

Medicare Program Integrity Manual

Chapter 5 – Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Items and Services Having Special DME Review Considerations

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(Rev. 12512; Issued: 02-15-24)

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5.1 – Home Use of DME, Prosthetics, Orthotics, and Supplies (DMEPOS)

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

The Social Security Act (the Act) defines those items and services covered by Medicare and identifies certain conditions for payment. In Section 1834(a)(11) of the Act, Congress sets forth prescription and face-to-face encounter requirements for certain items. We note that Section 1834(h)(3) of the Act requires that section 1834(a)(11) of the Act apply to orthotics and prosthetics in the same manner as it applies to items of DME.

See Pub. 100-04, chapter 20, section 10 for more information related to home use of DME.

5.2 – Rules Concerning DMEPOS Orders/Prescriptions

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

A written order/prescription is a written communication from a treating practitioner that documents the need for a beneficiary to be provided an item of DMEPOS. As used throughout this chapter, treating practitioner means a physician, as defined in section 1861(r)(1) of the Act, or physician assistant, nurse practitioner, or clinical nurse specialist, as those terms are defined in section 1861(aa)(5) of the Act.

All DMEPOS items require a written order/prescription from the treating practitioner for Medicare payment as a condition of payment.

Certain items require an order/prescription based on statute. In such instances, if the statutory requirements related to the order are not met, the claim will be denied as not meeting the benefit category. If the error cannot be cured, or can be cured but it is not cured within the prescribed timeframe, there may be financial implications for the beneficiary (see Pub. 100-04, Chapter 30, for more information on limitation on liability).

A supplier must maintain the written order/prescription and the supporting documentation provided by the treating practitioner and make them available to CMS and its contractors upon request.

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

5.2.1 - Standard Written Order/Prescription (SWO)

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

All claims for DMEPOS items billed to Medicare require a written order/prescription from the treating practitioner as a condition for payment. The required elements of a DMEPOS order/prescription have been codified at 42 CFR 410.38(d)(1) and are listed below.

5.2.2 - Required Elements of a SWO

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

A SWO must contain all of the following elements:

- Beneficiary name or Medicare Beneficiary Identifier (MBI);
- General description of the item.
 - The description can be either a general description (e.g., wheelchair or hospital bed), a brand name/model number, a HCPCS code, or a HCPCS code narrative;
 - For equipment – In addition to the description of the base item, the SWO may include all concurrently ordered options, accessories, or additional features that are separately billed or require an upgraded code (List each separately);
 - For supplies – In addition to the description of the base item, the SWO may include all concurrently ordered supplies that are separately billed
Note: If such items are not concurrently ordered, they nonetheless require an order for payment purposes
- Quantity to be dispensed, if applicable;
- Order Date;
- Treating Practitioner Name or National Provider Identifier (NPI); and
- Treating Practitioner Signature.

The elements of the SWO will be evaluated in accordance with Ch. 3, Section 3.3.2.1, which discusses using the totality of the record to verify compliance with required elements.

Note also that while the SWO has a limited number of required order elements, suppliers/providers are permitted to add elements that may provide clarity for issues such as length of need (LON), frequency of use, dosage form/strength, refills frequency, etc. This additional information shall be corroborated by information in the medical record.

Suppliers may also wish to consult state law or regulation since some states may have additional requirements for the elements of an order/prescription (e.g., refill frequency).

5.2.3 –Who can complete a SWO

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

\Statute requires that the treating practitioner who conducts the qualifying face-to-face encounter for Power Mobility Devices (PMDs) also prepare the SWO for the PMD base. For items other than PMDs appearing on the Required Face-to-Face and Written Order Prior to Delivery List, the treating practitioner who conducts the face-to-face encounter does not need to be the prescriber of the DMEPOS items— so long as the prescribing practitioner has knowledge of, and documentation to support (e.g., face-to-face), the condition that requires his or her writing an order/prescription.

