

Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)

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Contractor Information

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
CGS Administrators, LLC	DME MAC	17013 - DME MAC	J-B	Illinois Indiana Kentucky Michigan Minnesota Ohio Wisconsin
CGS Administrators, LLC	DME MAC	18003 - DME MAC	J-C	Alabama Arkansas Colorado Florida Georgia Louisiana Mississippi New Mexico North Carolina Oklahoma Puerto Rico South Carolina Tennessee Texas Virgin Islands Virginia West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC	J-A	Connecticut Delaware District of Columbia Maine Maryland Massachusetts New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island

CONTRACTOR NAME	CONTRACT TYPE	CONTRACT NUMBER	JURISDICTION	STATE(S)
				Vermont
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC	J-D	Alaska American Samoa Arizona California - Entire State Guam Hawaii Idaho Iowa Kansas Missouri - Entire State Montana Nebraska Nevada North Dakota Northern Mariana Islands Oregon South Dakota Utah Washington Wyoming

Article Information

General Information

Article ID

A55426

Original Effective Date

01/01/2017

Article Title

Standard Documentation Requirements for All Claims
Submitted to DME MACs

Revision Effective Date

04/06/2020

Article Type

Article

Revision Ending Date

N/A

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Retirement Date

N/A

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Article Guidance

Article Text:

Many errors reported in Medicare audits are due to claims submitted with incomplete or missing requisite documentation. Consequently, the Durable Medical Equipment Medicare Administrative Contracts (DME MACs) have created guidance to assist Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) suppliers in understanding the information necessary to justify payment.

The documentation requirements are compiled from Statutes, Code of Federal Regulations, Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations (NCDs), CMS rulings and sub-regulatory guidance (CMS manuals), and DME MAC publications. This article sets out the general requirements that are applicable to all

DMEPOS claims submitted to the DME MACs.

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

*****IMPORTANT*****

All Policy Specific Documentation Requirements are located in the LCD-related Policy Article, which is linked to the applicable LCD.

It is important that suppliers review the actual LCD, the related Policy Article, and the Standard Documentation Requirements (SDR) article to be sure to have all of the relevant information necessary and applicable to the item(s) provided.

Note: The information in this document supersedes the material currently contained in all LCDs and related policy articles. Where there are differences between the policies and this article, this document shall take precedence.

ORDERS

GENERAL

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

This written order/prescription is referred to as the Standard Written Order (SWO) (see below).

"All claims" refers to all claims submitted for payment of purchases or rentals to Medicare Part B.

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

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

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

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

For DMEPOS items other than PMDs, someone other than the treating practitioner may complete certain required

elements of the SWO; however, the SWO must be signed by the treating practitioner.

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

NEW ORDER REQUIREMENTS

A new order/prescription is required:

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

STANDARD WRITTEN ORDER (SWO)

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

A SWO must contain all of the following elements:

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

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

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

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

WRITTEN ORDERS PRIOR TO DELIVERY (WOPD)

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

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

The Required List will be comprised of:

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

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

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

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

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

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

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

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

DOCUMENTATION REQUIREMENTS

GENERAL

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

Before submitting a claim to Medicare, the DMEPOS supplier must have on file SWO, a WOPD (if applicable), a CMN (if applicable), a DIF (if applicable), information from the treating practitioner concerning the patient's diagnosis, and any information required for the use of specific modifiers or attestation statements as defined in certain DME MAC policies. The supplier should also obtain as much documentation from the patient's medical record in order to assure themselves that coverage criteria for an item have been met. If the information in the patient's medical record does

not adequately support the medical necessity for the item, the supplier is liable for the dollar amount involved unless a properly executed Advance Beneficiary Notice of Noncoverage (ABN) of possible denial has been obtained.

