

Chapter 4 Contents

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1. Certificates of Medical Necessity (CMNs) and DME MAC Information Forms (DIFs)

CMS Manual System, Pub. 100-04, *Medicare Claims Processing Manual*, Chapter 20, §100.2.1

NOTE: For claims with dates of service on or after January 1, 2023, you no longer need to submit CMNs or DIFs with claims. Due to electronic filing requirements, claims received with these forms attached will be rejected and returned.

For claims with dates of service prior to January 1, 2023, if a CMN or DIF is required, it must be submitted with the claim or be on file with a previous claim.

A Certificate of Medical Necessity (CMN) or DME Information Form (DIF) is required to help document the medical necessity and other coverage criteria for selected durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) items. The documentation section of a Local Coverage Determination (LCD) shows which items require one of these forms. See Chapter 9 of this manual for more information about LCDs.

Only Office of Management and Budget (OMB)-approved, active CMNs that are in use for the date of service on the claim under consideration for reimbursement will be recognized in support of medical need or, when completed properly, as a substitute for a written order. Use of inactive or “retired” CMNs will not be recognized for either medical necessity purposes or as a substitute for a written order.

CMNs contain four sections, A through D. You may complete sections A and C. Sections B and D must be completed by the beneficiary’s physician.

A DIF is a supplier-completed form and used by the DME MAC for claim processing purposes. It does not require a physician signature or a narrative description of equipment and cost. You may complete and sign a DIF in its entirety.

For certain items or services billed to a DME MAC, you must receive a signed CMN from the treating physician. You must have a faxed, photocopied, original signed order or an electronic CMN in your records before you can submit a claim for payment to Medicare. CMNs and DIFs are referred to by their CMS form numbers. The CMS form number is located in the bottom left corner of the form. DME MAC form numbers identify the CMN on electronic claims submitted to the DME MAC.

Signatures must comply with CMS signature requirements. Refer to Chapter 3 of this manual for information about signature requirements.

You must maintain a faxed, photocopied, original signed order or an electronic signed CMN/DIF and it must be available to the DME MACs or Unified Program Integrity Contractors (UPICs) on request. When hardcopy CMNs/DIFs are submitted to the DME MACs or UPICs, you must include a copy of

the front side. When CMNs are submitted electronically to the DME MAC, information from sections A and B are required.

Types of CMNs

There are three types of CMNs:

1. **Initial** – Establishes the initial medical need for an item
2. **Revised** – Documents a change in the order (such as a change in the physician, a change in the number of units prescribed, etc.)
3. **Recertification** – Confirms that the medical need is still present for oxygen equipment

CMNs

The following table indicates the current DME MAC CMN forms.

DME MAC FORM	CMS FORM	ITEMS ADDRESSED
484.03	484	Oxygen
04.04B	846	Pneumatic Compression Devices
04.04C	847	Osteogenesis Stimulators
06.03B	848	Transcutaneous Electrical Nerve Stimulators (TENS)
07.03A	849	Seat Lift Mechanisms
11.02	854	Section C Continuation Form

DIFs

The following table indicates the DIFs for external infusion pumps and enteral/parenteral nutrition.

DME MAC FORM	CMS FORM	ITEMS ADDRESSED
09.03	10125	External Infusion Pumps
10.03	10126	Enteral and Parenteral Nutrition

Printable copies of CMNs and DIFs are available on the CMS website at <http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-List.html>. To find the CMN/DIF you are looking for on the website, enter the name of the CMN/DIF in the “Filter On” field. For instance, if you are searching for the Oxygen CMN, enter the word “oxygen.” After finding the appropriate CMN/DIF, press the Form # link, and then open the PDF found under Downloads.

2. CMN and DIF Completion Instructions

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5, §5.5

The "Initial Date" found in Section A of the CMN or DIF should be either the specific date that the physician gives as the start of the medical necessity or, if the physician does not give a specific start date, the "Initial Date" would be the date of the order.

The "Signature Date" is the date the physician signed and dated Section D of the CMN or that you signed the DIF. This date will usually not be the same as the "Initial Date." Signatures must comply with CMS signature requirements. Refer to Chapter 3 of this manual for information about signature requirements.