For non-PMD items, and PMD separately billed accessories, certain elements of the order/prescription may be completed by someone other than the treating practitioner, so long as the treating practitioner identified in the order, via their name or national provider identifier (NPI), signs the document.

5.2.4 – Timing of the Order/Prescription

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

Written Order Prior to Delivery (WOPD)

For PMDs and other DMEPOS items selected for inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List (See section 5.3.1 below), the SWO must be communicated to the supplier prior to delivery. For items requiring a WOPD, the contractors shall verify that the date of the written order is on or before the date of delivery or on or before the date shipped, the shipping date is used as the date of service. For additional information, see Chapter 4, section 26.1.

Written Orders Prior to Claim Submission:

For DMEPOS items that are not PMDs or otherwise included on the Required Face-to-Face Encounter and Written Order Prior to Delivery List, the SWO must be communicated to the supplier prior to claim submission.

5.2.5 - When a New Order/Prescription is Required

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

A new order/prescription is required:

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

5.2.6 - Documentation Requirements for DMEPOS Supplied as Refills to the Original Order

(Rev. 12512; Issued: 02-15-24; Effective: 01-01-24; Implementation: 02-19-24)

*Per 42 CFR 410.38 related to DMEPOS products that are supplied as refills to the original order/prescription, suppliers must contact the beneficiary prior to dispensing the refill and not automatically ship on a pre-determined basis, even if authorized by the beneficiary. This shall be done to ensure that the refilled item remains reasonable and necessary and to confirm any changes/modifications to the SWO. **The DMEPOS supplier must document contact with the beneficiary or their representative to verify the refill is needed. This documentation must include the following:***

- *Evidence of the beneficiary or their representative's affirmative response of the need for supplies, which should be obtained as close to the expected end of the current supply as possible. However, such contact and affirmative response must be within 30 calendar days from the expected end of the current supply.*
 - *For shipped items: the beneficiary's name, date of contact, the item requested, and an affirmative response from the beneficiary, indicative of the need for refill, prior to dispensing the product is required. Beneficiary's need not count the remaining supply.*
 - *For items obtained in-person from a retail store, the delivery slip signed by the beneficiary or their representative or a copy of the itemized sales receipt is sufficient documentation of a request for refill.*

Suppliers are permitted to use any mode of communication so long as the beneficiary affirmation is received, and documentation of the contact is captured and can be provided upon request.

- *For example, automated text messaging or email may be used so long as the captured information demonstrates the beneficiary's name, item(s), date of contact, and affirmative response.*

For delivery of refills, the supplier must deliver the DMEPOS product no sooner than 10 calendar days prior to the end of usage for the current product. This is regardless of which delivery method is utilized. DME MACs shall allow for the processing of claims for refills delivered/shipped prior to the beneficiary exhausting his/her supply.

5.3 - Master List of DMEPOS Items Potentially Subject to a Face-to-Face Encounter and WOPD and/or Prior Authorization Requirements (Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

42 CFR 410.38 and Final Rule 1713 (84 Fed. Reg Vol 217) creates a “Master List of DMEPOS Items Potentially Subject to Face-To-Face Encounter and Written Order Prior to Delivery and/or Prior Authorization Requirements”. The Master List shall serve as a library of DMEPOS items from which items may be selected for inclusion on either the:

- Required Face-to-Face Encounter and Written Order Prior to Delivery List; or
- Required Prior Authorization List.

Items included in either Required List are subject to the face-to-face encounter and WOPD or prior authorization requirements, respectively, as a condition of payment.

See Chapter 3 for instructions regarding the requirements for items selected and included on the Required Prior Authorization List.

The following instructions are limited to those items selected and included on the Required Face-to-Face Encounter and Written Order Prior to Delivery List.

5.3.1 – Notification of DMEPOS Item(s) Selected and Included on the Required Face-to-Face Encounter and Written Order Prior To Delivery List

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

Items selected and included in the Required Face-To-Face Encounter and Written Order Prior to Delivery List are published in the Federal Register with no less than 60 days’ notice and posted on CMS’ and its contractors’ websites. Contractors shall include the effective date on their websites. Contractors shall apply the face-to-face encounter and WOPD requirement as a condition of payment for any item appearing on the Required Face-To-Face Encounter and Written Order Prior to Delivery List beginning on the published effective date.

