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

Links in PDF documents are not guaranteed to work. To follow a web link, please use the MCD Website.

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 North Carolina New Mexico Oklahoma Puerto Rico South Carolina Tennessee Texas Virginia Virgin Islands West Virginia
Noridian Healthcare Solutions, LLC	DME MAC	16013 - DME MAC J-A		Connecticut District of Columbia Delaware Massachusetts Maryland Maine New Hampshire New Jersey New York - Entire State Pennsylvania Rhode Island Vermont
Noridian Healthcare Solutions, LLC	DME MAC	19003 - DME MAC J-D		Alaska American Samoa Arizona California - Entire State Guam Hawaii Iowa Idaho Kansas Missouri - Entire State Montana North Dakota Nebraska Nevada

Contractor Name	Contract Type	Contract Number	Jurisdiction	State(s)
				Oregon South Dakota Utah Washington Wyoming Northern Mariana Islands

Back to Top

Article Information

General Information

Article ID
A55426

Article Title
Standard Documentation Requirements for All Claims Submitted to DME MACs

AMA CPT / ADA CDT / AHA NUBC Copyright Statement

Original Article Effective Date
01/01/2017

Revision Effective Date
06/01/2017

Revision Ending Date
N/A

Retirement Date
N/A

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 standardized language 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) 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.

*****IMPORTANT*****

Historically, general documentation requirements have appeared within individual policies (LCDs). Such information will be removed from all DME MAC LCDs whose effective date is on or after Jan 01, 2017. All general documentation requirements will thereafter be located in this Standard Documentation Requirements (SDR) article, which will be linked to all DME MAC LCDs.

Local Coverage Determinations (LCDs) often contain documentation requirements that are unique to that specific policy. These requirements are termed "Policy Specific Documentation Requirements". Historically, these requirements have appeared within individual policies (LCDs). Such information will be removed from all DME MAC LCDs whose effective date is on or after Jan 01, 2017. All Policy Specific Documentation Requirements will thereafter be located in the LCD-related Policy Article, which will be linked to the applicable LCD.

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

Note: This is a revision to the previous article published in May 2017 under the title "Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426)". 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.

PRESCRIPTION (ORDER) REQUIREMENTS

GENERAL

All claims for items billed to Medicare require a prescription (order). "All claims" refers to all claims submitted for payment of purchases and initial rentals by Medicare Part B.

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

An order for each item billed must be signed and dated by the prescribing physician. Items dispensed and/or billed that do not meet these prescription requirements and those below must be submitted with an EY modifier added to each affected HCPCS code.

The term "physician" is used throughout this document and except where specifically noted, refers to Doctor of Medicine (MD), Doctor of Osteopathy (DO), Doctor of Optometry (OD), Doctor of Medical Dentistry (DMD), Doctor of Dental Surgery (DDS), Doctor of Podiatric Medicine (DPM), physician assistants (PA), nurse physicians (NP) and clinical nurse specialists (CNS). Prescribing of DMEPOS is limited by Medicare regulations and by the treating physician's respective scope of practice as determined by the state wherein they practice. Chiropractors are not permitted to prescribe DMEPOS items.

The term "treating physician" is defined as the one who is directly providing care to the beneficiary for the condition(s) related to the DMEPOS ordered.

Signature and date stamps are not allowed. Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4.

NEW ORDER REQUIREMENTS

A new prescription (order) is required:

- For all claims for purchases or initial rentals

- If there is a change in the order for the accessory, supply, drug, etc.

- On a regular basis (even if there is no change in the order) only if it is so specified in the documentation section of a particular medical policy

- When an item is replaced

- When there is a change in the supplier, and the new supplier is unable to obtain a copy of a valid order and documentation from the original supplier.

DISPENSING ORDERS

Most equipment and supplies may be delivered upon receipt of a dispensing order. A dispensing order may be verbal or written. The dispensing order must contain:

- Description of the item

- Beneficiary's name

- Prescribing physician's name

- Date of the order

- Prescribing physician's signature (if a written order) or supplier signature (if verbal order)

For the "Date of the order" described above, use the date the supplier is contacted by the prescribing physician for verbal orders or the date entered by the prescribing physician for written dispensing orders.

In some cases, the prescribing physician may specify a future start date for therapy that is different from the date of the order. This start date does not impact the date of the order, date of service (DOS) entered on the claim, Medicare-required forms (e.g., Certificate of Medical Necessity (CMN), DME Information Form (DIF)) or refill/delivery timelines. As long as the supplier has a properly completed dispensing order with a correctly determined prescription date, an item may be shipped or delivered on or after the date of the dispensing order (except for items that require written orders prior to delivery).