The "Delivery Date/Date of Service" on the claim must not precede the "Initial Date" on the CMN or DIF or the start date on the written order. To ensure that an item is still medically necessary, the delivery date/date of service must be within three months after the "Initial Date" of the CMN or DIF or three months from the date of the physician's signature. The DME MACs and UPICs have the authority to request to verify the information on a CMN or DIF at any time. If the information contained either in your records or in the beneficiary's medical record maintained by the ordering physician fails to substantiate the CMN or DIF, or if it appears that the CMN or DIF has been altered, the DME MAC or UPIC will deny the service and initiate the appropriate administrative or corrective actions.

For revised and recertification CMNs or DIFs, physicians (or suppliers, for DIFs only) must enter the total cumulative number of months from the initial date in which the item will be needed when entering the estimated length of need. For instance, if an initial CMN has an original length of need of five months and the physician wishes to extend the length of need for an additional three months, then the length of need on the revised CMN must be entered as eight months (the total number of months from the initial date).

A new Initial DIF is required when:

1. An enteral formula billed with a different code, which has not been previously certified, is ordered; or,
2. For either enteral formulas or administration via pump, there has been a break in billing of more than 60 days (plus the remaining days in the rental month) and there has been a change in the underlying medical condition that justifies coverage for the item(s); or,
3. A beneficiary receiving enteral nutrition by the syringe or gravity method is changed to administration using a pump*.

**Change in method of administration from gravity or syringe to a pump requires a new initial DIF for the pump and a revised DIF for the enteral nutrient.*

A Revised DIF is required when:

1. There is a change in HCPCS code for the current enteral nutrient billed; or,
2. The number of days per week administered is changed; or,
3. The physician provides a new order changing the amount of calories administered; or,
4. Change in the method of administration from gravity to syringe or syringe to gravity (See above for gravity or syringe to pump); or,

5. Change in administration from tube feeding to oral feeding (if billing for denial); or,
6. The length of need previously entered on the DIF has expired and the ordering physician is extending the length of need for the item(s);
7. For infusion pumps:
 - a. A beneficiary begins using an infusion for one drug and subsequently the drug is changed, another drug is added, or the code for a current drug changes. The additional new or changed drug or the new HCPCS code for the existing drug must be listed along with all other drugs for which the pump is used.
 - b. There is a change in the route of administration or a change in the method of administration of a drug.
 - c. The length of need previously entered on the DIF has expired and the ordering physician is extending the length of need for the item(s).

In the event of an audit, you must be able to produce the CMN or DIF and, if requested by the DME MAC or UPIC, produce information to substantiate the information on the CMN or DIF. If you cannot produce this information, the DME MAC or UPIC will deny the service and initiate the appropriate administrative or corrective actions.

CMN Cover Letters

CMS Manual System, Pub. 100-08, Medicare Program Integrity Manual, Chapter 5, §5.3.2

The Social Security Act was amended in 1994 to specify the types of information that you may provide to physicians in a CMN. These are limited to an identification of the supplier and beneficiary, a description of the equipment and supplies being ordered, procedure codes for the equipment and supplies, and other administrative information not related to the medical condition of the beneficiary.

Cover letters may be used as a method of communication between you and the physician. It is not CMS's intent to restrict necessary communication between you and the physician. The CMS does not require nor regulate the cover letter.

Information contained in cover letters should address issues relating to CMS or Contractor regulation/policy changes, brief descriptions of the item(s) being provided, and changes in the patient regimen. You are encouraged to include language in your cover letters to remind physicians of their responsibility to determine both the medical need for, and the utilization of, all healthcare services and to assure that information relating to the beneficiary's condition is correct.

Section C of the CMN was designed not only to provide the physician with charge information, but also to function as a confirmation of the physician's order. However, if you wish to duplicate physician order information in a cover letter, you should feel free to do so.