5.4 – Face-to-Face Encounter Definition

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

A face-to-face encounter means an in-person or telehealth encounter between the treating practitioner and the beneficiary. The face-to-face encounter must be used for the purpose of gathering subjective and objective information associated with diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered. Telehealth encounters used to satisfy the face-to-face requirement must meet the requirements of 42 CFR §§ 410.78 and 414.65 for purposes of DMEPOS coverage.

5.4.1 – Timing of the Face-to-Face Encounter

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

For DMEPOS items appearing on the Required Face-to-Face and Written Order Prior to Delivery List, the treating practitioner must document and communicate to the DMEPOS supplier that the treating practitioner has had a face-to-face encounter with the beneficiary within the 6 months preceding the date of the written order/prescription.

A qualifying face-to-face encounter is required each time there is a new order/prescription for a DMEPOS items on the Required Face-to-Face and Written Order Prior to Delivery List. A single face-to-face encounter may document the clinical conditions necessitating multiple DMEPOS items. In this situation, regardless of whether the DMEPOS items are prescribed on different dates, the single face-to-face encounter may be utilized in support of the multiple items, so long as the encounter date is within 6 months prior to the date of the orders. As always, the supplier is responsible for submitting documentation to support each claim upon request.

The face-to-face requirement codified at 42 CFR 410.38 does not supplant other CMS coverage policies. For example, the National Coverage Determination § 240.2 “Home use of Oxygen” requires a physician examination within a month of starting home oxygen therapy.

5.4.2 – Documentation from the Face-to-Face Encounter (Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

A supplier must maintain the SWO and the supporting documentation provided by the treating practitioner and make them available to CMS and its contractors upon request. A supplier must submit additional documentation to CMS or its contractors, upon request, to support and/or substantiate the medical necessity for the DMEPOS.

The face-to-face encounter must support payment and be documented in the pertinent portion of the medical record (for example, history, physical examination, diagnostic tests, summary of findings, progress notes, treatment plans or other sources of information that may be appropriate). The supporting documentation must include subjective and objective beneficiary specific information used for diagnosing, treating, or managing a clinical condition for which the DMEPOS is ordered.

Section 1834(h)(5) of the Act states that for purposes of determining the reasonableness and medical necessity of orthotics and prosthetics, documentation created by orthotists and prosthetists shall be considered part of the individual’s medical record to support documentation created by eligible professionals as described in section 1848(k)(3)(B) of the Social Security Act. Documentation from a face-to-face encounter conducted by a treating practitioner, as well as documentation created by an orthotist or prosthetist, becomes part of the medical records. If the orthotist or prosthetist notes support the documentation created by eligible professionals described in section 1848(k)(3)(B), they can be used together to support medical necessity of an ordered DMEPOS item. In the

event the orthotist or prosthetist documentation does not support the documentation created by the eligible professional, payment may be denied.

If a supplier bills for an item listed on the Required Face-to-Face Encounter and Written Order Prior to Delivery List and does not possess documentation of the face-to-face encounter and/or the WOPD, the item will be denied.

5.4.3 – Suspension of Face-to-Face Encounter and WOPD Requirements (Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

CMS may suspend the face-to-face encounter and WOPD requirements generally or for a particular item or items at any time and without undertaking rulemaking, except those items for which inclusion on the Required Face-to-Face Encounter and Written Order Prior to Delivery List was statutorily imposed or codified in prior rule making, such as power mobility devices. CMS will post notification of the suspension on the CMS website. Upon direction from CMS, contractors shall post notification of the suspension on their websites and may utilize other communication tools to alert suppliers of the suspension.

