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Documentation Requirements for Prescribers of DMEPOS

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Jurisdiction C

Agenda

- Documentation Overview
- Orders
- CMNs and DIFs
- Continued Use and Need Documentation
- Common Documentation Issues for Specific Items

Acronyms

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

Documentation Overview

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.

Documentation Requirements

- Before billing to the DME MAC, the supplier will likely have the following:
  - Dispensing Order, 7 Element Order, or 5 Element Order (when applicable)
  - Detailed Written Order (DWO)
  - Certificate of Medical Necessity (CMN) (when applicable)
  - DME MAC Information form (DIF) (when applicable)
  - Beneficiary Authorization
  - Proof of Delivery
  - Advance Beneficiary Notice of Noncoverage (ABN) (where applicable)
  - Information required for use of specific modifiers
  - Clinical documentation to support medical need and continued use of the item

Documentation in the Beneficiary's Medical Record

- Practitioner's orders, CMNs, supplier-prepared statements, letters of medical necessity, or practitioner attestation statements by themselves do not provide sufficient documentation of medical necessity.
- Information to support medical necessity and to substantiate answers on the CMN, DIF, orders or supplier prepared statement must be corroborated in the beneficiary's medical record.

Signature Requirements

- The CMS Internet Only Manual outlines signature requirements for Medicare purposes.
  - "For medical review purposes, Medicare requires that services provided/ordered/certified be authenticated by the persons responsible for the care of the beneficiary in accordance with Medicare's policies. For example, if the physician's authenticated documentation corroborates the nurse's unsigned note, and the physician was the responsible party per Medicare's payment policy, medical reviewers would consider signature requirements to have been met. The method used shall be a handwritten or an electronic signature. Stamp signatures are not acceptable."
  - **CMS Program Integrity Manual 100-8, Chapter 3, Section 3.3.2.4:** https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf

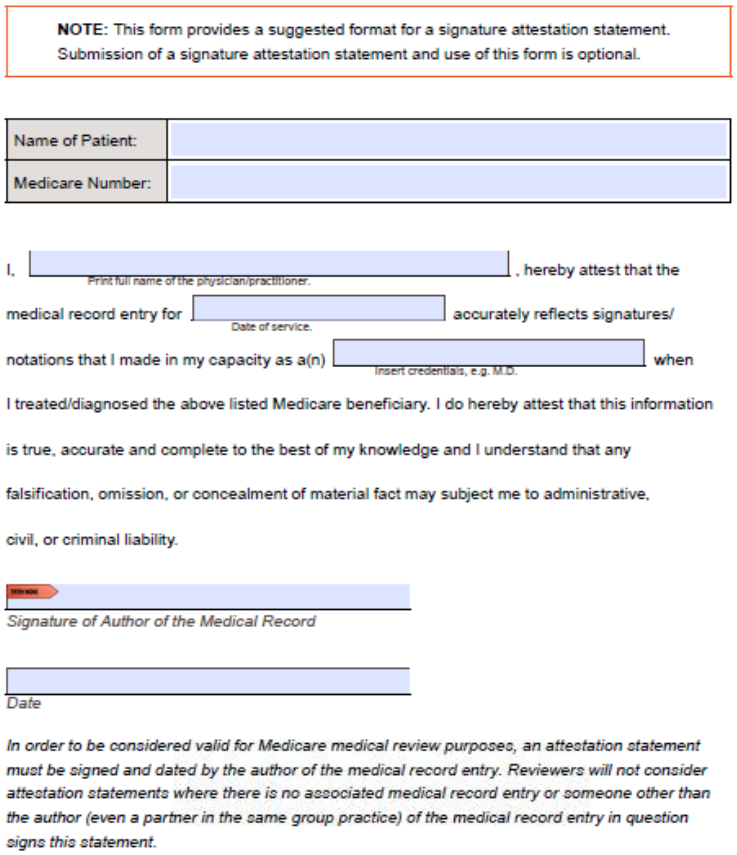
Handwritten Signatures

- 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

Sample Attestation Statement



NOTE: This form provides a suggested format for a signature attestation statement. Submission of a signature attestation statement and use of this form is optional.

Name of Patient:	
Medicare Number:	

I, _____ (Print full name of the physician/practitioner.), hereby attest that the medical record entry for _____ (Date of service.) accurately reflects signatures/ notations that I made in my capacity as a(n) _____ (Insert credentials, e.g. M.D.) when I treated/diagnosed the above listed Medicare beneficiary. I do hereby attest that this information is true, accurate and complete to the best of my knowledge and I understand that any falsification, omission, or concealment of material fact may subject me to administrative, civil, or criminal liability.