Transmission of the CMN to and from the Physician, Nurse Practitioner, Physician Assistant, or Clinical Nurse Specialist

When the CMN or DIF is submitted electronically and you choose to maintain a hardcopy CMN or DIF, the font may be modified as follows:

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

- Each form must have a minimum ¼-inch margin on all four sides.

Without exception, these modified hardcopy forms must contain identical questions/wording to the CMS forms, in the same sequence, with the same pagination, and identical instructions/definitions printed on the back. CMN question sets may not be combined.

You and the physician may choose to utilize electronic CMNs (e-CMNs) or electronic DIFs (e-DIFs). E-CMNs or e-DIFs must adhere to all privacy, security, and electronic signature rules and regulations promulgated by CMS and DHHS. Additionally, e-CMNs or e-DIFs must contain identical questions/wording to the CMS forms, in the same sequence, with the same pagination, and identical instructions/definitions as printed on the back of the hardcopy form.

When the UPIC is investigating potentially fraudulent behavior by a supplier, it is the supplier's responsibility to prove the authenticity/validity of the claim(s) under investigation. The UPIC may require you to prove the authenticity/validity of the signature on the CMN, DIF, order, or any other questionable portion of the claim(s) under investigation.

Changes to a Completed CMN

If there is a change made to any section of the CMN after the physician has signed the CMN, the physician **must** line through the error and initial and date the correction; or you may choose to have the physician complete a new CMN.

Treating Physician of Record No Longer Involved With Beneficiary

If the physician of record is no longer the treating physician, you should obtain a revised CMN from the treating physician currently responsible for the beneficiary's pulmonary condition. No new testing is required. This CMN is not routinely submitted to the DME MAC or UPIC, but must be available on request.

Physicians Charging for CMN Completion

Charging suppliers a fee for completing Medicare-required CMNs may be considered a potential felony by the Office of Inspector General (OIG). When physicians bill for their services, including examination, diagnosis, and treatment, any costs associated with paperwork are considered part of the charges made for their professional services. If a physician's patient genuinely needs an item of durable medical equipment, the completion of a CMN is a service to the physician's patient rather than to the supplier.

3. CMNs as Orders and Claim Submission

The CMN can serve as the physician's detailed written order if the narrative description in section C is sufficiently detailed. This would include quantities needed and frequency of replacement on accessories, supplies, nutrients, and drugs. For items requiring both a CMN and a written order prior to delivery (seat lift mechanisms and TENS units), you may utilize a completed and physician-signed CMN for this purpose. Otherwise, a separate order in addition to a subsequently completed and signed CMN is necessary.

You may not complete the information in section B of the CMN. A supplier who knowingly and willfully completes section B of the form is subject to a civil monetary penalty up to \$1,000 for each form or document so distributed.

You must complete the fee schedule amount, narrative description of the items furnished, and your charge for the medical equipment or supplies being furnished on a CMN prior to the CMN being furnished to the physician. If you knowingly and willfully fail to include this information, you may be subject to a civil monetary penalty up to \$1,000 for each form or document so distributed.

If an item requires a CMN or a DIF and you do not have a faxed, photocopied, or original hardcopy or an electronic signed CMN or DIF in your records before you submit a claim to Medicare, the claim will be denied. If the CMN or DIF is used to verify that statutory benefit requirements have been met, then the claim will be denied as not meeting the benefit category.

In cases where two or more suppliers merge, the resultant supplier should make all reasonable attempts to secure copies of all active CMNs or DIFs from the supplier(s) purchased. This document should be kept on file by the resultant supplier for future presentation to the DME MAC or UPIC.

When reviewing claims where the medical record contains a copied, faxed, or electronically maintained CMN or DIF (any CMN or DIF created, modified, and stored via electronic means, such as commercially available software packages and servers), the DME MAC or UPIC will accept the copied, faxed, or electronic document as fulfilling the requirements for these documents.

Upon request by the DME MAC or UPIC, you must provide the CMN or DIF, in a format that the DME MAC or UPIC can accept, in a timely manner. Upon medical review, the DME MAC or UPIC should not deny claims solely because the CMN or DIF is faxed, copied, or electronic. The DME MAC or UPIC may request you to download and print a hard copy of an electronic order, CMN, or DIF if the DME MAC or UPIC cannot access it electronically.

