

Medicare Program Integrity Manual

Chapter 5 – Items and Services Having Special DME Review Considerations

Table of Contents *(Rev. 281, 12-31-08)*

Transmittals for Chapter 5

- 5.1 – Home Use of DME
- 5.2 – Rules Concerning Orders
 - 5.2.1 – Physician Orders
 - 5.2.2 – Verbal and Preliminary Written Orders
 - 5.2.3 – Detailed Written Orders
 - 5.2.3.1 – Written Orders Prior to Delivery
 - 5.2.4 – Requirement of New Orders
- 5.3 – Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFs)
 - 5.3.1 – Completing a CMN or DIF
 - 5.3.2 – Cover Letters for CMNs
 - 5.3.3 - Reserved for Future Use
- 5.4 – DME MACs and DME PSC’s Authority to Initiate an Overpayment or CMP When Invalid CMNs Are Identified
- 5.5 – Nurse Practitioner or Clinical Nurse Specialist Rules Concerning Orders and CMNs
- 5.6 – Physician Assistant Rules Concerning Orders and CMNs
- 5.7 - Documentation in the Patient’s Medical Record
- 5.8 - Supplier Documentation
- 5.9 - Evidence of Medical Necessity
 - 5.9.1 - Evidence of Medical Necessity for the Oxygen CMN
 - 5.9.2 - Evidence of Medical Necessity: Wheelchair and Power Operated Vehicle (POV) Claims
- 5.10 - Period of Medical Necessity - Home Dialysis Equipment
- 5.11 - Safeguards in Making Monthly Payments
 - 5.11.1 - Reserved for Future Use
- 5.12 - Pick-up Slips
- 5.13 - Incurred Expenses for DME and Orthotic and Prosthetic Devices
- 5.14 - Reserved for Future Use
- 5.15 - Definitions of Customized DME

5.16 - Advance Determination of Medical Coverage (ADMC) of Customized DME

5.16.1 - Items Eligible for ADMC

5.16.2 - Instructions for Submitting ADMC Requests

5.16.3 - Instructions for Processing ADMC Requests

5.16.4 - Affirmative ADMC Decisions

5.16.5 - Negative ADMC Decisions

5.17 - DME MAC Tracking

5.1 – Home Use of DME

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

See Pub. 100-04, chapter 20, section 10.2, A2.a-e.

5.2 – Rules Concerning Orders

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

5.2.1 - Physician Orders

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

The supplier for all Durable Medical Equipment, Prosthetic, and Orthotic Supplies (DMEPOS) is required to keep on file a physician prescription (order). A supplier must have an order from the treating physician before dispensing any DMEPOS item to a beneficiary.

5.2.2 - Verbal and Preliminary Written Orders

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

Except as noted in chapter 5 section 5.2.3.1 suppliers may dispense most items of DMEPOS based on a verbal order or preliminary written order from the treating physician. This dispensing order must include: a description of the item, the beneficiary's name, the physician's name and the start date of the order. Suppliers must maintain the preliminary written order or written documentation of the verbal order and this documentation must be available to the DME MACs, DME PSCs, or Zoned Program Integrity Contractors (ZPICs) upon request. If the supplier does not have an order from the treating physician before dispensing an item, the item is noncovered.

For items that are dispensed based on a verbal order or preliminary written order, the supplier must obtain a detailed written order that meets the requirements of section 5.2.3 before submitting the claim.

5.2.3 – Detailed Written Orders

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

Detailed written orders are required for all transactions involving DMEPOS. Detailed written orders may take the form of a photocopy, facsimile image, electronically maintained, or original "pen-and-ink" document. (See chapter 3, section 3.4.1.1.B.)

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. (For example, an order for surgical dressings might specify one 4 x 4 hydrocolloid dressing that is changed 1-2 times per week for 1 month or until the ulcer heals.)

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 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.

The supplier must have a detailed written order prior to submitting a claim. For items listed in chapter 5 section 5.2.3.1, the detailed written order must be obtained prior to delivery. If a supplier does not have a faxed, photocopied, electronic or pen and ink signed detailed written order in their records before they submit a claim 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 (e.g., therapeutic shoes for diabetics, oral anticancer drugs, oral antiemetic drugs which are a replacement for intravenous antiemetic drugs), the claim will be denied as not meeting the benefit category and is therefore not appealable by the supplier (see Pub. 100-04, chapter 29, §10, 30.3, 60 for more information on appeals). For all other items (except those listed in section 5.2.3.1), 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.

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

In other sections of this chapter, the term “order” or “written order” means “detailed written order” unless otherwise specified.