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

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

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

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

REASONABLE AND NECESSARY CRITERIA (R&N)

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

MEDICAL RECORD DOCUMENTATION

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

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

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

CONTINUED MEDICAL NEED

For all DMEPOS items, the initial justification for medical need is established at the time the item(s) is first ordered; therefore, beneficiary medical records demonstrating that the item is reasonable and necessary are created just prior

to, or at the time of, the creation of the initial prescription. For purchased items, initial months of a rental item or for initial months of ongoing supplies or drugs, information justifying reimbursement will come from this timeframe. Entries in the beneficiary's medical record must have been created prior to, or at the time of, the initial DOS to establish whether the initial reimbursement was justified based upon the applicable coverage policy.

For ongoing supplies and rented DME items, in addition to information described above that justifies the initial provision of the item(s) and/or supplies, there must be information in the beneficiary's medical record to support that the item continues to remain reasonable and necessary. Information used to justify continued medical need must be timely for the DOS under review. Any of the following may serve as documentation justifying continued medical need:

- A recent order/prescription by the treating practitioner for refills;
- A recent change in an order/prescription;
- A properly completed CMN or DIF with an appropriate length of need specified;
- Timely documentation in the beneficiary's medical record showing usage of the item.

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in the policy.

CONTINUED USE

Continued use describes the ongoing utilization of supplies or a rented item by a beneficiary.

Suppliers are responsible for monitoring utilization of DMEPOS rental items and supplies. No monitoring of purchased items or capped rental items that have converted to a purchase is required. Suppliers must discontinue billing Medicare when rental items or ongoing supply items are no longer being used by the beneficiary.

Beneficiary medical records or supplier records may be used to confirm that a DMEPOS item continues to be used by the beneficiary. Any of the following may serve as documentation that an item submitted for reimbursement continues to be used by the beneficiary:

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

Timely documentation is defined as a record in the preceding 12 months unless otherwise specified elsewhere in this policy.

CLAIM NARRATIVES

Most DMEPOS accessory/supply items provided on a recurring basis can be dispensed with a three-month supply. Please review the REFILL REQUIREMENTS section of each individual LCD for further details. When billing more than one month's supply of these items, include a narrative in the NTE segment of the electronic claim indicating the number of months you are billing. For example, if you bill a three-month supply of PAP accessories (i.e., mask, tubing, cushions), you must add "90-day supply" or "three-month supply". This additional information is required so

that the DME MACs can correctly process the claim.

DATE SPANS ON CLAIMS

The following DMEPOS items require a date span on all claims submitted to the DME MACs:

- Diabetic testing supplies (i.e., test strips, lancets)
- Continuous passive motion devices (CPM)
- Parenteral and enteral nutrition
- Parenteral and enteral administration kits
- External infusion pump supplies (Recommended)

Suppliers must span the dates of service using "From" and "To" dates on any electronic or paper claim for the items listed above. The "From" date is when the items were provided to the Medicare beneficiary. The "To" date is the last date the supplies are expected to be used. For example, if you are providing a three-month supply (January – March 2019) of diabetic testing supplies for a beneficiary, the "From" date on the claim would be "01/01/2019" and the "To" date would be "03/31/2019". This additional information is required so that the DME MACs can correctly process the claim.

REFILL DOCUMENTATION REQUIREMENTS

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

A routine prescription for refills is not needed.

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

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

The refill record must include:

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

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

PROOF OF DELIVERY (POD)

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

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

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

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

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

The supplier should also have on file any documentation containing a description of the item delivered to the beneficiary to determine the accuracy of claims coding including, but not limited to, a voucher, invoice or statement in the supplier records. A description of the item(s) delivered must be noted on the POD. The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, the long description of a HCPCS code, or a brand name/model number.

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

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

Method 1—Direct Delivery to the Beneficiary by the Supplier

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

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

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

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

Method 2—Delivery via Shipping or Delivery Service Directly to a Beneficiary

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

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

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

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

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

Method 3—Delivery to Nursing Facility on Behalf of a Beneficiary

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

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

CORRECT CODING

Healthcare Common Procedure Coding System (HCPCS) CODING

The Medicare Program Integrity Manual (CMS Pub. 100-08), Chapter 3, Sections 3.3.B and 3.6.2.4 specify that for Medicare claims, only CMS and the Durable Medical Equipment Medicare Administrative Contractors (DME MACs) have the authority to establish HCPCS Level II Coding Guidelines. Pursuant to 42 CFR § 414.40 and 45 CFR § 162.1002, CMS has the authority to assign and manage HCPCS codes (create, delete, change code narrative etc.). The DME MACs have the authority to evaluate products to make benefit category and coding determinations for any DME item that does not logically fall into any of the generic categories listed in NCD 280.1.