5.5 – Certificates of Medical Necessity (CMNs) and DME Information Forms (DIFs) (Rev. 11431; Issued: 05-26-22; Effective: 06-28-22; Implementation: 06-28-22)

The CMS seeks to reduce burden and modernize processes to ensure a reduction in improper payments and an increase in customer satisfaction. The CMN form and DIF were originally required to help document the medical necessity and other coverage criteria for selected Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) items. In the past, a supplier received a signed CMN from the treating physician or created and signed a DIF to submit with the claim. Due to improvements in claims processing and medical records management, the information found on CMNs or DIFs is available either on the claim or in the medical record and is redundant. Therefore, to reduce burden and increase customer satisfaction, providers and suppliers no longer need to submit these forms for services rendered after January 1, 2023.

- **For claims with dates of service on or after January 1, 2023** – providers and suppliers no longer need to submit CMNs or DIFs with claims. Due to electronic filing requirements, claims received with these forms attached will be rejected and returned to the provider or supplier.
- **For claims with dates of service prior to January 1, 2023** – processes will not change and if the CMN or DIF is required, it will still need to be submitted with the claim, or be on file with a previous claim.

This statement applies throughout the Program Integrity Manual wherever CMNs and DIFs are mentioned.

A CMN or a DIF is a form required to help document the medical necessity and other coverage criteria for selected DMEPOS items. CMNs contain Sections A through D. Sections A and C are completed by the supplier and Sections 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. For the CMS forms 484, 846, 847, 848, 849, 854, 10125 and 10126, the OMB# is 0938-0679.

- CMN CMS-484 – Oxygen
- CMN CMS-846 – Pneumatic Compression Devices
- CMN CMS-847 -- Osteogenesis Stimulators
- CMN CMS-848 – Transcutaneous Electrical Nerve Stimulators
- CMN CMS-849 – Seat Lift Mechanisms
- CMN CMS-854 – Section C Continuation Form
- DME Information Form CMS-10125 – External Infusion Pumps
- DME Information Form CMS-10126 – Enteral & Parenteral Nutrition

The TENS CMN is for purchases only. A TENS CMN will no longer be necessary for rentals.

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 when submitting a claim for payment to Medicare.

A signed original, faxed, photocopied, or electronic CMN or DIF must be maintained by the supplier and be available to the DME MACs, UPICs, SMRC, and DME RACs on request. When hardcopy CMNs or DIFs are submitted to the DME MACs, UPICs, SMRC and DME RACs, 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.

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.

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:

- Pitch may vary from 10 characters per inch (cpi) to 17.7 cpi;
- Line spacing must be 6 lines per inch

- 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 (e.g., seat lift mechanisms) 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 UPICs 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 UPICs, refer the supplier to the primary GTL or associate GTL and SME) as a potential civil monetary penalty case.

The CMS will not accept any other certifications of medical necessity by other insurers or government agencies.

Suppliers and physician may choose to utilize electronic CMNs (e-CMNs) or electronic DIFs (e-DIFs). E-CMNs or e-DIFS must adhere to all privacy, security, and electronic signature rules and regulations promulgated by CMS and DHHS. Additionally, e-CMNs 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, original hardcopy, or an electronic signed CMN or DIF in their records when they submit a claim to Medicare, the claim will be denied.

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, and UPICs.

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, or UPICs must accept the copied, faxed or electronic document as fulfilling the requirements for these documents.

When a UPIC is 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. UPICs 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 DME MACs, UPICs, SMRC or DME RACs, suppliers must provide the CMN or DIF, in a format that the DME MACs, UPICs, SMRC, and DME RACs can accept, in a timely manner. Upon medical review, the DME MACs, UPICs, SMRC, and DME RACs should not deny claims solely because the CMN or DIF is faxed, copied, or electronic. The DME MACs, UPICs, SMRC, and DME RACs may request the supplier to download and print a hard copy of an electronic order, CMN or DIF if the DME MACs, UPICs, SMRC, and DME RACs 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 when 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 UPICs need not make any shared system changes to electronically accept e-CMN or e-DIFs as CMS views e-CMN or e-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 UPICs.