5.2.3.1- Written Orders Prior to Delivery

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

A detailed written order prior to delivery is required for: pressure reducing pads, mattress overlays, mattresses, and beds; seat lift mechanisms; TENS units; power operated vehicles and power wheelchairs. DME MACs, DME PSCs, and ZPICs 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 of section 5.2.3 before dispensing the item.

If a supplier bills for an item without a detailed written order, when the supplier is required to have a written order prior to delivery, the item will be denied as excluded by statute (see Pub. 100-04, chapter 29, §10, 30.3, 60 for more information on appeals).

5.2.4 – Requirement of New Orders

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

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; and
- When there is a change in the supplier.

5.3 - Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFs)

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

A Certificate of Medical Necessity (CMN) (see Table 1) or a DME Information Form (DIF) (see Table 2) is a form 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.

The following forms below have been approved by the Office of Management and Budget (OMB). For the CMS- 484 form, the OMB# is 0938-0534. For the CMS forms- 846, 847, 848, 849, 854, 10125 and 10126, the OMB# is 0938-0679.

Table 1 identifies the CMNs:

DME FORM	CMS FORM	ITEMS ADDRESSED
		The forms below can be accessed at: http://www.cms.hhs.gov/CMSForms/CMSForms/list.asp#TopOfPage
484.03	484	Oxygen
04.04B	846	Pneumatic Compression Devices
04.04C	847	Osteogenesis Stimulators
06.03B	848	Transcutaneous Electrical Nerve Stimulators

07.03A	849	Seat Lift Mechanisms
11.02	854	Section C Continuation Form

Table 1

*Beginning January 1, 2007, the new TENS CMN is for purchases only. A TENS CMN will no longer be necessary for rentals.

Table 2 identifies the DIFs:

DME FORM	CMS FORM	ITEMS ADDRESSED
-----------------	-----------------	------------------------

The forms below can be accessed at:

<http://www.cms.hhs.gov/CMSForms/CMSForms/list.asp#TopOfPage>

09.03	10125	External Infusion Pumps
10.03	10126	Enteral and Parenteral Nutrition

Table 2

For certain items or services billed to a DME MAC, the supplier must receive a signed CMN from the treating physician or a signed DIF from the supplier. For these items, a supplier must have a signed original, faxed, photocopied, or electronic CMN or DIF in their records before they can submit a claim for payment to Medicare. CMNs or DIFs have a DME form number (e.g., 01, 02, 03) and a revision number (e.g., .01, .02). Some forms also have an alpha suffix (e.g., A, B, C).

All CMNs and DIFs have a CMS form number in addition to the DME form number. (See the following listing of form numbers.) The CMS form number is in the bottom left corner of the form. CMNs and DIFs are referred to by their CMS form numbers. DME form numbers identify the CMN on electronic claims submitted to the DME MAC. For example, CMS Form 484 serves as the CMN for oxygen; CMS Form 10125 serves as the DIF for External Infusion Pump.

A signed original, faxed, photocopied, or electronic CMN or DIF must be maintained by the supplier and be available to the DME MACs, DME PSCs, or ZPICs on request. When hardcopy CMNs or DIFs are submitted to the DME MACs, DME PSCs, or ZPICs, the supplier must include a copy of only the front side. When CMNs are submitted electronically to the DME MAC, information from sections A and B are required.

The CMN sent to the physician must be two-sided with instructions on the back. If the CMN is mailed to the physician, the supplier must send the two-sided form. If the CMN is faxed, the supplier must fax both the front and back of the form. It is in the supplier's

interest to maintain a copy of what they faxed to the physician. Suppliers must maintain a copy of the completed CMN or DIF in their records. However, if the physician only faxes the front of the completed CMN then the supplier is only required to maintain the front portion of the CMN. The DIF must be two-sided with instructions on the back and completed by the supplier.

However, when the CMN or DIF is submitted electronically and the supplier chooses to maintain a hard copy CMN or DIF, the font may be modified as follows:

- o Pitch may vary from 10 characters per inch (cpi) to 17.7 cpi;
- o Line spacing must be 6 lines per inch
- o Each form must have a minimum 1/4 inch margin on all four sides.

Without exception, these modified hard copy forms must contain identical questions/wording to the CMS forms, in the same sequence, with the same pagination, and identical instructions/definitions printed on the back; and CMN question sets may not be combined.

The CMN can serve as the physician's detailed written order if the narrative description in section C is sufficiently detailed. This would include quantities needed and frequency of replacement for accessories and supplies. For items requiring both a CMN and a written order prior to delivery (seat lift mechanisms and TENS units) suppliers may utilize a completed and physician-signed CMN for this purpose. Otherwise, a separate order in addition to a subsequently completed and signed CMN is necessary.