Correct HCPCS coding is a determination that the item provided to a beneficiary is billed using the appropriate HCPCS code for that item. Suppliers are required to correctly code for the item billed. An item/service is correctly coded when it meets all the coding guidelines listed in CMS HCPCS guidelines, LCDs, LCD-related Policy Articles, or DME MAC articles.

The Pricing, Data Analysis, and Coding (PDAC) contractor maintains product listings for many HCPCS codes on their [website](#) (Select, DMECS to search for HCPCS codes and associated product lists). Not every HCPCS code has a product classification list; but reviewed products are added to the listings for each code as coding determinations are completed. For Medicare claim purposes, this product classification listing is accepted as evidence of correct coding.

Each supplier is ultimately responsible for the HCPCS code they select to bill for the item provided. Resources such as LCDs, LCD-related Policy Articles, DME MAC articles, code determinations letters and DMECS are useful; but many products currently on the market have not been reviewed. For these un-reviewed products, each supplier must use their best judgment in selecting HCPCS codes for billing and are encouraged to check with The PDAC Contact Center, which can provide information that will assist in correct code selection.

Information that is sufficiently detailed to unambiguously identify the specific product delivered to the beneficiary and the HCPCS code used to bill for that item must be maintained by the supplier and be available upon request.

Not Otherwise Classified (NOC) BILLING INFORMATION

Items billed with any HCPCS code with a narrative description that indicates miscellaneous, NOC, unlisted, or non-specified, must also include the following information in loop 2400 (line note), segment NTE02 (NTE01=ADD) of the ANSI X12N, version 5010A1 professional electronic claim format or on Item 19 of the paper claim form:

- Description of the item or service
- Manufacturer name
- Product name and number
- Supplier Price List (PL) amount
- HCPCS code of related item (if applicable)

Miscellaneous HCPCS codes billed without this information will be rejected and will need to be resubmitted with the missing information included.

If you have questions, please contact the PDAC HCPCS Helpline at (877) 735-1326 during the hours of 9:30 a.m. to 5:00 p.m. ET, Monday through Friday. You may also visit the PDAC [website](#) to chat with a representative or select the Contact Us button at the top of the page for email inquiry, FAX or postal mail information.

EQUIPMENT RETAINED FROM A PRIOR PAYER

When a beneficiary receiving a DMEPOS item from another payer (including a Medicare Advantage plan) becomes eligible for the Medicare Fee For Service (FFS) program, the first Medicare claim for that item or service is considered a new initial Medicare claim. Medicare does not automatically continue coverage for any item obtained from another payer when a beneficiary transitions to Medicare coverage.

For Medicare to provide payment, the beneficiary must meet all Medicare coverage, coding, and documentation requirements for the DMEPOS items in effect on the DOS of the initial Medicare claim.

A POD is required for all items, even those in the beneficiary's possession provided by another insurer prior to Medicare eligibility.

PROOF OF DELIVERY REQUIREMENTS FOR RECENTLY ELIGIBLE MEDICARE FFS

The supplier record must document:

- A statement, signed and dated by the beneficiary (or beneficiary's designee), that the supplier has examined the item, meets the POD requirements; and
- A supplier attestation that the item meets Medicare requirements.

For the purposes of reasonable useful lifetime and calculation of continuous use, the first day of the first rental month in which Medicare payments are made for the item (i.e., DOS) serves as the start date of the reasonable useful lifetime and period of continuous use. In these cases, the POD documentation serves as evidence that the beneficiary is already in possession of the item.

FACE-TO-FACE ENCOUNTER

As a condition for payment, 42 CFR 410.38 and Final Rule 1713 (84 Fed. Reg Vol 217) require that a treating practitioner have a face-to-face encounter with a beneficiary within the six (6) months prior to prescribing items that appear on the Required List.