_____
Signature of Author of the Medical Record

_____
Date

In order to be considered valid for Medicare medical review purposes, an attestation statement must be signed and dated by the author of the medical record entry. Reviewers will not consider attestation statements where there is no associated medical record entry or someone other than the author (even a partner in the same group practice) of the medical record entry in question signs this statement.

- Attestation statements may be submitted to authenticate an illegible or missing signature on medical documentation
- Reviewers will consider all attestations that meet CMS requirements regardless of the date the attestation was created, except in cases where the regulations or policy indicate a signature must be in place prior to a given event or given date.

Order Requirements

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

Dispensing Order

- Supplier must obtain prior to dispensing an item to beneficiary
- The dispensing order may be a written or verbal order
- 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)

Written Order Prior to Delivery WOPD

- There are two categories of DMEPOS items that require a Written Order Prior to Delivery (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)
    - 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 at:
      - https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/Downloads/DME_List_of_Specified_Covered_Items_updated_March_26_2015.pdf

7-Element Order Requirements: Power Mobility Devices (PMD)

- **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

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 prescription, 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.

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

Detailed Written Orders

- Beneficiary's name
- Prescribing practitioner's name
- Date of the order
- All items, options or additional features that are separately billed or require an upgraded code. The description can be either a narrative description, a HCPCS code, a HCPCS code narrative, or a brand name/model number
- Prescribing physician or practitioner's signature (and date if applicable)

Detailed Written Orders - Supplies

- Supply items provided on a periodic basis:
  - List all supplies that are separately billable to the Medicare program
  - Description of the supply items (general description, a HCPCS code, a HCPCS narrative or brand name/model number)
  - Frequency of use (i.e., replacement timeframe or number per day)
  - Quantity to be dispensed

Detailed Written Orders - Drugs

- Drugs used as a supply for a DME item:
  - Beneficiary name
  - Name of the drug
  - Dosage or concentration (if applicable)
  - Frequency of administration (if applicable) – NOT “as needed” or “PRN”
  - Duration of infusion (if applicable)
  - Quantity to be dispensed
  - Number of refills
  - Order Date
  - Physician/practitioner’s signature

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 (RUL or during RUL)
  - 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

Certificates of Medical Necessity and DME MAC Information Forms

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

DME MAC Information Forms (DIF)

- Required for:
  - External infusion pumps
  - Parenteral and Enteral nutrition
- Completed by supplier based on physician's orders

Continued Need and Continued Use Documentation

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 Documentation

- 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

Continued Use Documentation

- Describes ongoing utilization of supplies or rental items by beneficiary
- Suppliers responsible for monitoring utilization of DMEPOS rental items and supplies
  - No monitoring of purchased items or capped rental items converted to purchase required
- Discontinue billing when rental items and ongoing supplies are no longer being used
- Beneficiary medical records or supplier records may be used to confirm items continue to be used

Continued Use Documentation

- Any of the following may serve as continued use documentation:
  - Timely documentation in the beneficiary's medical record showing usage of the item, related options/accessories and supplies
  - Supplier records documenting the request for refill/replacement of supplies in compliance with the refill request documentation requirements
  - Supplier records documenting confirmation of continued use of a rental item
- Timely documentation is a record in the preceding 12 months unless otherwise specified in the applicable policy

Common Documentation Issues for Specific Items from the CERT Contractor

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 prosthetist, 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

Orthoses Common CERT Denials – Custom Fabricated

- No documentation to support custom fabricated
  - A custom fabricated orthosis is covered when there is a documented physical characteristic which requires the use of a custom fabricated orthosis instead of a prefabricated orthosis

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 ▪ MUST be an M.D. or D.O. ▪ May not furnish footwear unless he/she practices in a defined rural area ▪ Complete the Statement of Certifying Physician	Writes the order for the therapeutic shoes, modifications and inserts ▪ May be a Podiatrist, M.D., D.O., P.A., Nurse Practitioner, or a Clinical Nurse Specialist ▪ Must be knowledgeable in fitting diabetic shoes and inserts ▪ 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:

a. Previous amputation of the other foot, or part of either foot
b. History of previous foot ulceration on either foot
c. History of pre-ulcerative calluses of either foot
d. Peripheral neuropathy with evidence of callus formation of either foot
e. Foot deformity of either foot
f. 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

- 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.
  - 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