The supplier may not complete the information in section B of the CMN. A supplier who knowingly and willfully completes section B of the form is subject to a civil monetary penalty up to \$1,000 for each form or document so distributed. Any supplier who remains in non-compliance after repeated attempts by the contractor to get the supplier into compliance, refer to your RO (for DME PSCs and ZPICs, refer the supplier to the primary GTL or associate GTL and SME) as a potential civil monetary penalty case.

The fee schedule amount, narrative description of the items furnished and the supplier's charge for the medical equipment or supplies being furnished must be completed on a CMN by the supplier prior to it being furnished to the physician. A supplier who knowingly and willfully fails to include this information may be subject to a civil monetary penalty up to \$1,000 for each form or document so distributed. Any supplier who remains in non-compliance, after repeated attempts by the contractor to get the supplier into compliance, refer to your RO (for DME PSCs and ZPICs, refer the supplier to the primary GTL or associate GTL and SME) as a potential civil monetary penalty case.

Do not modify the language or content when reprinted. Also, do not accept any CMN or DIF that has been modified in any way by any other party. In addition, do not accept any other certifications of medical necessity by other insurers or government agencies.

Suppliers and physician may choose to utilize electronic CMNs (e-CMN) or electronic DIFs (e-DIFs). E-CMN or e-DIFs must adhere to all privacy, security, and electronic signature rules and regulations promulgated by CMS and DHHS. Additionally, e-CMN or e-DIFs must contain identical questions/wording to the CMS forms, in the same sequence, with the same pagination, and identical instructions/definitions as printed on the back of the hardcopy form.

If an item requires a CMN or a DIF and the supplier does not have a faxed, photocopied, an original hardcopy, or an electronic signed CMN or DIF in their records before they submit a claim to Medicare, the claim will be denied. If the CMN or DIF is used to verify that statutory benefit requirements have been met, then the claim will be denied as not meeting the benefit category.

In cases where two or more suppliers merge, the resultant supplier should make all reasonable attempts to secure copies of all active CMNs or DIFs from the supplier(s) purchased. This document should be kept on file by the resultant supplier for future presentation to the DME MACs, DME PSCs, or ZPICs.

When reviewing claims where the medical record contains a copied, faxed or electronically maintained CMN or DIF (any CMN or DIF created, modified, and stored via electronic means such as commercially available software packages and servers), the DME MACs, DME PSCs, or ZPICs must accept the copied, faxed or electronic document as fulfilling the requirements for these documents.

When a DME PSCs and ZPICs are investigating potentially fraudulent behavior by a supplier, it will be the supplier's responsibility to prove the authenticity/validity of the claim(s) under investigation. DME PSCs and ZPICs may require the supplier to prove the authenticity/validity of the signature on the CMN, DIF, order, or any other questionable portion of the claim(s) under investigation.

Upon request by the MACs, DME PSCs, and ZPICs, suppliers must provide the CMN or DIF, in a format that the DME MACs, DME PSCs, and ZPICs can accept, in a timely manner. Upon medical review, the DME MACs, DME PSCs, and ZPICs should not deny claims solely because the CMN or DIF is faxed, copied, or electronic. The DME MACs, DME PSCs, or ZPICs may request the supplier to download and print a hard copy of an electronic order, CMN or DIF if the DME MACs, DME PSCs, or ZPICs cannot access it electronically.

For items that require a 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 (as described above). This applies to both hard copy and

electronic orders or CMNs. A DIF does not contain a section for a narrative description and is not applicable.

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 or DIFs are in accordance with any regulations published by CMS.

The DME MACs or DME PSCs need not make any shared system changes to electronically accept e-CMN or DIFs as CMS views e-CMN or DIFs as a transaction between the physician and suppliers. Suppliers must continue to use current systems for transmitting claim information to the DME MAC or DME PSC.

5.3.1 – Completing a CMN or DIF

(Rev. 281, Issued: 281, Effective: 02-02-09, Implementation: 02-02-09)

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. Medicare requires a legible identifier for services provided/ordered. The method used *shall be handwritten or an electronic signature in accordance with chapter 3, section 3.4.1.1* to sign an order or other medical record documentation for medical review purposes. Signature and date stamps are *not* acceptable for use on CMNs and DIFs.

The "Delivery Date/Date of Service" on the claim must not precede the "Initial Date" on the CMN or DIF or the start date on the written order. To ensure that an item is still medically necessary, the delivery date/date of service must be within 3 months from the "Initial Date" of the CMN or DIF or 3 months from the date of the physician's signature.