For items that require a CMN, and for accessories, supplies, and drugs related to an item requiring a CMN, the CMN may serve as the written order if the narrative description in Section C is sufficiently detailed (as described above). This applies to both hard copy and electronic orders or CMNs. A DIF does not contain a section for a narrative description and thus is not applicable.

Only OMB-approved, active CMNs that are in use for the date of service on the claim under consideration for reimbursement will be recognized as a substitute for a written order. Use of inactive or "retired" CMNs will not be recognized for either medical necessity purposes or as a substitute for a written order.

You must have a hard copied, faxed, or electronic order, CMN, or DIF in your records before you can submit a claim for payment to Medicare. You must ensure the security and integrity of electronically maintained CMNs or DIFs are in accordance with any regulations published by CMS.

Supporting Medical Documentation

Refer to Chapter 3 of this manual for information regarding supporting medical documentation.

4. Oxygen CMNs

CMS Manual System, Pub. 100-08, *Medicare Program Integrity Manual*, Chapter 5, §5.9.1

Evidence of Medical Necessity for the Oxygen CMN

If DME MACs or UPICs learn that the physician of record is no longer the treating physician, you must obtain a current, fully-completed oxygen CMN from the physician currently responsible for the beneficiary's pulmonary condition. After review of this oxygen CMN, DME MACs continue monthly

payments if the evidence establishes medical necessity. Your records must be updated to identify the new treating physician.

For more information concerning coverage and claim submission for oxygen therapy, refer to the *Oxygen and Oxygen Equipment Local Coverage Determination (LCD)*.

Initial Oxygen Certifications

For the situations that require an initial oxygen CMN, refer to the LCD entitled "Oxygen and Oxygen Equipment." In determining coverage, the dates of treatment and testing are critical. For example, the initial date of need for home oxygen coverage cannot precede the date of the order or the date of the test(s), the results of which are used to determine if the coverage criteria are met. Once coverage is established, the estimated length of need, along with the circumstances and results of testing that established the medical necessity at the start of home oxygen therapy, will determine when recertification is necessary.

Qualifying tests must be conducted by the treating physician or a provider certified to conduct such tests. Because of the potential for conflict of interest, the results of oximetry tests conducted by a DME supplier cannot be accepted to establish the need for home oxygen therapy services, either in initial claims or when accompanying recertification CMNs. This prohibition does not extend to the results of tests conducted by a hospital that is a certified provider of such services that may also be furnishing home oxygen therapy to the beneficiary.

The date of oxygen testing must be within 30 days prior to the date of initial certification. Therefore, for initial oxygen certifications the CMN may be completed by the physician no more than 30 days prior to initial coverage of oxygen. An exception to this is if a beneficiary begins taking oxygen while under a Medicare Advantage Plan. In this case, you must obtain an initial CMN and submit it to the DME MAC at the time that FFS coverage begins; however, the beneficiary does not have to obtain the blood gas study on the CMN within 30 days prior to the date on the CMN. In this situation the test must be the most recent study the beneficiary obtained while in the Medicare Advantage Plan, under the guidelines specified in the medical policy. It is important to note that, just because a beneficiary qualified for oxygen under a Medicare Advantage Plan, it does not necessarily follow that he/she will qualify for oxygen under FFS. These instructions apply whether a beneficiary voluntarily returns to FFS or if he or she involuntarily returns to FFS because their Medicare Advantage Plan no longer participates in the Medicare + Choice program.

When both arterial blood gas (ABG) and oxygen saturation (oximetry) tests have recently been performed, greater weight is given to the ABG result. That test is generally acknowledged as the more reliable indicator of hypoxemia. In a review situation, if documentation in the medical record contains the result of an ABG performed on the same day as an oximetry saturation recorded on the CMN, and they are the most recent tests taken on or before the certification date on the CMN, the ABG will be used to determine oxygen coverage for that certification. If the ABG does not substantiate the need for oxygen therapy, the claim(s) will be denied as not reasonable and necessary.