5.5.1 – Completing a CMN or DIF

(Rev. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

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 and UPICs 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 and UPICs 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 or UPICs DME produce information to substantiate the information on the CMN or DIF. If the supplier cannot produce this information, the DME MACs and UPICs 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.

5.5.2 – Cover Letters for CMNs

(Rev. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

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 and UPICs 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 UPICs should encourage suppliers to include language in their cover letters to remind physicians of their responsibilities.

5.5.3 – Reserved for Future Use

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

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

(Rev. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

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 or UPICs 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 and UPICs 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 or UPIC identifies a supplier that has a pattern of improperly completing the CMN or DIF, the DME MAC or UPIC 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.

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

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

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.

5.8 – Physician Assistant Rules Concerning Orders and CMNs (Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

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.

5.9 – Documentation in the Patient’s Medical Record (Rev. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

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). When a CMN or DIF and a medical record contain conflicting information due to a minor error or omission within the CMN or DIF, but all coverage, coding and payment criteria are substantiated through the medical record, the reviewer shall rely upon the content of the medical record (absent suspicion of abuse or gaming) and shall not issue a denial.

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 or UPICs. However, the DME MACs or UPICs may request this information in selected cases. If the DME MACs or UPICs 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.

5.10 - Supplier Documentation

(Rev. 11032; Issued: 09-30-21; Effective: 10-12-21; Implementation: 11-10-21)

A. General

Before submitting a claim to the DME MAC (or before dispensing the item – see section 5.2.4), the supplier must have on file a standard written order, the CMN (if applicable), the DIF (if applicable), information from the treating practitioner concerning the patient's diagnosis, and any information required for the use of specific modifiers or attestation statements as defined in certain DME MAC policies. The supplier should also obtain as much documentation from the patient's medical record as they determine they need to assure themselves that coverage criteria for an item have been met. If the information in the patient's medical record does not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved unless a properly executed ABN of possible denial has been obtained.

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

B. Proof of Delivery

Section 424.57(c)(12) requires suppliers, as part of their standards to be met for enrollment and participation, to maintain proof of delivery documentation in their files. In certain instances, compliance with proof of delivery may be required as a condition of payment, and must be available to the DME MAC, RAC, SMRC, CERT, and UPIC on request. For such items, if the supplier does not have appropriate proof of delivery documentation within the prescribed timeframes, associated claims will be denied and overpayments recouped. We note that non-compliance with supplier standards may also result in revocation from the Medicare program. Suppliers who consistently do not provide documentation to support their services may be referred to the OIG or NSC for investigation and/or imposition of sanctions. If the beneficiary is newly eligible to the Medicare program, the proof of delivery standards require the supplier to obtain a statement, signed and dated by the beneficiary (or beneficiary's designee), that the supplier has examined the item.

Please refer to IOM 100-08. Ch. 4, Section 4.7.3.1 for additional information regarding all proof of delivery requirements.

5.10.1 - Suppliers Documentation for DMEPOS Repair Claims (Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

When reviewing DMEPOS claims for repairs, the contractor shall review for continued medical necessity of the item and necessity of the repair. Contractors are not required to determine that the requirements for provision of the DMEPOS item as when it was originally ordered were met. For example, even though a face-to-face encounter is required for the initial provision of certain wheelchairs, it is not needed for the repair of a wheelchair already covered and paid for by Medicare. However, documentation from the treating practitioner that indicates the wheelchair being repaired continues to be medically necessary is required. For this purpose, documentation is considered timely when it is on record in the preceding 12 months, unless otherwise specified in relevant Medicare policy.

In addition, the contractor shall ensure that the supplier's record includes the nature of the repair required and work performed to restore the item to its functionality to meet the Medicare beneficiary's medical need.

