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# Documentation Requirements for Prescribers of DMEPOS

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# Agenda

- Documentation Overview
- Orders & CMNs
- Continued Use and Need Documentation
- Common Documentation Issues for Specific Items
- Provider Outreach and Education

# Acronyms

- ACA – Affordable Care Act
- CMN – Certificate of Medical Necessity
- DME – Durable Medical Equipment
- DMEPOS – Durable Medical Equipment, Prosthetics, Orthotics, and Supplies
- WOPD – Written Order Prior to Delivery

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# Documentation Overview

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# DMEPOS Suppliers Need Your Help

- DMEPOS suppliers are your partners in caring for your patient.
- They will not receive payment from Medicare for the items that are ordered if you do not provide information from your medical records when it is requested.
- Furthermore, not providing this information may result in your patients having to pay for the item themselves.

# HIPAA Privacy Rules

- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule permits disclosure of protected health information without beneficiary authorization to carry out treatment, payment or health care operations.
- The DME MAC, UPIC and CERT perform health care operations as agents of the Centers for Medicare and Medicaid Services (CMS). Providing the requested documentation is in keeping with the HIPAA Privacy Rule.
- Help your DMEPOS supplier continue to provide good service to your patients by promptly providing the information from your medical records that is requested.

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# Principles of Documentation

- Reasonable documentation that services are consistent with Medicare coverage is required, upon request, in order to validate:
  - **The site of service;**
  - **The medical necessity and appropriateness of the supplies, equipment, and services provided; and/or**
  - **That items furnished have been accurately reported.**
- All documentation must be maintained for seven years and be available upon request.

# Documentation in the Beneficiary's Medical Record

- Should substantiate the medical necessity for the item and quantity ordered and frequency of use.

- Should include (but not limited to):
  - **Beneficiary's diagnosis**
  - **Duration of condition**
  - **Clinical course**
  - **Prognosis**
  - **Functional limitations**
  - **Past experience with related items**

- Supplier-produced records are deemed not part of the medical record for Medicare payment purposes.

- Certificates of Medical Necessity (CMN), DME Information Forms (DIF), supplier prepared statements and physician attestations by themselves do NOT provide sufficient documentation of medical necessity, even if signed by the ordering physician.

# Amendments and Corrections to Medical Records

- In all cases, regardless of whether the documentation is maintained or submitted in paper or electronic form, any medical records that contain **amendments, corrections, or addenda** must:
  - **Clearly and permanently identify any amendment, correction or delayed entry as such, and**
  - **Clearly indicate the date and author of any amendment, correction, or delayed entry, and**
  - **Not delete, but instead, clearly identify all original content.**

# Handwritten Signatures

- Illegible signature – may use a signature log or attestation statement
- If the signature is missing from an order, MACs and CERT **shall disregard the order** during the review of the claim (e.g., the reviewer will proceed as if the order was not received).
- If the signature is missing from any other medical documentation (other than an order), MACs and CERT shall accept a signature attestation from the author of the medical record entry.

# Electronic Signatures

- An electronic signature is part of an electronic record and must be executed by the person who performs the service.
- Some examples of acceptable notations of electronic signatures (not all inclusive list):
  - **Electronically signed by**
  - **Authenticated by**
  - **Approved by**
  - **Completed by**
  - **Finalized by**
  - **Signed by**
  - **Validated by**

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# Order Requirements

## Dispensing, Written Order Prior to Delivery, and Detailed Written Order

# Who Can Order DMEPOS?

- Physician (MD or DO)
- Nurse Practitioner (NP)
- Clinical Nurse Specialist (CNS)
- Physician Assistant (PA)
- Podiatrist (DPM) (for certain DMEPOS items based on licensure)

# Orders

- Dispensing Order
  - **Items not on the ACA 6407 list or Power Mobility Devices (PMDs)**
- Detailed Written Orders
  - **Any item provided based on a dispensing order MUST have a complete DWO prior to claim submission**
- Written Orders Prior to Delivery
  - **5 Element Order (5EO)**
    - Any item on the ACA 6407 list
  - **7 Element Order (7EO)**
    - Power Mobility Devices
      - **Power Wheelchairs (PWC) or Power Operated Vehicles (POV)**
      - **Detailed Product Description (DPD)also required prior to delivery**