The DME MACs, DME PSCs, and ZPICs 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 MACs, DME PSCs, and ZPICs should deny the service and initiate the appropriate administrative or corrective actions.

In the event of a post pay audit, the supplier must be able to produce the CMN or DIF and, if requested by the DME MACs, DME PSCs, or ZPICs DME produce information to substantiate the information on the CMN or DIF. If the supplier cannot produce this information, the DME MACs, DME PSCs, and ZPICs should deny the service and initiate the appropriate administrative or corrective actions.

If there is a change made to any section of the CMN after the physician has signed the CMN, the physician must line through the error, initial and date the correction; or the supplier may choose to have the physician complete a new CMN.

5.3.2 – Cover Letters for CMNs

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

Cover letters can be used by a supplier as a method of communication between the supplier and the physician. It is not CMS's intent to restrict necessary communication between the supplier and the physician. CMS does not require nor regulate the cover letter. The DME MACs, DME PSCs, and ZPICs should not take adverse action against suppliers that solely involve cover letters.

The DME MACs should regularly publish an article in their bulletins asking suppliers to remind physicians and suppliers of their responsibility in completing and signing the CMN or DIF. It is the physician's and supplier's responsibility to determine both the medical need for, and the utilization of, all health care services. The physician and supplier should ensure that information relating to the beneficiary's condition is correct. The DME MAC and DME PSCs should encourage suppliers to include language in their cover letters to remind physicians of their responsibilities.

5.3.3 – Reserved for Future Use

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

5.4 – DME MACs and DME PSCs Authority to Initiate an Overpayment and/or Civil Monetary Penalty (CMP) When Invalid CMNs or DIFs Are Identified

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

Section 1862(a)(1)(A) of the Act prohibits Medicare payment for services that are not reasonable and necessary. Section 1833(e) of the Act requires that Medicare be furnished by providers and suppliers "such information as may be necessary in order to determine the amount due...." These sections provide support that a failure to have a valid CMN or DIF on file or to submit a valid CMN or DIF to the DME MACs, DME PSCs, or ZPICs makes the underlying claim improper because Medicare does not have sufficient information to determine whether the claim is reasonable and necessary. 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 individuals have completed the medical portion of the CMN. A valid DIF is one in which the supplier has attested to and signed supporting the medical need for the item. When the DME MACs, DME PSCs, and ZPICs identify a claim for which a CMN or DIF is not valid, they may deny the claim and/or initiate overpayment action.

If a DME MAC, DME PSC, or ZPIC identifies a supplier that has a pattern of improperly completing the CMN or DIF, the DME MAC or DME PSC or ZPIC may choose to initiate a potential Civil Monetary Penalty (CMP) case against the supplier. The authority

for such action is found in §1834(j)(2)(A)(iii) of the Act which states that "any supplier of medical equipment and supplies who knowingly and willfully distributes a CMN in violation of clause (I) or fails to provide the information required under clause (ii) is subject to a civil money penalty in an amount not to exceed \$1,000 for each such certificate of medical necessity so distributed." The provisions of §1128A of the Act (other than subsections (a) and (b) shall apply to CMPs penalties under this subparagraph in the same manner as they apply to a penalty or proceeding under §1128(A)(a) of the Act.

5.5 – Nurse Practitioner or Clinical Nurse Specialist Rules Concerning Orders and CMNs

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

A nurse practitioner or clinical nurse specialist may give the dispensing order and sign the detailed 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; and
- 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.

5.6 – Physician Assistant Rules Concerning Orders and CMNs

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

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

- They meet the definition of physician assistant found in §1861(aa)(5)(A) of the 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 NPI; and
- 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.

5.7 – Documentation in the Patient’s Medical Record

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

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

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

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

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

5.8 - Supplier Documentation

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

Before submitting a claim to the DME MAC the supplier must have on file a dispensing order, the detailed written order, the CMN (if applicable), the DIF (if applicable), information from the treating physician concerning the patient's diagnosis, and any information required for the use of specific modifiers or attestation statements as defined

in certain DME MAC policies. The supplier should also obtain as much documentation from the patient's medical record as they determine they need to assure themselves that coverage criteria for an item have been met. If the information in the patient's medical record does not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved unless a properly executed ABN of possible denial has been obtained.

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

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

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

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

5.9 – Evidence of Medical Necessity

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

If replacement supplies are needed for the therapeutic use of purchased DMEPOS, the treating physician must specify on the order, or on the CMN, the type of supplies needed and the frequency with which they must be replaced, used, or consumed. DME MACs, DME PSCs, and ZPICs evaluate supply utilization information as part of the medical necessity determination for DMEPOS. They do not accept "PRN" or "as needed" utilization estimates for supply replacement, use, or consumption.