Some dispensing orders are required by statute and/or CMS regulations, to have specific elements and other requirements, which are described in subsequent sections below.

For items that are delivered based on a dispensing order, the supplier must obtain a detailed written order (DWO)

before submitting a claim.

DETAILED WRITTEN ORDERS (DWO)

A DWO is required before billing. Someone other than the physician may complete the DWO of the item unless statute, manual instructions, the contractor's LCD or policy articles specify otherwise. However, the prescribing physician must review the content and sign and date the document. It must contain:

- Beneficiary's name
- Prescribing physician's name
- Date of the order
- Detailed description of the item(s) (see below for specific requirements for selected items)
- Prescribing physician's signature
- Signature date, if applicable (see below)

For items provided on a periodic basis, including drugs, the written order must include:

- Item(s) to be dispensed
- Dosage or concentration, if applicable
- Route of Administration, if applicable
- Frequency of use
- Duration of infusion, if applicable
- Quantity to be dispensed

- Number of refills

For the "Date of the order" described above, use the dispensing order date i.e., the date the supplier was contacted by the prescribing physician (for verbal orders) or the date entered by the prescribing physician (for written dispensing orders).

Additional order date instructions:

- If the prescriber creates the DWO, only a single date - the "order date" - is required. This order date may be the date that the prescriber signs the document.

- If someone other than the prescriber (e.g., DME supplier) creates the DWO then the prescription must be reviewed and, "…personally signed and dated…" by the prescriber. In this scenario, two dates are required: an "order date" and a prescriber-entered "signature date".

In some cases, the prescribing physician may specify a future start date for therapy that is different from the date of the order. This start date does not impact the date of the order, DOS entered on the claim, Medicare-required forms (e.g., CMN, DIF) or refill/delivery timelines. As long as the supplier has a properly completed dispensing order with a correctly determined prescription date, an item may be shipped or delivered on or after the date of the dispensing order (except for items that require written order prior to delivery).

Frequency of use information on orders must contain detailed instructions for use and specific amounts to be dispensed. Reimbursement shall be based on the specific utilization amount only. Orders that only state "PRN" or "as needed" utilization estimates for replacement frequency, use, or consumption are not sufficient to justify payment.

The detailed description in the written order may be either a narrative description or a brand name/model number.

WRITTEN ORDERS PRIOR TO DELIVERY (WOPD)

GENERAL

Someone other than the prescribing physician may complete the WOPD of the item unless statute, manual instructions, the contractor's LCD or policy articles specify otherwise. However, the WOPD must be both signed and dated by the prescribing physician before the item is dispensed. The supplier must have received the WOPD before dispensing the item. The date of the written order shall be on or before the date of delivery. The DMEPOS supplier shall have on file the completed written order prior to the delivery of these items.

For base items that require a WOPD, the supplier must also obtain a DWO before submitting a claim for any associated options, accessories, and/or supplies that are separately billed.

There are two categories of DMEPOS items that require a WOPD:

- As a condition of payment pursuant to 42 CFR 410.38(c), Power Mobility Devices (PMDs) require a 7 Element Order (7EO). A separate Detailed Product Description (DPD) is also required for any associated options and accessories. Please review the PMD policy for additional information.

- As a condition of payment pursuant to 42 CFR 410.38(g), certain specified covered items of DME require a written order prior to delivery of the item (5 Element Order or 5EO).

POWER MOBILITY DEVICES WOPD (7 ELEMENT ORDER)

42 CFR 410.38(c) requires a specific WOPD of PMDs for the HCPCS codes specified in the table contained in the

POLICY SPECIFIC DOCUMENTATION REQUIREMENTS section of the LCD related Policy Article. The required prescription has seven (7) mandatory elements. For the purposes of this document, the 42 CFR 410.38(c) required order is referred to as a 7EO.

The 7EO must be received by the supplier within 45 days after the completion of the face-to-face examination.

The 7EO must meet all of the requirements below:

- Beneficiary's name
- Description of the item that is ordered. This may be general – e.g., "power operated vehicle", "power wheelchair", or "power mobility device"– or may be more specific.
- Date of the face-to-face examination
- Pertinent diagnoses/conditions that relate to the need for the POV or power wheelchair
- Length of need
- Prescribing physician's signature
- Date of prescribing physician's signature

The Supplier may provide a template order listing the seven required elements but is prohibited from completing any part of it. The treating physician completing the face-to-face requirements must write the 7EO. The 7EO may only be written after the completion of the face-to-face exam requirements.

The DMEPOS supplier shall have on file the 7EO prior to the delivery of these items. A date stamp or equivalent must be used by the supplier to document receipt date.