These instructions do not replace or alter other longstanding instructions related to coverage and payment for reasonable and necessary repairs and maintenance and servicing of DMEPOS items. Contractors shall continue to adhere to these program policies and procedures. Examples include, but are not limited to, Chapter 15, section 110.2 of the Benefit Policy Manual and Chapter 20, sections 10.2 and 40 of the Claims Processing Manual. Contractors are also reminded that parts and labor covered under a manufacturer or supplier warranty are not to be considered reasonable and necessary under regulation; therefore, contractors shall determine for each claim whether billed parts and labor are covered under a warranty. For reasonable and necessary parts,

payment is made on a lump sum basis based on the contractor's individual consideration of a reasonable payment amount for the part. For reasonable and necessary labor, payment is based on a reasonable fee established by the contractor for labor associated with repairing the item.

5.10.2 - Suppliers Documentation for Claims for Replacement of Essential Accessories for Beneficiary-Owned Continuous Positive Airway Pressure (CPAP) and Respiratory Assist Devices (RADs) (Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

When reviewing claims for replacement of essential accessories for beneficiary-owned CPAP and RADs, the contractor shall review for continued medical necessity of the DME and necessity of the replacement accessory. Contractors are not required to determine that the requirements for provision of the CPAP and RAD as when it was originally ordered were met. For example, even though a face-to-face encounter is required for the initial provision of the CPAP device, it is not needed for replacement of a CPAP mask for a patient-owned CPAP device covered by Medicare in the past. However, documentation from the treating practitioner that indicates the CPAP or RAD which requires replacement accessories continues to be medically necessary is required. For this purpose, documentation is considered timely when it is on record in the preceding 12 months, unless otherwise specified in relevant Medicare policy.

In addition, the contractor shall ensure that the supplier's record includes the reason why the accessory(s) need to be replaced to meet the Medicare beneficiary's medical need. The contractor shall also ensure that the supplier's record includes the reason why any new accessories (e.g., heated humidifier or heated tubing) need to be furnished to meet the Medicare beneficiary's medical need. These instructions do not replace or alter other longstanding instructions related to coverage and payment for reasonable and necessary accessories for patient-owned DME. Contractors shall continue to adhere to these program policies and procedures.

5.11 - Evidence of Medical Necessity (Rev. 10538; Issued: 12-30-20; Effective: 01-01-20; Implementation: 12-29-20)

If replacement supplies are needed for the therapeutic use of purchased DMEPOS, the treating practitioner must specify on the standard written order, or on the CMN, the type of supplies needed, in such a manner that the supplier may calculate the necessary disbursement and assess the continued need for refill with the beneficiary. DME MACs, UPICs, and other contractors evaluate supply utilization information as part of their medical necessity and coverage determinations for DMEPOS.

Absent a State law to the contrary or a supply utilization problem, the standard written order or CMN submitted for the DMEPOS may also serve as medical evidence for supply replacement claims. However, when a standard written order for DMEPOS is renewed or revised, supply utilization information must be specified or updated by the treating

practitioner on the CMN. DME MACs, UPICs, and other contractors assess the continuing medical necessity.

The DME MACs, UPICs, and other contractors 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, UPICs, and other contractors 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, UPICs, and other contractors on request.

If necessary or appropriate for a medical necessity determination, the DME MAC, UPIC, or other contractor must ask the supplier to obtain documentation from the treating practitioner, 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 practitioner.

If the DME MAC, UPIC, or other contractor 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, UPIC, or other contractor must resolve the issue.

5.11.1 – Evidence of Medical Necessity for the Oxygen Claims (Rev. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

If DME MACs, CERT, UPICs, Recovery Auditors or the SMRC 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.

For an initial claim, the physician must submit a signed certification of medical necessity that includes an oxygen/blood gas lab result. This certification must be corroborated with information in the medical record. A physician signature on the oxygen lab test result is not necessary to corroborate the certification. Instead, the reviewer should consider all submitted records from all of the beneficiary's healthcare professionals.

Therefore, contractors shall not deny an oxygen or oxygen equipment claim solely because the claim lacks a physician signature on the oxygen lab test result.