Absent a State law to the contrary or a supply utilization problem, the order or CMN submitted for the DMEPOS may also serve as medical evidence for supply replacement claims. However, when an order for DMEPOS is renewed or revised, supply utilization information must be specified or updated by the physician on the CMN. DME MACs, DME PSCs, and ZPICs assess the continuing medical necessity.

The DME MACs, DME PSCs, and ZPICs must establish procedures for monitoring the utilization of replacement supplies. Suppliers must have documentation to support the medical necessity of changes in the equipment, device, or supply utilization requirements. Absent such notification, DME MACs, DME PSCs, and ZPICs do not allow claims for unexplained increases in supply utilization above the usage level they previously

determined as medically necessary. Suppliers shall make this information available to the DME MACs, DME PSCs, or ZPICs on request.

If necessary or appropriate for a medical necessity determination, the DME MAC, DME PSC, or ZPIC must 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, DME PSC, or ZPIC 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, DME PSC, or ZPIC must resolve the issue.

5.9.1 - Evidence of Medical Necessity for the Oxygen CMN (Rev. 242: Issued: 02-22-08; Effective/Implementation Dates: 03-01-08)

If DME MACs, DME PSCs, or ZPICs learn that the physician of record is no longer the treating physician, the supplier shall obtain from the physician currently responsible for the patient's pulmonary condition a current fully-completed oxygen CMN. After review of this oxygen CMN, DME MACs continue monthly payments if the evidence establishes medical necessity. Their records must be updated to identify the new treating physician.

5.9.2 - Evidence of Medical Necessity: Wheelchair and Power Operated Vehicle (POV) Claims (Rev. 242: Issued: 02-22-08; Effective/Implementation Dates: 03-01-08)

The physician or treating practitioner (a physician assistant, nurse practitioner or clinical nurse specialist) must conduct a face-to-face examination of the beneficiary and write a written order for the power mobility device (PMD).

The face-to-face examination requirement does not apply when only accessories for power mobility devices are being ordered, nor does it apply for the ordering of replacement PMDs. A replacement PMD would be the same device as previously ordered. For instance, if a beneficiary has a POV but would like to replace the POV with a power wheelchair, then a face-to-face examination would need to be conducted. The written order must include the beneficiary's name; the date of the face-to-face examination; the diagnoses and conditions that the PMD is expected to modify; a description of the item; the length of need; the physician or treating practitioner's signature; and the date the order is written.

The written order for the PMD must be in writing and signed and dated by the physician or treating practitioner (a physician assistant, nurse practitioner or clinical nurse specialist) who performed the face-to-face examination. The face-to-face examination requirement does not apply when only accessories for power mobility devices are being ordered.

The physician or treating practitioner must submit a written order for the PMD and the report of the face-to-face examination to the supplier. These documents must be received by the supplier within 45 days after the face-to-face examination. For those instances of a recently hospitalized beneficiary, the written order and report of the face-to-face examination must be received by the supplier within 45 days after the date of discharge from the hospital.

Prior to dispensing a PMD, the DME supplier must obtain from the physician or treating practitioner who performed the face-to-face examination the written order accompanied by supporting documentation of the beneficiary's need for the PMD in the home. Pertinent parts from the documentation of the beneficiary's PMD evaluation may include the history, physical examination, diagnostic tests, summary of findings, diagnoses, and treatment plans. The physician or treating practitioner should select only those parts of the medical record that clearly demonstrate medical necessity for the PMD. The parts of the medical record selected should be sufficient to delineate the history of events that led to the request for the PMD; identify the mobility deficits to be corrected by the PMD; and document that other treatments do not obviate the need for the PMD, that the beneficiary lives in an environment that supports the use of the PMD and that the beneficiary or caregiver is capable of operating the PMD. In most cases, the information recorded at the face-to-face examination will be sufficient. However, there may be some cases where the physician or treating practitioner has treated a patient for an extended period of time and the information recorded at the face-to-face examination refers to previous notes in the medical record. In this instance, those previous notes would also be needed. The physician, treating practitioner or supplier that is a HIPAA covered entity should make sure to remove or edit any materials that may be contained within the medical record that are not necessary to support the order. For example, a gynecologic report would not be needed in the records submitted for a beneficiary whose clinical need for a PMD is based solely on disability secondary to a stroke.

As defined in the PIM, chapter 3, if data analysis indicates potentially aberrant billing, contractors shall continue to follow the general guidance for performing medical review on claims.