POWER MOBILITY DEVICES DETAILED PRODUCT DESCRIPTION

Once the supplier has determined the specific power mobility device that is appropriate for the beneficiary based on the physician's 7EO, the supplier must prepare a written document (termed a DPD). This DPD must comply with the requirements for a DWO (See section above).

The physician must sign and date the DPD, and the supplier must receive it prior to delivery of the PMD.

Signatures must comply with the CMS signature requirements outlined in PIM 3.3.2.4. Signature and date stamps are not allowed.

A date stamp or equivalent must be used to document the supplier receipt date of the DPD.

WOPD FOR SPECIFICIED DMEPOS ITEMS (5 ELEMENT ORDER)

42 CFR 410.38(g) requires a specific written order prior to delivery for specified HCPCS codes. CMS provides a list of the specified codes, which is periodically updated, and located here on CMS's website.

The required prescription has five (5) mandatory elements. For the purposes of this document, the 42 CFR 410.38(g) required order is referred to as a 5EO. The 5EO must meet all of the requirements below:

- The 5EO must include all of the following elements:
    - Beneficiary's name
    - Item of DME ordered - this may be general – e.g., "hospital bed"– or may be more specific.
    - Signature of the prescribing practitioner
    - Prescribing practitioner's NPI
    - The date of the order
- The 5EO must be completed within six (6) months after the required face-to-face examination
- The date of the written order shall be on or before the date of delivery

The DMEPOS supplier shall have on file the 5EO prior to the delivery of these items.

Note that the 5EO for these specified DME items require the NPI to be included on the prescription. Prescriptions for other DME items do not have this NPI requirement. Suppliers should pay particular attention to orders that include a mix of items, some of which are subject to these new order requirements. For example, oxygen concentrators (E1390) are often ordered in conjunction with portable oxygen (E0431). Orders for code E0431 require inclusion of the NPI while orders for E1390 do not.

Suppliers should pay particular attention to orders that include a mix of items to which 42 CFR 410.38(g) does and does not apply, to assure that these 42 CFR 410.38(g) order requirements are met.

All other date and timing requirements specified in the CMS PIM regarding specific items or services remain unchanged.

Upon request by a contractor, all DMEPOS suppliers must provide documentation of the completed 5EO.

For items that are provided based on a 5EO, the supplier must obtain a detailed written order (see DETAILED WRITTEN ORDER section above) before submitting a claim for any associated options, accessories and/or supplies that are separately billed.

DOCUMENTATION REQUIREMENTS

GENERAL

There are numerous CMS manual requirements, reasonable and necessary (R&N) requirements, benefit category, and other statutory and regulatory requirements that must be met in order for payment to be justified. In the

event of a claim review, a DMEPOS supplier must provide sufficient information to demonstrate that the applicable criteria have been met thus justifying payment.

Before submitting a claim to Medicare, the DME MAC supplier must have on file a dispensing order (if applicable), a DWO, a WOPD (if applicable), a CMN (if applicable), a DIF (if applicable), information from the treating physician concerning the patient's diagnosis, and any information required for the use of specific modifiers or attestation statements as defined in certain DME MAC policies. The supplier should also obtain as much documentation from the patient's medical record 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.

REASONABLE AND NECESSARY CRITERIA (R&N)

CMS NCD and contractor LCD 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 physician’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 prescribing physician, 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 by the treating physician for refills

- A recent change in prescription

- A properly completed CMN or DIF with an appropriate length of need specified

- Timely documentation in the beneficiary's medical record showing usage of the item

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

CONTINUED USE

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

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

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

- Timely documentation in the beneficiary's medical record showing usage of the item, related option/accessories and supplies.

- Supplier records documenting the request for refill/replacement of supplies in compliance with the REFILL DOCUMENTATION REQUIREMENTS section. This is deemed sufficient to document continued use for the base item, as well.

- Supplier records documenting beneficiary confirmation of continued use of a rental item.

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

REFILL DOCUMENTATION

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 proof of delivery 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 date of service).

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. There must be a sufficient level of detail in the item description to definitively determine the appropriate HCPCS to be appended to the claim. The long description of the HCPCS code, may be used as a means to provide a detailed description of the item being delivered.

Proof of delivery documentation must be available to the Medicare contractor on request. All services that do not have appropriate proof of delivery from the supplier will be denied and overpayments will be requested. Suppliers who consistently 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.

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
- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description). The long description of the HCPCS code, may be used as a means to provide a detailed description of the item being delivered
- 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 date of service.