5.11.2 - Evidence of Medical Necessity: Wheelchair and Power Operated Vehicle (POV) Claims

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

The physician or treating practitioner (a physician assistant, nurse practitioner or clinical nurse specialist) must conduct a face-to-face encounter of the beneficiary and write a written order for the power mobility device (PMD). The face-to-face examination and the written order must comply with the instructions found under Required Elements of a SWO, Written Order Prior to Deliver, Face-to-Face Encounter Definitions and Timing of the Face-to-Face Encounter.

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. However, 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.

Prior to dispensing a PMD, the DMEPOS 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 medically 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.

5.12 – Period of Medical Necessity - Home Dialysis Equipment

(Rev. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

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 or UPICs 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.

5.13 - Safeguards in Making Monthly Payments

(Rev. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

The DME MACs and UPICs 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 UPICs 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 UPICs 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.)

5.13.1 – Reserved for Future Use

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

5.14 – Pick-up Slips

(Rev. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

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 and UPICs 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 and UPICs to deny claims solely based on lack of a pick-up slip. DME MACs and UPICs should develop these claims to determine which piece of equipment is medically necessary.

5.15 – Incurred Expenses for DMEPOS

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

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.

5.16 – Reserved for Future Use

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

5.17 - Definition of Customized DMEPOS

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

42 CFR 414.224 defines 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. See Pub. 100-04, Chapter 20, Section 30.3 for information on customized DME.

5.18 – Advance Determination of Medicare Coverage (ADMC) of Customized DMEPOS

(Rev. 10749; Issued: 05-11-21; Effective: 06-11-21; Implementation: 06-11-21)

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, UPICs may not require an ADMC request as a prerequisite for submitting a claim.

5.18.1 – Items Eligible for ADMCs

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

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.

5.18.2 – Instructions for Submitting ADMC Requests

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

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.

5.18.3 – Instructions for Processing ADMC Requests

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

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.

5.18.4 – Affirmative ADMC Decisions

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

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.

5.18.5 – Negative ADMC Decisions

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

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.

5.19 - DME MAC Tracking

(Rev. 10190; Issued: 06-19-2020; Effective: 01-01-2020; Implementation: 07-01-2020)

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>R12512PI</u>	02/15/2024	Documentation Requirements for Refillable Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)	02/19/2024	13480
<u>R12468PI</u>	01/18/2024	Documentation Requirements for Refillable Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)- – Rescinded and replaced by transmittal 12512	02/19/2024	13480
<u>R11431PI</u>	05/26/2022	Publication (Pub.) 100-08, Chapter 5 Update - Planned Elimination of Certificates of Medical Necessity (CMN) and Durable Medical Equipment Information (DIF) Forms	06/28/2022	12726
<u>R11032PI</u>	09/30/2021	Updates to Chapters 1, 3, 4, 5, 8 and 9 of Publication (Pub.) 100-08	11/10/2021	12375
<u>R10984PI</u>	09/09/2021	Updates to Chapters 1, 3, 4, 5, 8 and 9 of Publication (Pub.) 100-08 – Rescinded and replaced by transmittal 11032	11/10/2021	12375
<u>R10749PI</u>	05/11/2021	Updates to Chapter 4 and Chapter 5 of Publication (Pub.) 100-08	06/11/2021	12257
<u>R10538PI</u>	12/30/2020	Clarifying The Use of As-Needed/PRN Orders for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)	12/29/2020	11997
<u>R10492PI</u>	11/25/2020	Clarifying The Use of As-Needed/PRN	12/29/2020	11997

