "Delivery Date/Date of Service" on the claim **must not** precede the "Initial Date" on the CMN or DIF or start date on the written order. To ensure that an item is still medically necessary, the delivery date/date of service **must** be within three (3) months from the "Initial Date" of the CMN or DIF or three months from the date of the physician's signature.

Signature and date stamps are not acceptable for use on CMNs and DIFs.

The DME MACs have the authority to request to verify the information on a CMN or DIF at any time. If the information contained either in the supplier's records, or in the patient's medical record maintained by the ordering physician, fails to substantiate the CMN or DIF or if it appears that the CMN or DIF has been altered, the DME MAC will consider the service **not** reasonable and necessary and initiate the appropriate administrative actions.

If there is a change made to any section of the CMN after the physician has completed Section B and signed Section D of the CMN, the **physician must** line through the correction, initial, and date the correction. The supplier may choose to have the physician complete a new CMN. The supplier may **not** complete the information in Section B of the CMN.

A valid CMN is one in which the treating physician has attested to and signed supporting the medical need for the item, and the appropriate individual(s) have completed the medical portion of the CMN. When the DME MAC identifies a claim for which a CMN is not valid, they may deny the claim and/or initiate overpayment action. Any supplier who knowingly and willfully distributes a CMN in violation of clause (I), of Section 1834(j)(2)(A)(iii) of the Act, or fails to provide the information required under clause (ii) is subject to a civil monetary penalty in an amount not to exceed \$1,000 for **each** such CMN so distributed.

For more information on CMNs, refer to Section 5.3.3 in Chapter 5 of Pub. 100-8, *Medicare Program Integrity Manual*, <http://www.cms.hhs.gov/manuals/downloads/pim83c05.pdf>. Further information is available within Section 100.2 (and its subsections) in Chapter 20 of Pub. 100-4, *Medicare Claims Processing Manual*, <http://www.cms.hhs.gov/manuals/downloads/clm104c20.pdf>

Documentation Requirements

The following information provides general requirements. Suppliers should refer to the individual medical policies for specific documentation provisions.

Documentation in the Patient's Medical Record

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

The patient's medical record is **not** limited to the physician's office records. It may include hospital, nursing home, or home health agency (HHA) records, and records from other professionals including, but **not** limited to, nurses, physical or occupational therapists, prosthetists, and orthotists.

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

Supplier Documentation

Before submitting a claim to the DME MAC, the supplier **must** have on file a dispensing order, the written order, the CMN (if applicable), information from the treating physician concerning the patient's diagnosis (if an ICD-9-CM code is required on the claim), and any information required for the use of specific modifiers, or attestation statements, as defined in certain DME MAC medical policies. The supplier should also obtain as much documentation from the patient's medical record as they determine they need to assure themselves that coverage criterion for an item has been met. If the information in the patient's medical record does **not** adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved, unless a properly executed ABN of possible denial has been obtained. Documentation **must** be maintained in the supplier's files for seven (7) years.

Additionally, one of the requirements for suppliers of DMEPOS, as described below, requires suppliers to maintain a proof of delivery for DMEPOS items provided to Medicare beneficiaries. This information is only made available to the DME MACs upon request as supportive documentation and is **not** included in the processing of claims.

Proof of Delivery Documentation Requirements - Suppliers are required to maintain proof of delivery documentation in their files. Documentation **must** be maintained in the supplier's files for seven (7) years.

Proof of delivery is required in order to verify that the beneficiary received the DMEPOS. Proof of delivery is one of the supplier standards as noted in 42 CFR 424.57(12). Proof of delivery documentation **must** be made available to the DME MAC upon request. For any services which do **not** have proof of delivery from the supplier, such claimed items and services shall be denied and overpayments recovered. Suppliers who consistently do **not** provide documentation to support their services may be referred to the Office of the Inspector General (OIG) for investigation and/or imposition of sanctions.

Proof of Delivery and Delivery Methods - For the purpose of the delivery methods noted below, **designee** is defined as:

“Any person who can sign and accept the delivery of durable medical equipment on behalf of the beneficiary.”

Suppliers, their employees, or anyone else having a financial interest in the delivery of the item 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, etc.). The signature of the designee should be legible. If the signature of the designee is **not** legible, the supplier should note the name of the designee on the delivery slip.

Suppliers may deliver directly to the beneficiary or the designee. An example of proof of delivery to a beneficiary is having a signed delivery slip, and it is recommended that the delivery slip include:

1. The patient's name;
2. The quantity delivered;
3. A detailed description of the item being delivered;
4. The brand name; and
5. The serial number.