# Dispensing Order

- Most equipment and supplies may be delivered upon receipt of a dispensing order
- A dispensing order may be verbal or written
- Must be obtained prior to dispensing an item to beneficiary
- Must include:
  - Description of the item
  - Beneficiary's name
  - Prescribing practitioner's name
  - Date of the order
  - Prescribing practitioner's signature (written order) or supplier signature (verbal order)
- **The supplier must obtain a Detailed Written Order (DWO) before submitting a claim**

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# Detailed Written Orders

Required Elements:

- Beneficiary's name
- Date of the order
- A description of all items, options, accessories or additional features that are separately billed or require an upgraded code. 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 supplies – list all supplies that are separately billable, and for each include the frequency of use (if applicable), and the quantity dispensed
- Prescribing physician/practitioner's signature (and date if applicable)

# Detailed Written Orders for Drugs

- For drugs used as a supply for a DME item, the written order must include:
  - **Beneficiary name**
  - **The name of the drug**
  - **Dosage or concentration (if applicable)**
  - **Frequency of administration (if applicable)**
  - **Duration of infusion (if applicable)**
  - **Quantity to be dispensed**
  - **Number of refills**
  - **Date of the order**
  - **Physician/practitioner's signature**

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# Written Orders Prior to Delivery

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

- Power Mobility Devices (PMDs) require a 7 Element Order (7EO)
  - **A separate Detailed Product Description (DPD) is required for any associated options and accessories**
- Certain specified covered items of DME require a 5 Element Order (5EO)
  - **Items associated with ACA6407**
  - **https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring- Programs/Medicare-FFS-Compliance-Programs/Medical-Review/FacetoFaceEncounterRequirementforCertainDurableMedicalEquipment.html**
  - **A separate Detailed Written Order (DWO) is required for any associated options and accessories**

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# 7-Element Order Requirements

- A 7-Element Order prior to delivery is required for all PMDs and it must include the following information:
  - **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 completion of the face-to-face examination**
  - **Pertinent diagnoses/conditions that relate to the need for the power mobility device**
  - **Length of need**
  - **Physician's signature**
  - **Signature date**

# Face-to-Face Examination: Date Scenarios for 7EO

| Event | Face-to-Face Date Is |
|---|---|
| Physician sees beneficiary and conducts exam | Date on Progress Note/Exam |
| Physician sees beneficiary, refers beneficiary to LCMP for evaluation then receives, reviews, dates and signs LCMP exam without seeing beneficiary a 2nd time | Date physician signs the LCMP's exam |
| Physician sees beneficiary, refers beneficiary to LCMP for evaluation, receives and reviews LCMP exam then sees beneficiary a 2nd time | Date of 2nd physician visit |
| Physician refers beneficiary to LCMP for evaluation, receives and reviews exam, sees beneficiary | Date physician sees the beneficiary |
| Exam performed while beneficiary is in hospital or SNF | Date of discharge |

# Detailed Product Description

- Must comply with Detailed Written Order Requirements:
  - **The description can be either a narrative description (e.g., lightweight wheelchair base), a HCPCS code, a HCPCS code narrative, or a brand name/model number and all options and accessories that will be separately billed to Medicare.**
  - **Date of the Order**
  - **Beneficiary's name**
  - **Prescriber's name**
  - **Prescriber's signature and signature date**
  - **NPI of the ordering physician for some accessories (Section 6407 ACA)**

# 5 Element Order (5EO) for ACA 6407

- The 5EO must include all of the following elements:
  - **Beneficiary's name**
  - **Item of DME ordered - this may be general or specific**
  - **Signature of the prescribing practitioner**
  - **Prescribing practitioner's National Practitioner Identifier (NPI)**
  - **The date of the order**
- Must be completed within six (6) months after the required ACA 6407 face- to-face examination; and
- Must be received by the supplier before delivery
  - **The physician’s signature date is acceptable to document receipt prior to delivery**

# Face-to-Face Examination for ACA 6407

- As a condition for payment, Section 6407 of the Affordable Care Act requires the treating physician, has had a face-to-face encounter examination with a beneficiary within the six months prior to the written order for certain items of DME.
- Who may conduct the FTF exam:
  - **The treating practitioner 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 in-person visit occurred within the 6-months prior to the date of their rescription, and
    - Have documentation of the face-to-face examination that was conducted.