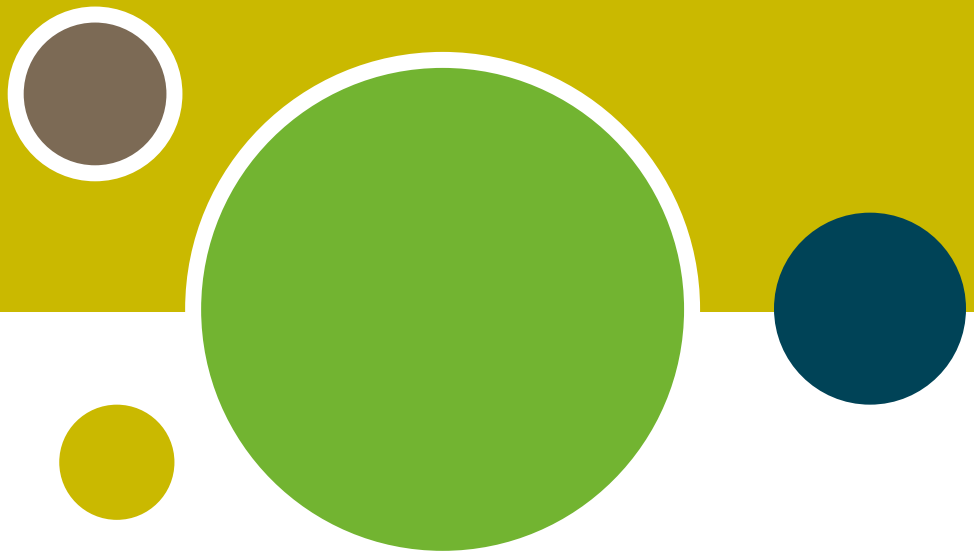
Oxygen Alternative Treatment Measures – Insufficient Documentation

- 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?

SUMMARY



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.

DME MAC Jurisdiction C Resources

Contact and Resources

- Michael Hanna, Provider Outreach, DME MAC Jur C
  - Office: 615.660.5871
  - Email: michael.hanna@cgsadmin.com
- DME MAC Jurisdiction C Website
  - www.cgsmedicare.com/jc
  - Physician's Corner:
  - http://www.cgsmedicare.com/jc/mr/phys_corner.html
    - "Dear Physician" Letters
    - Local Coverage Determinations
    - Medicare Minute MD videos

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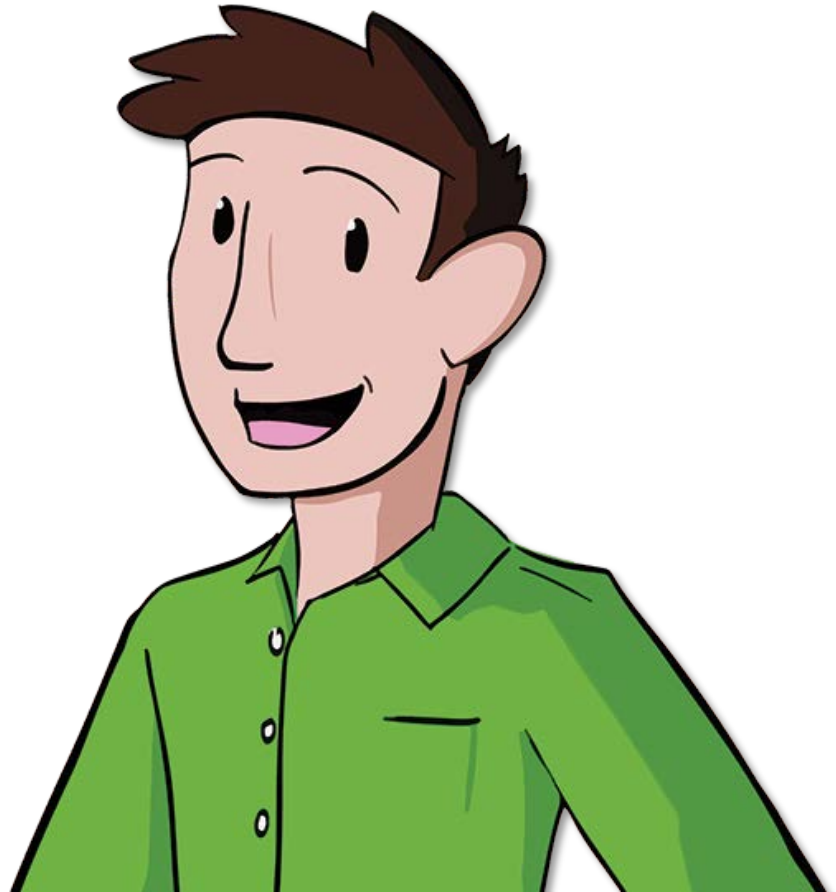

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