There are no professionally accepted formulas for converting the results of tests taken while the beneficiary is on oxygen to what the same beneficiary would have shown had he or she been breathing room air. Coverage may not be established by use of any suggested formula to convert this information.

Where PO₂ levels exceed 59 mm Hg or the arterial blood oxygen saturation exceeds 89 percent at rest, a rebuttable presumption of noncoverage exists. Form CMS-484 certification must be supplemented by additional documentation from the attending physician designed to overcome this

presumption and justify the oxygen order, including a summary of other, more conservative therapy that has not relieved the beneficiary's condition.

The CMS stipulates that claims may be denied **without development** if:

- The only qualifying test results came from oximetry tests conducted by a supplier of DME other than a hospital;
- The claim lacks information necessary to justify coverage in accordance with guidelines in section 240.2 of the *Medicare National Coverage Determinations Manual* (Pub. 100-03);
- Hardcopy claims where Form CMS-484 lacks the certifying physician's original signature; or
- Electronic claims where Form CMS-484 fails to indicate that the attending physician's handwritten signature is on file in the supplier's office.

Treating Physician Identification

Form CMS-484 must be personally signed and dated by the treating physician, nurse practitioner, physician assistant, or clinical nurse specialist.

Revised Oxygen Certifications

New medical documentation written by the beneficiary's treating physician must be submitted to the DME MAC in support of revised oxygen requirements when there has been a change in the beneficiary's condition and need for oxygen therapy; therefore, physicians are encouraged to file a revised Form CMS-484 as soon as possible when the order for oxygen changes. A revised certification is appropriate under the circumstances described in the "Oxygen and Oxygen Equipment" LCD.

Recertifications of Oxygen CMNs

Recertification scheduling and documentation requirements depend on the date when home oxygen therapy began. See the "Oxygen and Oxygen Equipment" LCD for situations requiring a recertification. The following information is needed on all recertifications:

- Date and results of the most recent arterial blood gas or oximetry tests conducted prior to the recertification date;
- Name of the provider conducting the most recent ABG or oximetry tests prior to the recertification date;
- The conditions under which these tests were conducted;
- Estimated length of need for oxygen (in section B of Form CMS-484);
- Date of the **current** oxygen order;
- Details of the **current** oxygen order.

Additionally, for beneficiaries who initially qualify for oxygen coverage with Group II blood gases, a repeat blood gas study must be performed between the 61st and 90th day of home oxygen therapy (see below).

The schedule for recertifying the need of oxygen for beneficiaries beginning home oxygen therapy is established in accordance with the requirements below.

Recertification Required at Three Months for Group II Patients

Recertification is required for beneficiaries who initially qualify for oxygen coverage with Group II results (an ABG result of 56-59 mm Hg or an arterial oxygen saturation of 89 percent). Payment may be made for the fourth month of service **only** upon presentation of test results that meet presumed coverage levels. The recertification at three months must reflect the results of an ABG or oxygen saturation test conducted between the 61st and 90th day of home oxygen therapy. If the beneficiary no longer requires home oxygen therapy after three months, retesting is not necessary.

Recertifications at three months should be completed in full. If the order has already been discontinued, the physician should write the date that it was stopped.

You, or the current oxygen supplier, must make the request for recertification to the physician. The physician should be instructed to complete the recertification CMN and return it to you. You must then forward a copy of this information with a hardcopy claim or transcribe it exactly as it appears into the record of an electronic claim for the fourth monthly payment for oxygen therapy. The physician should be encouraged to retain a copy of this recertification CMN. You or physician must retain a copy of the completed CMN (photocopy, facsimile image, electronically maintained, or original "pen and ink" document) Form CMS-484. No payment will be made for the fourth or later months of oxygen service unless the recertification CMN and retest results establish continuing medical necessity.

Recertification for Long Term Therapy

If additional tests have been conducted since the prior certification, these results and other pertinent information must be recorded on the recertification. Additional testing will not be requested for beneficiaries with established chronic pulmonary problems.