5.10 - Period of Medical Necessity - Home Dialysis Equipment (Rev. 242: Issued: 02-22-08; Effective/Implementation Dates: 03-01-08)

Situations may occur causing temporary non-use of equipment:

- Beneficiary requires in-facility treatment for re-stabilization or as a result of some acute condition. The beneficiary is expected to return to home dialysis;

- Beneficiary is temporarily without a suitable home dialysis assistant;
- Beneficiary is away from home but expects to return; or
- Beneficiary is a transplant candidate and is taken off home dialysis preparatory to transplant. (If the transplant cannot occur, or if the transplant is not successful, the patient will very likely resume home dialysis and an evaluation can be made whether it will be within the immediate or foreseeable future.)

Under such circumstances, DME MACs, DME PSCs, or ZPICs determine that medical necessity exists and pay for a period of up to 3 months after the month home dialysis equipment was last used. This does not eliminate the necessity for periodic reevaluation of medical necessity. It provides a tolerance to avoid frequent reevaluation in renal dialysis situations and provides for continuity of payments where economically advantageous.

5.11 - Safeguards in Making Monthly Payments

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

The DME MACs and DME PSCs shall establish appropriate safeguards to assure that payments are not made beyond the last month of medical necessity. They must develop appropriate safeguards to identify and investigate the following:

- Multiple claims for rental of the same or similar equipment from the same supplier within the same rental month (e.g., rental claims with different start dates but within the same rental period); Pub. 100-04, chapter 20, §30.5 specifically forbids payments for multiple claims for rental of the same or similar equipment from either the same or a different supplier during the same rental month.
- Contraindicated items of rented or purchased equipment;
- Incompatible claims information (e.g., liquid oxygen contents billed for a purchased gas delivery system);
- Medical equipment rentals or purchases after a beneficiary's death;
- Rental start dates on or after the purchase of the same or comparable equipment (absent evidence that the beneficiary has disposed of purchased equipment);
- Rental claims for the same or similar equipment from different suppliers for the same or overlapping rental months; and
- Equipment rental start dates within periods of confinement in an institution that cannot be considered a patient's home.

The DME MACs and DME PSCs shall resolve these situations on a prepayment basis. Development, if necessary, may be via written or telephone contact per Pub. 100-08 subject to any other documentation or development guidelines specified in Pub. 100-02, chapter 15, §100-01, Pub. 100-04, chapter 20, §10.1.1 and Pub. 100-04, chapter 20, §100.2.3.

To the extent possible, DME MACs and DME PSCs give beneficiaries and supplier-assignees advance notice of the date and reason that payments are scheduled to stop. (See Pub. 100-04, chapter 21 for EOMB language.)

5.11.1 – Reserved for Future Use

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

5.12 – Pick-up Slips

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

For purposes of this section, a pick-up slip is written confirmation, provided by a supplier, that the supplier has removed an item of DME from the beneficiary's home.

When making determinations, DME MACs, DME PSCs, and ZPICs must ascertain not only whether equipment is present in the home, but must determine which equipment is actually being used by the patient. Therefore, it is inappropriate to determine, solely based on lack of a pick up slip that a piece of equipment may still be in use. Likewise, it is inappropriate for DME MACs, DME PSCs, and ZPICs to deny claims solely based on lack of a pick up slip. DME MACs, DME PSCs, and ZPICs should develop these claims to determine which piece of equipment is medically necessary.

5.13 - Incurred Expenses for DME and Orthotic and Prosthetic Devices

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

The first month's expense for rental is incurred on the date of delivery of the equipment. Expenses for subsequent months are incurred on the same date of the month. Where equipment is purchased, benefits are payable on the same basis. Suppliers may submit claims as of the date expenses are incurred. If the date of delivery is not specified on the claim, reviewers assume, in the absence of evidence to the contrary, that the date of purchase or rental was the date of delivery.

Generally, for all DMEPOS, the supplier's date of service (DOS) is the date of delivery to a beneficiary's home. For DMEPOS provided to a beneficiary immediately following a hospital inpatient stay and/or DME immediately following a nursing home stay, the DOS is the date of final discharge to the beneficiary's home. For mail order DMEPOS provided immediately subsequent to a hospital inpatient stay and/or DME immediately following a nursing home stay, the DOS is the later of the actual delivery date or the date of the discharge. Under no circumstances can the DOS be earlier than the date of delivery.