In instances where the supplies are delivered directly by the supplier, the date the beneficiary received the DMEPOS supply must be the date of service 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

- Sufficiently detailed description to identify the item(s) being delivered (e.g., brand name, serial number, narrative description). The long description of the HCPCS code, may be used as a means to provide a detailed description of the item being delivered

- Quantity delivered

- Date delivered

- Evidence of delivery

If a supplier utilizes a shipping service or mail order, suppliers must use the shipping date as the date of service on the claim.

Suppliers may also utilize a return postage-paid delivery invoice from the beneficiary or designee as a 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 CMS Internet Only Manual (IOM), Publication 100-08, PIM, 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 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, "Durable Medical Equipment Coding System (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.

For questions about correct coding, contact the PDAC Contact Center at (877) 735-1326 during the hours of 8:30 a.m. to 4 p.m. CT, Monday through Friday, or e-mail the PDAC by completing the DME PDAC Contact Form located on the PDAC website.

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 date of service 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; or

- Notation in the supplier's records that a supplier staff member examined the item in the beneficiary's possession and confirmed it is in good working order.

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., date of service) serves as the start date of the reasonable useful lifetime and period of continuous use. In these cases, the proof of delivery documentation serves as evidence that the beneficiary is already in possession of the item.

FACE-TO-FACE EXAMINATION FOR SPECIFIED DMEPOS ITEMS

42 CFR 410.38(g) contains provisions that are applicable to certain specified DMEPOS items. CMS provides a list of the specified items, which is periodically updated, and located here on CMS' website.

These items require an in-person, face-to-face interaction between the beneficiary and their treating physician prior to prescribing the item. This face-to-face requirement includes examinations conducted via the CMS-approved use of telehealth examinations (as described in Chapter 15 of the Medicare Benefit Policy Manual and Chapter 12 of the Medicare Claims Processing Manual - CMS Internet-Only Manuals, Publ. 100-02 and 100-04, respectively). This face-to-face evaluation must specifically document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered. A dispensing order is not sufficient to provide these items. A 5EO (see 5EO section above) must be received prior to delivery. Refer to the applicable LCD-related Policy Article NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section for information about these statutory requirements.

FACE-TO-FACE REQUIREMENTS

As a condition for payment, 42 CFR 410.38(g) requires that a treating physician has had a face-to-face examination with a beneficiary within the six (6) months prior to the written order for certain items of DME.

For the treating physician prescribing a specified DME item:

- The face-to-face examination with the beneficiary must be conducted within the six (6) months prior to the date of the prescription.

- The face-to-face examination must document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item(s) of DME ordered.

Remember that all other Medicare coverage and documentation requirements for DMEPOS also apply. 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.

The treating physician that conducted the face-to-face examination does not need to be the prescriber for the DME item; however, the prescriber must:

- Verify that the qualifying in-person visit occurred within the 6-months prior to the date of their prescription; and,

- Have documentation of the qualifying face-to-face examination that was conducted.

A new face-to-face examination is required each time a new prescription for one of the specified items is ordered (see GENERAL PRESCRIPTION REQUIREMENTS section above for new prescription requirements).

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

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

A CMN, which has been completed, signed, and dated by the treating physician, must be kept on file by the supplier and made available upon request. The CMN may act as a substitute for the detailed written order if it contains the same information as required in a detailed written order. The CMN for XXX is CMS Form ### (DME form ###). In addition to the order information that the treating physician 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 physician can enter the other details directly.

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

DME INFORMATION FORM (PIM 5.3)

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 ###).

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 CMS Benefit Policy Manual (Internet-only manual 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 physician'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 physician must document that the DMEPOS item being repaired continues to be reasonable and necessary (see Continued Medical Need section above); and,

- Either the treating physician 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 CMS Benefit Policy Manual (Internet-only manual 100-02), Chapter 15, Section 110.2.C. That section generally defines replacement as the provision of an entire 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 cases 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 physician'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 physician 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 physician's order and documentation supporting the reason for the replacement. The reason for replacement must be documented by the treating physician, 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 PIM 3.3.2.4.

Back to Top

Coding Information

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 article does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the article 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 article, 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 article should be assumed to apply equally to all Revenue Codes.

N/A

CPT/HCPCS Codes N/A
ICD-10 Codes that are Covered N/A

ICD-10 Codes that are Not Covered N/A
Back to Top

Revision History Information

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

Back to Top **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 06/02/2017 with effective dates 06/01/2017 - N/A Updated on 05/26/2017 with effective dates 06/01/2017 - N/A Updated on 05/18/2017 with effective dates 05/25/2017 - N/A Updated on 04/12/2017 with effective dates 04/20/2017 - N/A Updated on 03/03/2017 with effective dates 01/01/2017 - N/A
Back to Top

Keywords

N/A Read the **Article Disclaimer** Back to Top