The date of signature on the delivery slip **must** be the date that the DMEPOS item was received by the beneficiary or designee. In instances where the supplies are delivered directly by the supplier, the date the beneficiary received the DMEPOS supply shall be the date of service on the claim. If the supplier utilizes a shipping service or mail order, an example of proof of delivery would include the delivery service's tracking slip and the supplier's own shipping invoice. If possible, the supplier's records should also include the delivery service's package identification number for that package sent to the beneficiary. The shipping service's tracking slip should reference **each** individual package, the delivery address, the corresponding package identification number given by the shipping service, and if possible, the date delivered. If a supplier utilizes a shipping service or mail order, suppliers shall use the shipping date as the date of service on the claim. Suppliers may also utilize a return, postage-paid delivery invoice from the beneficiary or designee as a form of proof of delivery. The descriptive information concerning the DMEPOS item (i.e., the patient's name, the quantity, detailed description, brand name, and serial number) as well as the required signatures from either the beneficiary or the beneficiary's designee should be included on this invoice as well.

For DMEPOS products that are supplied as refills to the original order, suppliers **must** contact the beneficiary **prior** to dispensing the refill. This shall be done to ensure that the refilled item is necessary and to confirm any changes/modifications to the order. Contact with the beneficiary or designee regarding refills should take place **no sooner** than approximately seven (7) days prior to the delivery/shipping date. For subsequent deliveries of refills, the supplier should deliver the DMEPOS product **no sooner** than approximately five (5) days **prior** to the end of usage for the current product. This is regardless of which delivery method is utilized.

For those patients that are residents of a nursing facility, upon request from the DME MAC, suppliers should obtain copies of the necessary documentation from the nursing facility to document proof of delivery or usage by the beneficiary (e.g., nurse's notes).

Exceptions - Exceptions to the preceding statements concerning the date(s) of service on the claim occur when the items are provided in anticipation of discharge from a hospital or nursing facility. A supplier may deliver a DMEPOS item to a patient in a hospital or nursing facility for the purpose of fitting or training the patient in the proper use of the item. This may be done up to two (2) days prior to the patient's anticipated discharge to their home. The supplier should bill the date of service on the claim as the date of discharge and shall use the place of service (POS) as 12 (patient's home). The item **must** be for subsequent use in the patient's home. **No** billing may be made for the item on those days the patient was receiving training or fitting in the hospital or nursing facility.

A supplier may **not** bill for drugs or other DMEPOS items used by the patient **prior** to the patient's discharge from the hospital or a Medicare Part A nursing facility stay. Billing the DME MAC for surgical dressings, urological supplies, or ostomy supplies that are provided in the hospital or during a Medicare Part A nursing facility stay is **not** allowed. These items are payable to the facility under Part A of Medicare. This prohibition applies even if the item is worn home by the patient from the hospital or nursing facility. 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 to be fraudulent. These statements apply to durable medical equipment delivered to a patient in hospitals, skilled nursing facilities (POS = 31), or nursing facilities providing skilled services (POS = 32).

A supplier may deliver a DMEPOS item to a patient's home in anticipation of a discharge from a hospital or nursing facility. The supplier may arrange for actual delivery of the item approximately two (2) days prior to the patient's anticipated discharge to their home. The supplier shall bill the date of service on the claim as the date of discharge and should use POS as 12 (patient's home).

For more information on proof of delivery, refer to Section 4.26 in Chapter 4 of Pub. 100-8, *Medicare Program Integrity Manual*, <http://www.cms.hhs.gov/manuals/downloads/pim83c04.pdf>

Signature Requirements

Beneficiary - Generally, the payment authorization on the Medicare claim form applies **only** to the particular service(s) listed on the form. However, providers may obtain and retain in their files a **one-time payment authorization** from a beneficiary (or authorized representative), applicable to any current and future treatment that the provider may furnish the beneficiary. The provider should have the beneficiary sign a brief statement substantially as follows:

(Name of Beneficiary)	(Health Insurance Claim Number)	(Date)
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I request that payment of authorized Medicare benefits be made either to me or on my behalf to _____ for any items or services furnished me by that provider. I authorize any holder of medical information about me to release to the Centers for Medicare & Medicaid Services and its agents any information needed to determine these benefits or the benefits payable for related items or services.

If the beneficiary has a Medigap policy, the following statement should also be signed:

(Name of Beneficiary)	(Health Insurance Claim Number)	(Medigap Policy Number)	(Date)

I request that payment of authorized Medigap benefits be made either to me or on my behalf to _____ for any items or services furnished me by that provider. I authorize any holder of medical information about me to release to (name of Medigap insurer) any information needed to determine these benefits or the benefits payable for related items or services.

For services furnished to inpatients of a hospital or SNF, the authorization statement is effective for the period of confinement. For services furnished by an HHA under a plan of treatment, the request is effective for the plan of treatment. For other services, the request is effective until revoked.

If the beneficiary is physically or mentally unable to sign the statement, an authorized representative may sign on the beneficiary's behalf. In this event, the statement's signature line **must** indicate the beneficiary's name followed by "by" the representative's name, address, relationship to the beneficiary, and the reason the beneficiary cannot sign. When an illiterate or physically handicapped beneficiary signs by mark, a witness **must** enter his/her name and address next to the mark.