You must send recertification requests to the attending physician for completion. You should emphasize that the completed Form CMS-484 is to be returned to you in all cases. To reduce misrouting problems, you may want to provide self-addressed, return envelopes. You must forward a copy of the completed Form CMS-484 with its next claim for monthly rental of oxygen equipment. It is advisable for the physician to retain a copy of the completed Form CMS-484 with other records for the beneficiary. You or physician must retain a copy of the completed CMN (photocopy, facsimile image, electronically maintained or original "pen and ink" document) Form CMS-484.

While the recertification is being obtained, payments will continue through the 12th month of service, based on the estimated length of need for oxygen therapy in the initial certification. Payment will be suspended for the 13th or later months if a satisfactory recertification CMN, including any test results that may be required, has not been received by the time the payment would otherwise be authorized.

Subsequent Recertifications

Most beneficiaries who require home oxygen therapy beyond a few months require it lifelong. Therefore, once a Form CMS-484 recertification establishes that the medical necessity continues, subsequent recertifications are not routinely required; however, they may be requested in conjunction with quality control sampling or if there is an indication of significant change in the beneficiary's status, e.g., large, unexplained variations in the use of oxygen or evidence of confinement to a hospital or skilled nursing facility (SNF) throughout an equipment rental period. Because orders have a fixed, prospective life and payments can only be made pursuant to a currently valid order, physicians must keep orders current at all times. You must also retain orders so as to be immediately available should they be requested during medical review audits or for other purposes.

5. CMN Common Scenarios

Suppliers frequently approach the DME MACs or UPICs with questions about what CMN type should be submitted for a given situation. All CMN requirements detailed below are based on assumptions about the most common scenarios seen by the DME MACs. The facts of any individual supplier's claim may result in an alternate requirement. You should use this information only as general guidance and should consult with the DME MAC Customer Support department as necessary (see Chapter 13 of this manual for information about Customer Support).

#	Capped Rental Equipment	Certification Required	Notes
1	Break in service > 60 days (change in medical condition) No change in HCPCS	initial	1
2	Break in service > 60 days (no change in medical condition) No change in HCPCS	none	1
3	Break in service < 60 days (change in medical condition) No change in HCPCS	none	1
4	Break in service < 60 days (no change in medical condition) No change in HCPCS	none	1
5	Break in service > 60 days (change in medical condition) Change in HCPCS (e.g., K1 to K3 or K3 to K1)	initial	1, 3
6	Break in service > 60 days (no change in medical condition) Change in HCPCS (e.g., K1 to K3 or K3 to K1)	initial	1, 3
7	Break in service < 60 days (change in medical condition) Change in HCPCS (e.g., K1 to K3 or K3 to K1)	initial	1, 3
8	Break in service < 60 days (no change in medical condition) Change in HCPCS (e.g., K1 to K3 or K3 to K1)	initial	1, 3
9	Change in supplier (no break in service, no change in HCPCS)	revised in supplier's files	1, 2
10	Change in supplier (no break in service,	initial	1, 2, 3

	HCPSC changed e.g., K1 to K3)		
11	Initial CMN did not qualify, patient re-evaluated and now qualifies	initial	
12	Change in doctor	revised in supplier's files	
13	Added elevating leg rests after wheelchair provided	none	
14	Changed billing assignment (non-assigned to assigned)	none	
15	Change from Medicare secondary to Medicare primary	none	
16	Change from non-Medicare insurance to Medicare	initial	

Notes:

1. "Break in service" for the purpose of this table is defined as break in monthly billing.

"Change in medical condition" means that the patient's condition changed to the point that they no longer needed the original device. The patient's condition then changed again and the patient needed to resume using the original item. It could be for the same or different diagnosis.

"No change in medical condition" means that there is a break in billing but the patient still needed the same equipment. For example, the patient was in a SNF, hospital, Medicare Advantage Plan, or hospice and the DME MAC was not being billed during this time. This could also include situations in which the patient continued to need the equipment, but it was removed from the patient's home.

2. Requirement is for the new supplier.
3. Submission of a new Initial CMN does not guarantee that a new capped rental period will be started.