The face-to-face encounter must support payment for the item(s) ordered/prescribed, 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.

This face-to-face requirement also includes examinations conducted via the CMS-approved use of telehealth examinations, which must meet the requirements of 42 CFR §§ 410.78 and 414.65 for purposes of DMEPOS coverage.

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

Refer to the applicable LCD-related Policy Article NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for more information regarding documentation requirements.

The 6-month timing requirement does not supplant other coverage or documentation requirements. For example, the National Coverage Determination § 240.2 "Home use of Oxygen" requires a face-to-face examination within a month of starting home oxygen therapy.

There must be sufficient medical information included in the medical record to demonstrate that all other applicable coverage criteria are met. Refer to the applicable Local Coverage Determination for information about the medical necessity criteria for the item(s) being ordered.

For items other than PMDs that appear on the Required List, the treating practitioner that conducted the face-to-face encounter does not need to be the prescriber for the DMEPOS item; however, the prescriber must:

- Verify that a qualifying face-to-face encounter occurred within the 6-months prior to the date of their prescription; and,
- Have documentation of the qualifying face-to-face encounter that was conducted.

A qualifying face-to-face encounter is required each time a new order/prescription for one of the specified items on the Required List is ordered.

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

Upon request by a contractor, all DMEPOS suppliers must provide documentation of the face-to-face encounter.

CERTIFICATE OF MEDICAL NECESSITY (CMN) & DME INFORMATION FORM (DIF)

A CMN, which has been completed, signed, and dated by the treating practitioner, must be kept on file by the supplier and made available upon request. The CMN for XXX is CMS Form ### (DME form ###). In addition to the order information that the treating practitioner enters in Section B, the supplier can use the space in Section C for a written confirmation of other details of the order or the treating practitioner can enter the other details directly.

The CMN may act as a substitute for a SWO if it contains all the required elements.

For items requiring both a CMN and a WOPD (e.g., items on the Required Face-to-Face and WOPD List) suppliers may utilize a completed and treating practitioner signed CMN for this purpose. Otherwise, a separate WOPD in addition to a subsequently completed and signed CMN is necessary.

A new CMN is not required just because the supplier changes assignment status on the submitted claim.

For certain items or services billed to a DME MAC, the supplier must receive a signed CMN from the treating practitioner. For these items, a supplier must have a signed original, faxed, photocopied, or electronic CMN in their records when submitting a claim for payment to Medicare.

DME INFORMATION FORM

A DIF, which has been completed, signed, and dated by the supplier, must be kept on file and made available upon request. The DIF for XXX is CMS Form ### (DME form ###).

The supplier must have a signed and dated DIF in their records when submitting a claim for payment to Medicare.

REPAIRS/REPLACEMENT

GENERAL

For the purposes of Medicare reimbursement, repairs are not synonymous with replacements. Repairs (parts and labor) of DMEPOS items are performed on the base item. The replacement of parts or components that make up the base item is considered to be a repair. Conversely, the furnishing of new separately payable accessories that were not part of the initial base item is considered to be replacement, which is addressed in the section below.

Replacement of a beneficiary owned DMEPOS item typically involves providing an identical or nearly identical item.

REPAIRS

The definition of a repair is found in the Medicare Benefit Policy Manual (CMS Pub. 100-02), Chapter 15, Section 110.2.A. That section generally defines repair as to fix or mend and to put the item back in good condition after damage or wear.

Repairs to items which a beneficiary owns are covered when necessary to make the items serviceable. However, "routine periodic maintenance", such as testing, cleaning, regulating, and checking is not covered.

Medicare does not separately reimburse for repairs of:

- Items in the frequent and substantial servicing payment category; or,
- Oxygen equipment; or,
- Items in the capped rental payment category during the capped rental period; or,
- Items covered under a manufacturer's or supplier's warranty; or,
- Previously denied items.

A new CMN and/or treating practitioner's order is not needed for repairs.