Rev #	Issue Date	Subject	Impl Date	CR#
		Orders for Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)		
<u>R10190PI</u>	06/19/2020	Revising Chapters 3 and 5 of Publication (Pub.) 100-08, to Reflect the Recent Final Rule CMS-1713-F	07/01/2020	11599
<u>R834PI</u>	10/12/2018	Order Requirements When Prescribing Practitioner is Also the Supplier and is Permitted to Furnish Specific Items of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)	11/13/2018	10984
<u>R812PI</u>	07/27/2018	Clarify Detailed Written Orders For Durable Medical Equipment, Prosthetics, Orthotics, And Supplies (DMEPOS)	08/28/2018	10345
<u>R806PI</u>	07/06/2018	Clarify Detailed Written Orders For Durable Medical Equipment, Prosthetics, Orthotics, And Supplies (DMEPOS) – Rescinded and replaced by Transmittal 812	08/07/2018	10345
<u>R750PI</u>	10/20/2017	Proof of Delivery Documentation Requirements	11/20/2017	10324
<u>R753PI</u>	10/27/2017	Certificates of Medical Necessity (CMN) and Durable Medical Equipment (DME) Information Forms (DIF)	11/28/2017	10244
<u>R733PI</u>	07/27/2017	Clarification of Certificate of Medical Necessity (CMN) and Durable Medical Equipment Information Forms (DIFs)	08/28/2017	10148
<u>R722PI</u>	05/26/2017	Clarifying Date and Timing Requirements for Certain Durable Medical Equipment Prosthetics Orthotics and Supplies (DMEPOS)	06/27/2017	10106
<u>R705PI</u>	03/24/2017	Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Order Requirements for Changing Suppliers	04/24/2017	9886
<u>R693PI</u>	12/30/2016	Clarification of Appeal Rights for Denials Stemming from Statutory Requirements	01/31/2017	9910
<u>R672PI</u>	08/19/2016	Documentation for Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) Claims for Replacement of Essential Accessories for Beneficiary-Owned Continuous Positive Airway Pressure (CPAP) Devices and	11/23/2016	9741

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		Respiratory Assist Devices (RADs)		
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<u>R623PI</u>	11/03/2015	Written Orders Prior to Delivery (WOPD)	10/10/2015	9364
<u>R618PI</u>	10/09/2015	Written Orders Prior to Delivery (WOPD) – Rescinded and replaced by Transmittal 623	10/10/2015	9364
<u>R612PI</u>	09/10/2015	Changes to Supplier Documentation and Evidence of Medical Necessity for Oxygen Claims	09/29/2015	9063
<u>R611PI</u>	08/28/2015	Changes to Supplier Documentation and Evidence of Medical Necessity for Oxygen Claims – Rescinded and replaced by Transmittal 612	09/29/2015	9063
<u>R608PI</u>	08/14/2015	Update to Pub. 100-08 to Provide Language-Only Changes for Updating ICD-10 and ASC X12	09/14/2015	8747
<u>R598PI</u>	06/12/2015	Proof and Date of Delivery	07/13/2015	9194
<u>R546PI</u>	10/17/2014	Documentation for Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) Repair Claims. This CR rescinds and fully replaces CR 8843.	11/04/2014	8952
<u>R533PI</u>	08/01/2014	Documentation for Durable Medical Equipment Prosthetics, Orthotics and Supplies (DMEPOS) Repair Claims – Rescinded and replaced by CR 8952, Transmittal 546	11/04/2014	8843
<u>R528PI</u>	07/03/2014	Proof of Delivery	08/05/2014	8643
<u>R468PI</u>	05/31/2013	Detailed Written Orders and Face-to-Face Encounters	07/01/2013	8304
<u>R460PI</u>	04/19/2013	Clarify the Definition of Customized Durable Medical Equipment (DME) Items	07/19/2013	8194
<u>R378PI</u>	07/01/2011	Prospective Billing for Refills of DMEPOS Items Provided on a Recurring Basis	08/02/2011	7452
<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	01/02/2007	5107

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		Necessity (CMN) for Purchases: Form CMS-848		
<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 and Power Operated Vehicle (POV) Claims - Replaced by Transmittal 128	10/25/2005	3952
<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	05/10/2004	3030

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		Chapter 10) to Apply to PSCs		
<u>R061PI</u>	01/02/2004	Clarification of Proof of Delivery Requirements	02/02/2004	2903
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<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
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