# Documentation of Face to Face Examination

- There must be documentation of a face to face encounter between the beneficiary and ordering practitioner that occurred within six (6) months prior to completion of the written order.
- The notes of the face to face encounter record that the encounter occurred specifically to document that the beneficiary was evaluated and/or treated for a condition that supports the need for the item.
- All Medicare coverage and documentation requirements also apply. There must be sufficient medical information included in the record to demonstrate applicable coverage criteria as outlined in the applicable LCD.

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# Face to Face Examination

Commonly ordered items with exceptions to FTF timing

- The LCD requirements for FTF evaluations supersede the ACA requirements
- Be sure to review the LCD to ensure timely evaluations

| Policy | Face to Face Requirement |
|---|---|
| Oxygen | Must be **within 30 days** prior to the date of initial certification |
| PAP | ***Prior to the sleep test***, which assessed the beneficiary for obstructive sleep apnea (OSA) |
| PMD | The supplier must receive the 7EO within 45 days after completion of the face-to-face examination |

# Requirements of New Orders

- New order is required when:
  - **Initial purchase or rental**
  - **Change in the order for the accessory, supply, drug, etc.**
  - **On a regular basis only when specified by a particular medical policy**
  - **When an item is replaced**
  - **When there is a change in the supplier, if the recipient supplier is unable to obtain a copy of a valid order and documentation for the DMEPOS item from the original supplier**

# Certificate of Medical Necessity (CMN)

- Required for:
  - **Oxygen**
  - **Pneumatic Compression Devices**
  - **Osteogenesis stimulators**
  - **TENS (purchase only)**
  - **Seat lift mechanisms**
- May serve as the detailed written order if Section C sufficiently detailed
- If no original, faxed or photocopied in records before the claim is filed, the claim will be denied

# CMN Reminders

- Section A: (Supplier)
  - **Initial date is date ordered or date delivered, establishes date of medical need**
  - **Revision dates do not affect recertification dates**
  - **Place of service is where equipment is being used**
- Section B: (Physician)
  - **Include name, title and employer if someone other than the prescribing practitioner completes**
  - **Indicate “D” if question does not apply to the condition of the beneficiary**
  - **Report diagnosis codes**

# CMN Reminders

- Section C: (Supplier)
  - **Include narrative description of all items provided**
  - **Report supplier's charge and Medicare fee schedule allowance for each item**
  - **Complete before submitting to prescribing practitioner**
- Section D: (Physician)
  - **Physician, CNS, NP, or PA can sign**
  - **Signature stamps are not acceptable**

Note: The NP, CNS, or PA may complete Section B and sign Section D of the CMN.

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# Continued Use and Need Documentation

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# Initial Need Documentation

- Initial justification for medical need is established at the time items are first ordered
- Medical records demonstrating the items are reasonable and necessary are created just prior to, or at the time of, the creation of the initial prescription

# Continued Need

- In addition to initial justification documentation, for ongoing supplies and rental DME items, there must be information in the medical record to support items continue to remain reasonable and necessary
- Information used to justify continued medical need must be timely for the date of service under review

# Continued Need Documentation

- Any of the following may serve as documentation justifying continued medical need:
  - **A recent order by the treating practitioner for refills**
  - **A recent change in prescription**
  - **A properly completed CMN or DIF with an appropriate length of need specified**
  - **Timely documentation in the medical record showing usage of items**
- Timely documentation is a record in the preceding 12 months unless otherwise specified in the applicable policy

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# CERT Common Documentation Errors for Specific Items

# Lower Limb Prostheses Common CERT Denials

- No physician documentation to support amputation
- No documentation to support functional level

# Lower Limb Prostheses Coverage

- A lower limb prosthesis is covered when the beneficiary will reach or maintain a defined functional state within a reasonable period of time and is motivated to ambulate.
- A determination of the medical necessity for certain components/additions to the prosthesis is based on the beneficiary's potential functional abilities
- Potential functional ability is based on the reasonable expectations of the prosthesis, and treating physician, considering factors including, but not limited to:
  - **The beneficiary's past history (including prior prosthetic use if applicable); and**
  - **The beneficiary's current condition including the status of the residual limb and the nature of other medical problems; and**
  - **The beneficiary's desire to ambulate**