In the case of repairs to a beneficiary-owned DMEPOS item, if Medicare paid for the base item initially, medical necessity for the base item has been established. With respect to Medicare reimbursement for the repair, there are two documentation requirements:

- The treating practitioner must document that the DMEPOS item being repaired continues to be reasonable and necessary (see Continued Medical Need section above); and,
- Either the treating practitioner or the supplier must document that the repair itself is reasonable and necessary.

The supplier must maintain detailed records describing the need for and nature of all repairs including a detailed explanation of the justification for any component or part replaced as well as the labor time to restore the item to its functionality.

REPLACEMENT

The definition of replacement is found in the Medicare Benefit Policy Manual (CMS Pub. 100-02), Chapter 15, Section 110.2.C. That section generally defines replacement as the provision of an entirely identical or nearly identical item when it is lost, stolen or irreparably damaged.

Beneficiary owned items or a capped rental item may be replaced in cases of loss or irreparable damage. Irreparable damage may be due to a specific accident or to a natural disaster (e.g., fire, flood). Contractors may request documentation confirming details of the incident (e.g., police report, insurance claim report).

Replacement of items due to irreparable wear takes into consideration the Reasonable Useful Lifetime (RUL) of the item. The RUL of DME is determined through program instructions. In the absence of program instructions, carriers may determine the RUL, but in no case can it be less than 5 years. If the item has been in continuous use by the beneficiary on either rental or purchase basis for its RUL, the beneficiary may elect to obtain a replacement.

Medicare does not cover replacement for items in the frequent and substantial servicing payment category, oxygen equipment, or inexpensive or routinely purchased rental items.

A treating practitioner's order and/or new CMN, when required, is needed to reaffirm the medical necessity of the item for replacement of an item.

There are special rules for the replacement of artificial arms, legs and eyes.

Adjustments and repairs of prostheses and prosthetic components are covered under the original order for the prosthetic device.

Medicare payment may be made for the replacement of prosthetic devices, which are artificial limbs, or for the replacement of any part of such devices, without regard to continuous use or useful lifetime restrictions if a treating practitioner determines that the replacement device, or replacement part of such a device, is necessary.

Claims involving the replacement of a prosthesis or major component (foot, ankle, knee, socket etc.) must be supported by a new treating practitioner's order and documentation supporting the reason for the replacement. The

reason for replacement must be documented by the treating practitioner, either on the order or in the medical record, and must fall under one of the following:

- A change in the physiological condition of the patient resulting in the need for a replacement. Examples include but are not limited to, changes in beneficiary weight, changes in the residual limb, beneficiary functional need changes; or,
- An irreparable change in the condition of the device, or in a part of the device resulting in the need for a replacement; or,
- The condition of the device, or the part of the device, requires repairs and the cost of such repairs would be more than 60 percent of the cost of a replacement device, or, as the case may be, of the part being replaced.

The prosthetist must retain documentation of the prosthesis or prosthetic component replaced, the reason for replacement, and a description of the labor involved irrespective of the time since the prosthesis was provided to the beneficiary. This information must be available upon request. It is recognized that there are situations where the reason for replacement includes but is not limited to changes in the residual limb; functional need changes; or irreparable damage or wear/tear due to excessive beneficiary weight or prosthetic demands of very active amputees.

SIGNATURE REQUIREMENTS

All signatures must comply with the CMS signature requirements outlined in the Medicare Program Integrity Manual (CMS Pub. 100-08), Chapter 3, Section 3.3.2.4.

Coding Information

CPT/HCPCS Codes

N/A

ICD-10 Codes that Support Medical Necessity

N/A

ICD-10 Codes that DO NOT Support Medical Necessity

N/A

Additional ICD-10 Information

N/A

Bill Type Codes:

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service.

Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

N/A

Revenue Codes:

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory. Unless specified in the policy, services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

N/A

Revision History Information

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
04/06/2020	R14	<p>Revision Effective Date: 04/06/2020</p> <p>STANDARD WRITTEN ORDER (SWO): Revised: Reference to the Medicare Program Integrity Manual from 'Internet only manual' to 'CMS Pub.'</p> <p>DOCUMENTATION REQUIREMENTS: Revised: "DME MAC supplier" to "DMEPOS supplier" in second paragraph</p> <p>CORRECT CODING: Revised: Reference to the Medicare Program Integrity Manual from 'Internet only manual' to 'CMS Pub.'</p> <p>Added: "45 CFR" in front of 162.1002 reference in first paragraph Revised: 'Durable Medical Equipment Coding System' reference to 'DMECS' to match the PDAC website</p> <p>REPAIRS/REPLACEMENT: Revised: References to the Medicare Benefit Policy Manual from 'Internet only manual' to 'CMS Pub.'</p> <p>SIGNATURE REQUIREMENTS: Revised: Reference to the Medicare Program Integrity Manual from 'Internet only manual' to 'CMS Pub.'</p> <p><i>03/11/2021: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
04/06/2020	R13	<p>Revision Effective Date: 04/06/2020</p> <p>REFILL DOCUMENTATION:</p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		<p>Added: "REQUIREMENTS" to title PROOF OF DELIVERY (POD): Added: Prohibition for billing prior to discharge date</p> <p><i>04/02/2020: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
01/01/2020	R12	<p>Revision Effective Date: 01/01/2020 PRESCRIPTION (ORDER) REQUIREMENTS: Revised: Title to ORDERS Revised: Language based on Final Rule 1713-F NEW ORDER REQUIREMENTS: Revised: Language based on Final Rule 1713-F DISPENSING ORDERS: Deleted: Entire section based on Final Rule 1713-F DETAILED WRITTEN ORDER: Revised: Title to STANDARD WRITTEN ORDER (SWO) based on Final Rule 1713-F Revised: Language based on Final Rule 1713-F WRITTEN ORDERS PRIOR TO DELIVERY (WOPD): Revised: Language based on Final Rule 1713-F POWER MOBILITY DEVICES WOPD (7 ELEMENT ORDER): Deleted: Entire section based on Final Rule 1713-F POWER MOBILITY DEVICES DETAILED PRODUCT DESCRIPTION: Deleted: Entire section based on Final Rule 1713-F WOPD FOR SPECIFIED DMEPOS ITEMS (5 ELEMENT ORDER): Deleted: Entire section based on Final Rule 1713-F DOCUMENTATION REQUIREMENTS: Revised: Language based on Final Rule 1713-F FACE-TO-FACE EXAMINATION FOR SPECIFIED DMEPOS ITEMS: Revised: Title to FACE-TO-FACE ENCOUNTER Revised: Language based on Final Rule 1713-F FACE-TO-FACE REQUIREMENTS: Deleted: Title of section CERTIFICATE OF MEDICAL NECESSITY (CMN) & DME INFORMATION FORM (DIF): Revised: Language based on Final Rule 1713-F</p> <p><i>01/02/2020: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
01/01/2019	R11	<p>Revision Effective Date: 01/01/2019 DOCUMENTATION REQUIREMENTS: Added: Narrative section to clarify longstanding claims processing instructions Added: Date Span section to clarify longstanding claims processing instructions</p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
		<p><i>08/08/2019: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
01/01/2019	R10	<p>Revision Effective Date: 01/01/2019 ARTICLE TEXT: Removed: Last updated date POWER MOBILITY DEVICES WOPD (7 ELEMENT ORDER): Revised: 42 CFR 410.38(c) paragraph to remove the reference to HCPCS table PROOF OF DELIVERY (POD): Added: Postage paid delivery invoice option for POD documentation</p> <p><i>04/04/2019: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
01/01/2019	R9	<p>Revision Effective Date: 01/01/2019 DETAILED WRITTEN ORDERS (DWO): Added: Exception to DWO when the prescribing practitioner is also the supplier PROOF OF DELIVERY (POD): Removed: Postage paid delivery invoice option from POD documentation CORRECT CODING: Removed: Link to PDAC Contact Form</p> <p><i>01/31/2019: At this time 21st Century Cures Act applies to new and revised LCDs which require comment and notice. This revision is to an article and not a local coverage determination.</i></p>
08/28/2018	R8	<p>Revision Effective Date: 08/28/2018 PRESCRIPTION (ORDER) REQUIREMENTS Removed: Future start date language Revised: Elements of the DWO Removed: Prescribing physician's name from the DWO Removed: Additional order date instructions Added: Specific references to WOPD requirements Added: Practitioner to all physician references DOCUMENTATION REQUIREMENTS Clarified: Supplier documentation as it relates to specific products provided to beneficiary</p> <p><i>08/23/2018: At this time 21st Century Cures Act applies to new and revised LCDs that restrict coverage, which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
05/07/2018	R7	<p>Revision Effective Date: 05/07/2018 PRESCRIPTION (ORDER) REQUIREMENTS Correction: Corrected "nurse physician" to "nurse practitioner" WOPD FOR SPECIFIED DMEPOS ITEMS (5 ELEMENT ORDER) Correction: Corrected typo "SPECIFICIED" to "SPECIFIED" Clarified: Date of written order before date of delivery to include or shipped date PROOF OF DELIVERY (POD) Added: General Medicare DOS rule Added: Two options for DOS utilizing a shipping service REPLACEMENT Correction: Changed "cases" to "case"</p> <p><i>05/03/2018: At this time 21st Century Cures Act applies to new and revised LCDs that restrict coverage, which require comment and notice. This revision is to an article that is not a local coverage determination.</i></p>
12/21/2017	R6	<p>Revision Effective Date: 12/21/2017 PROOF OF DELIVERY: Revised: Description of item being delivered</p> <p>12/21/2017: At this time 21st Century Cures Act applies to new and revised LCDs that restrict coverage, which require comment and notice. This revision is to an article that is not a local coverage determination.</p>
11/20/2017	R5	<p>Revision Effective Date: 11/20/2017 DETAILED WRITTEN ORDERS: Revised: Description of all items ordered GENERAL: Added: Seven (7) year documentation retention direction PROOF OF DELIVERY: Revised: POD shipping date definition for Method 2 PROOF OF DELIVERY REQUIREMENTS FOR RECENTLY ELIGIBLE MEDICARE FFS: Revised: Supplier record information to an "and" from an "or" REPLACEMENT: Revised: updated word "entire" to "entirely"</p> <p>11/16/2017: At this time 21st Century Cures Act applies to new and revised LCDs that restrict coverage, which require comment and notice. This revision is to an article that is not a local coverage determination.</p>