No payment may be made for rental for any month throughout which the patient is in an institution that does not qualify as his or her home (see Pub. 100-02, chapter 15, §110.3) or is outside the U.S. (See Pub. 100-02, chapter 16, §60.) If the patient is at home as of the first day of a rental month and, for part of the same rental month, is in an institution which cannot qualify as his or her home, or is outside the U.S., payment may be made for the entire rental month. Similarly, if an item of rental equipment is returned to the supplier before the end of a payment month because the beneficiary died in that rental month or because the equipment became unnecessary in that month, payment may be made for the entire rental month. However, if the supplier charges for only part of a month, or the DME MAC is aware that the supplier customarily follows such a practice, it pays on a prorated basis. If the individual is outside the U.S. for more than 30 days and returns to the U.S. (before resuming payments), it determines medical necessity as in an initial case.

Note that in the case of purchased equipment, Pub. 100-02, chapter 16, §60 requires that the beneficiary must have been in the United States when the item was delivered, and Pub. 100-01, chapter 2, §40.1 requires that the individual must have had Supplementary Medical Insurance (SMI) coverage at the time the item was delivered. Therefore, where a purchased item of equipment was delivered to an individual outside the United States or before his/her coverage period began (i.e., the effective date of his/her enrollment), the entire expense of the item is excluded from coverage whether it was paid for in its entirety at purchase or on a deferred or installment basis. Payment cannot be made in such cases even though the individual uses the item inside the United States or after his/her coverage begins.

Contractor systems must maintain the outcome (e.g., audit trail) of prepayment decisions such as approved, denied, or partially denied.

5.14 – Reserved for Future Use

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

5.15 – Definition of Customized DME

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

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.

For instance, a wheelchair which has been; (1) measured, fitted, or adapted in consideration of the patient's body size, disability, period of need, or intended use, (2) assembled by a supplier or ordered from a manufacturer who makes available customized features, modifications, or components for wheelchairs, and (3) is intended for an individual patient's use in accordance with instructions from the patient's physician would be considered "customized".

5.16 – Advance Determination of Medicare Coverage (ADMC) of Customized DME

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

Section 1834(a)(15)(C) of the Act provides that carriers 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.

This section provides for direction in implementing §1834 (a)(15)(C) of the Act. It is important to note that 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. Beneficiaries and suppliers are not required to submit ADMC requests in order to submit claims for items. Additionally, DME PSCs may not require an ADMC request as a prerequisite for submitting a claim.

5.16.1 – Items Eligible for ADMCs

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

The DME MACs shall publish examples of the types of items for which ADMCs are available. These examples shall be published yearly in the DME MAC's Supplier Manual or yearly in the DME MAC's Supplier Bulletin. Examples will be published in the form of HCPCS codes eligible for this program. Because HCPCS codes describe general "categories" of equipment, this list is not a list of specific items, but rather a general list of the categories of types of items eligible for this program.

5.16.2 – Instructions for Submitting ADMC Requests

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

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. Each DME MAC shall publish the mailing address to which requests should be sent.

5.16.3 – Instructions for Processing ADMC Requests

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

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 should 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.

Upon receipt of a request, the DME MAC shall render an advance determination of Medicare coverage within 30 calendar days. DME MACs shall provide the requestor with their decision, be it affirmative or negative, in writing.

If requests are received for the wrong item(s), the request will be rejected. Rejected requests should not be counted as workload.

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.

5.16.4 – Affirmative ADMC Decisions

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

When making an ADMC, the DME MAC should review the information submitted with the request to determine; 1) if a benefit category exists, 2) if a statutory exclusion exists, and 3) if the item is reasonable and necessary.

An affirmative ADMC decision will provide the supplier and the 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 ADMC decision does not provide assurance that the beneficiary meets Medicare eligibility requirements nor does it assure that any other Medicare requirements (MSP, etc.) have been met. Only upon submission of a complete claim, can the DME MAC make a full and complete determination.

An affirmative ADMC decision does not extend to the price that Medicare will pay for the item.

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

The DME MACs reserve the right to review claims on a pre- or post-payment basis and, notwithstanding the requirements of this section, may deny claims and take appropriate remedy if they determine that an affirmative ADMC decision was made based on incorrect information.

5.16.5 – Negative ADMC Decisions

(Rev. 167, Issued: 10-27-06; Effective: 10-01-06; Implementation: 10-02-06)

A negative ADMC decision communicates to the supplier and the 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 ADMC decision should indicate why the request was denied.

A beneficiary or a 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 submitted once during a 6-month period.