# Documentation of Knee Instability for Certain Knee Braces

- No documentation of knee instability (knee braces)
- Knee instability must be documented by:
  - **Examination of the beneficiary; and,**
  - **Objective description of joint laxity (e.g., varus/valgus instability, anterior/posterior Drawer test).**
- Claims will be denied as not reasonable and necessary when the beneficiary does not meet the above criteria for coverage.
  - **For example, they will be denied if only pain or a subjective description of joint instability is documented.**

# Therapeutic Shoes for Persons with Diabetes: Physician Roles

| Certifying Physician | Prescribing Physician |
|---|---|
| Responsible for diagnosing and treating the beneficiary's diabetic systemic condition through a comprehensive plan of care<br>▪ MUST be an M.D. or D.O.<br>▪ May not furnish footwear unless he/she practices in a defined rural area<br>▪ Complete the Statement of Certifying Physician | Writes the order for the therapeutic shoes, modifications and inserts<br>▪ May be a Podiatrist, M.D., D.O., P.A., Nurse Practitioner, or a Clinical Nurse Specialist<br>▪ Must be knowledgeable in fitting diabetic shoes and inserts<br>▪ Can be the supplier |

# Documentation of the Foot Exam for Diabetic Shoes

- Certifying physician has documented in the beneficiary's medical record
  - **One or more of the following conditions:**
  - **Previous amputation of the other foot, or part of either foot**
  - **History of previous foot ulceration on either foot**
  - **History of pre-ulcerative calluses of either foot**
  - **Peripheral neuropathy with evidence of callus formation of either foot**
  - **Foot deformity of either foot**
  - **Poor circulation in either foot**

# Statement of Certifying Physician

- Certifying physician has certified that the beneficiary has diabetes mellitus, one of the covered foot conditions, and that they are treating the beneficiary for their diabetes and that the beneficiary needs diabetic shoes
  - **Have an in-person visit with the beneficiary during which diabetes management is addressed within 6 months prior to delivery of the shoes/inserts; and**
  - **Sign the certification statement on or after the date of the in-person visit and within 3 months prior to delivery of the shoes/inserts**

# Medical Records for Diabetic Shoe Coverage

- Beneficiary's medical record from the Certifying Physician must:
  - **Document management of the beneficiary's diabetes**
  - **Document detailed information about the condition that qualifies the beneficiary for coverage (2a-2f listed in related policy article)**
- The Statement of Certifying Physician by itself does NOT meet this requirement for documentation in the medical record

# Common Denial for PMD Claims

- Error: The face-to-face examination does not demonstrate the beneficiary's upper extremity function is insufficient to self-propel an optimally-configured manual wheelchair in the home.

- Error: The face-to-face examination does not demonstrate the use of a power operated vehicle has been excluded.

# F2F for PMD Documentation – Upper Extremity Function

Documentation must verify:

- The beneficiary does not have sufficient upper extremity function to self- propel an optimally-configured manual wheelchair in the home to perform MRADLs during a typical day.
  - **Limitations of strength, endurance, range of motion, or coordination, presence of pain, or deformity or absence of one or both upper extremities are relevant to the assessment of upper extremity function.**
  - **An optimally-configured manual wheelchair is one with an appropriate wheelbase, device weight, seating options, and other appropriate non-powered accessories.**

# F2F for PMD Documentation – Rule out POV

Documentation must verify:

- The beneficiary does not meet the following coverage for a Power Operative Vehicle
  - **The beneficiary is able to: Safely transfer to and from a POV, operate the tiller steering system, and maintain postural stability and position while operating the POV in the home**
  - **The beneficiary's mental capabilities (e.g., cognition, judgment) and physical capabilities (e.g., vision) are sufficient for safe mobility using a POV in the home.**
  - **The beneficiary's home provides adequate access between rooms, maneuvering space, and surfaces for the operation of the POV that is provided**

# Common Denials for Manual Wheelchair Claims

- Error: The medical record documentation does not support that use of a manual wheelchair will significantly improve the beneficiary's ability to participate in mobility related activities of daily living and the beneficiary will be using it on a regular basis in the home.