REVISION HISTORY DATE	REVISION HISTORY NUMBER	REVISION HISTORY EXPLANATION
06/01/2017	R4	Revision Effective Date: 06/01/2017 REFILL REQUIREMENTS: Revised: Deleted refill requirements that are policy specific and are currently located in the applicable LCDs
06/01/2017	R3	Revision Effective Date: 06/01/2017 PROOF OF DELIVERY: Revised: Corrects clerical error introduced with 01/01/2017 version. Language reverts to original three methods of delivery found in 04/28/16 version of SDL article.
05/25/2017	R2	Revision Effective Date: 05/25/17 WRITTEN ORDERS PRIOR TO DELIVERY (WOPD) Removed: Requirement for "Standard WOPD" for specific items identified by CMS or DME MACs such as Negative Pressure Wound Therapy (NPWT)
04/20/2017	R1	Revision Effective Date: 04/20/17 NEW ORDER REQUIREMENTS Revised: Change in supplier direction PROOF OF DELIVERY Revised: Proof of Delivery requirements and use of long description of the HCPCS code Previous Revisions 10/31/14; 11/05/15; 04/28/16; 01/01/17 Originally published 02/17/12

Associated Documents

Related Local Coverage Document(s)

N/A

Related National Coverage Document(s)

N/A

Statutory Requirements URL(s)

N/A

Rules and Regulations URL(s)

N/A

CMS Manual Explanations URL(s)

N/A

Other URL(s)

N/A

Public Version(s)

Updated on 03/04/2021 with effective dates 04/06/2020 - N/A

Updated on 03/27/2020 with effective dates 04/06/2020 - N/A

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Keywords

N/A