Once the provider has obtained the beneficiary's one-time authorization, the provider may submit any later Medicare claims, on either an assigned or non-assigned basis, without obtaining any additional signature of the beneficiary. In submitting claims, the provider should indicate in the beneficiary's signature space, "Beneficiary's request for payment on file." The other items on the claim form **must** be completed in the usual manner (in order to complete the item of the form relating to possible worker's compensation coverage, the provider would need to ascertain from the beneficiary whether the illness or injury was employment-related - refer to Chapter 3 of this manual for details on completing the claim form). The provider may, of course, accept or reject an assignment of any particular bill, unless it is subject to an assignment mandate.

A beneficiary may refuse to assign benefits. If this is the case, the provider should obtain a signed statement of refusal from the beneficiary or authorized representative. If the beneficiary or representative is unwilling to sign, the provider should record that he/she was unwilling to sign the statement. In submitting claims, the provider should enter the statement, "Beneficiary refuses to assign benefits," in Item 19 of the CMS-1500. For more information on beneficiary signature requirements, refer to Chapter 1 of Pub. 100-4, *Medicare Claims Processing Manual* (<http://www.cms.hhs.gov/manuals/downloads/clm104c01.pdf>).

Supplier - The following rules apply to both assigned **and** non-assigned claims, unless otherwise indicated.

1. In a claim for services furnished by an individual provider, the provider may:
 - a. Sign Item 31 of the CMS-1500 form.
 - b. Sign one-time certification letter for machine-prepared claims submitted on other than paper vehicles.
 - c. Authorize an employee (e.g., nurse, secretary) to enter the provider's signature in Item 31 of the CMS-1500 form:
 - i. Manually
 - ii. By stamp-facsimile or block letters
 - iii. By computer
 - d. Authorize a non-employee agent, e.g., billing service or association, to enter as in d. above, the provider's signature in Item 31 of the CMS-1500 form, followed by the agent's name, title, and organization (e.g., a billing agent might enter by stamp "Dr. Tom Jones by Robert Smith, Secretary, Ajax Billing Service"). Alternatively, the agent may simply enter the provider's signature.
2. In a claim by a clinic, hospital, or other entity authorized to bill and receive payment in its name for the services of the provider, the entity may:
 - a. Have authorized official sign in Item 25 of the CMS-1500 form (Item 13 of CMS-1554 form, Item 6 of CMS-1556 form).
 - b. Have authorized official sign one-time certification letter for machine-prepared claims submitted on other than paper vehicles.
 - c. Have authorized employee, e.g., a secretary, enter authorized official's signature in Item 25 of the CMS-1500 form (Item 13 of CMS-1554 form, Item 6 of CMS-1556 form) as in 1.d. above.
 - d. Have non-employee agent enter authorized official's signature in Item 25 of the CMS-1500 form (Item 13 of CMS-1554 form, Item 6 of CMS-1556 form) as in 1.e. above.

For more information on signature requirements, refer to Section 50.1.6 in Chapter 1 of Pub. 100-4, *Medicare Claims Processing Manual* (<http://www.cms.hhs.gov/manuals/downloads/clm104c01.pdf>).

Individual Consideration

The primary authority for **all** coverage provisions and subsequent policies is the Social Security Act (the Act). Contractors use Medicare policies in the form of regulations, National Coverage Determinations (NCDs), coverage provisions in interpretive manuals, and local coverage

determinations (LCDs) to apply the provisions of the Act. An item or service **may** be covered by a contractor if:

- It is reasonable and necessary under Section 1862(a)(1)(A) of the Act

Contractors may review claims on either a prepayment or postpayment basis regardless of whether an NCD, coverage provision in an interpretive manual, or LCD exists for that item or service. Contractors shall apply NCDs, coverage provisions in interpretive manuals, and LCDs to individual claims. When making individual claim determinations, contractors shall determine whether the item or service in question is covered based on an LCD or the clinical judgment of the medical reviewer. An item or service **may** be covered by a contractor if it meets **all** of the conditions listed below:

- The item or service is determined to be safe and effective;
- It is not experimental or investigational; and
- It is appropriate, including the duration and frequency that is considered appropriate for the item or service, in terms of whether it is:
- Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment or the patient's condition or to improve the function of a malformed body member;
- Furnished in a setting appropriate to the patient's medical needs and condition;
- Ordered and furnished by qualified personnel;
- One that meets, but does **not** exceed, the patient's medical need; and
- At least as beneficial as an existing and available medically appropriate alternative.

For more information, refer to Section 13.5.1 in Chapter 13 of Pub. 100-8, *Medicare Program Integrity Manual*, <http://www.cms.hhs.gov/manuals/downloads/pim83c13.pdf>

Suppliers are also encouraged to visit the DME MAC Web site on a regular basis to remain current with the latest information regarding the LCDs for Jurisdiction A. In addition to the **current** medical policies section, http://www.medicarehnic.com/dme/medical_review/mr_lcd_current.shtml, suppliers should check for **recent** information concerning medical policy development under the DME MAC Medical Review Bulletins Web page, http://www.medicarehnic.com/dme/medical_review/mr_bulletin_current.shtml