- Error: The medical records do not document that the beneficiary either has sufficient upper extremity function and other physical and mental capabilities needed to, in the home during a typical day, safely self-propel the manual wheelchair that is provided or has a caregiver who is available, willing, and able to provide assistance with the wheelchair.

# Documentation for Manual Wheelchairs

Documentation must support:

- Use of a manual wheelchair will significantly improve the beneficiary's ability to participate in mobility-related activities of daily living (MRADLs) and the beneficiary will use it on a regular basis in the home.
- The beneficiary has sufficient upper extremity function and other physical and mental capabilities needed to safely self-propel the manual wheelchair that is provided in the home during a typical day. Limitations of strength, endurance, range of motion, or coordination, presence of pain, or deformity or absence of one or both upper extremities are relevant to the assessment of upper extremity function.

# Common Oxygen Claim Denials

- Documentation does not support the beneficiary has a severe lung disease or hypoxia-related symptoms that might be expected to improve with oxygen therapy.
- If the qualifying blood gas study is not performed during an inpatient hospital stay, the reported test must be performed while the beneficiary is in a chronic stable state – i.e., not during a period of acute illness or an exacerbation of their underlying disease.
- No documentation of alternative treatment measures have been tried or considered and deemed clinically ineffective.

# Oxygen – Documentation of a Severe Lung Disease

- The NCD for oxygen does not have an approved diagnosis list for oxygen coverage
- There has to be a specific disease that affects the lungs and/or oxygen levels in the blood
- Hypoxia is the result of a disease but is not an actual diagnosis
- The NCD for oxygen lists examples of what would be considered acceptable for "hypoxia-related symptoms or findings that might be expected to improve with oxygen therapy"
  - **The examples provided include pulmonary hypertension, recurring congestive heart failure due to chronic cor pulmonale, erythrocytosis, impairment of the cognitive process, nocturnal restlessness, and morning headaches**

# Oxygen – Documentation Testing In a Chronic Stable State

- The beneficiary needs to exhibit significant hypoxemia while in a chronic stable state and not during a period of acute illness or exacerbation of the underlying disease.
- Not in the emergency room of a hospital for a condition impacting the beneficiary's pulmonary function.
- Medicare requires the beneficiary have a severe, underlying chronic lung disease (i.e., COPD or diffuse interstitial lung disease). The policy has no mention of pneumonia or an undefined hypoxia. Medicare expects medical records to show the underlying cause of a diagnosis of hypoxia or hypoxemia.

# Oxygen Alternative Treatment Measures – Insufficient Documentation

- Missing medical records to verify that standard treatment regimen associated with the disease condition producing the hypoxia-related symptoms was tried or considered and deemed clinically ineffective
  - **Each beneficiary must receive optimum therapy before long-term home oxygen therapy is ordered. Medical documentation must indicate that other forms of treatment (e.g., medical and physical therapy directed at secretions, bronchospasm and infection) have been tried, have not been sufficiently successful, and oxygen therapy is still required**

# Oxygen Alternative Treatment Measures Documentation

- Documentation should indicate how the condition is being treated or managed.
  - **If the main diagnosis is COPD, what steps have previously been taken to help the beneficiary?**
  - **Have inhalation medications and nebulizer treatments for inhalers been prescribed but they no longer help the beneficiary?**

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# Physician Resources

- Dear Physician Letters – Documentation Requirements
  - https://cgsmedicare.com/jc/mr/doc_req.html
- Physician's Corner
  - https://cgsmedicare.com/jc/mr/phys_corner.html
  - **"Physicians! Are You Ordering..." Articles**
  - **Resources for Physicians that Order Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)**
  - **MD Corner**

# Summary

- There is a strong relationship between the physician and the DME supplier as advocates for beneficiary care.
- This information was presented to provide a brief overview of the DME documentation requirements for suppliers based on IOM, NCD and LCD requirements and guidelines.
- There are six entities that may audit a DME supplier's claims. These auditing entities (both pre-pay and post-pay) usually request medical records, dispensing orders, detailed written orders, delivery information, and other documentation required per the LCD that support the claim billed to the Medicare program.

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# Questions?