5.17 - DME MAC Tracking

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

The DME MACs shall develop the capability to track ADMC requests in order to assure that decisions are rendered in a timely and appropriate fashion. DME MACs shall also develop the capability to ensure that: 1) items for which an affirmative ADMC decision was made are not denied as not meeting the medical necessary requirements of the policy, and 2) claims for item that received a negative ADMC decision are denied as not covered, unless additional medical documentation submitted with the claims supports coverage.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
<u>R281PI</u>	12/31/2008	Signature and Date Stamps for DME Supplies-CMNs and DIFs	02/02/2009	6261
<u>R242PI</u>	02/22/2008	Items and Special Services Having Special DME Review Considerations	03/01/2008	5909
<u>R168PI</u>	10/31/2006	DMEPOS Transcutaneous Electrical Nerve Stimulators (TENS) Certificate of Medical Necessity (CMN) for Purchases: Form CMS-848	01/02/2007	5107
<u>R167PI</u>	10/27/2006	New DMEPOS Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFS) for Claims Processing	10/01/2006	4296
<u>R166PI</u>	10/06/2006	DMEPOS Transcutaneous Electrical Nerve Stimulators (TENS) Certificate of Medical Necessity (CMN) for Purchases: Form CMS-848 – Replaced by Transmittal 168	01/02/2007	5107
<u>R159PI</u>	09/22/2006	New DMEPOS Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFS) for Claims Processing – Replaced by Transmittal 167	10/02/2006	4296
<u>R157PI</u>	08/25/2006	Evidence of Medical Necessity: Wheelchair and Power-Operated Vehicle (POV) Claims (Clarification of CR 3952, Transmittal 128, Dated October 28, 2005)	10/16/2006	5128
<u>R156PI</u>	08/18/2006	Evidence of Medical Necessity: Wheelchair and Power-Operated Vehicle (POV) Claims (Clarification of CR 3952, Transmittal 128, Dated October 28, 2005)- Replaced by Transmittal R157	09/18/2006	5128
<u>R142PI</u>	03/02/2006	New DMEPOS Certificates of Medical Necessity (CMNs) and DME MAC Information Forms (DIFS) for Claims Processing - Replaced by Transmittal 159	10/02/2006	4296
<u>R138PI</u>	02/10/2006	New DMEPOS Certificates of Medical Necessity (CMNs) and DME MAC Information Forms (DIFS) for Claims Processing - Replaced by Transmittal 142	10/02/2006	4296
<u>R128PI</u>	10/28/2005	Evidence of Medical Necessity: Wheelchair and Power Operated Vehicle (POV) Claims	10/25/2005	3952
<u>R124PI</u>	09/23/2005	Evidence of Medical Necessity: Wheelchair	10/25/2005	3952

Rev #	Issue Date	Subject	Impl Date	CR#
		and Power Operated Vehicle (POV) Claims - Replaced by Transmittal 128		
<u>R121PI</u>	09/14/2005	Evidence of Medical Necessity: Wheelchair and Power Operated Vehicle (POV) Claims - Replaced by Transmittal 124	10/17/2005	3952
<u>R100PI</u>	01/21/2005	Review of Documentation During Medical Review	02/22/2005	3644
<u>R071PI</u>	04/09/2004	Rewrite of Program Integrity Manual (except Chapter 10) to Apply to PSCs	05/10/2004	3030
<u>R061PI</u>	01/02/2004	Clarification of Proof of Delivery Requirements	02/02/2004	2903
<u>R059PI</u>	11/28/2003	Written Orders	01/05/2004	2937
<u>R050PI</u>	09/26/2003	Advance Determination of Medicare Coverage (ADMC) Requests	10/10/2003	2866
<u>R048PIM</u>	09/12/2003	Items Denied as not Meeting Benefit Category	10/01/2003	2872
<u>R037PI</u>	01/17/2003	Written Orders	02/01/2003	2471
<u>R030PI</u>	09/27/2002	Written Orders	10/15/2002	2202
<u>R016PIM</u>	11/28/2001	Adds Various Program Memoranda for BI Requests for Information, Organizational Requirements, Unsolicited Voluntary Refund Checks, Anti-Kickback Statute Implications	11/28/2001	1732
<u>R011PIM</u>	09/18/2001	Completing a CMN	09/24/2001	1773
<u>R005PIM</u>	02/26/2001	Advance Determination of Medicare Coverage (ADMC) of Customized Durable Medical Equipment (DME)	07/2001	1187
<u>R004PIM</u>	01/31/2001	Physician Assistant Rules Concerning Orders and CMNs	01/31/2001	1471
<u>R003PIM</u>	11/22/2000	Complete Replacement of PIM Revision 1.	NA	1292
<u>R001PIM</u>	06/2000	Initial Release of Manual	NA	931