Medicare
Carriers Manual
Part 3 – Claims Process

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

Transmittal 1685 **Date: NOVEMBER 17, 2000**

CHANGE REQUEST 1135

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
Table of Contents – Chapter IV	4-1 - 4-2 (2 pp.)	4-1 - 4-2 (2 pp.)
4105.2 – 4105.4 (Cont.)	4-21 - 4-24.4 (8 pp.)	4-21 (1 p.)

NEW/REVISED MATERIAL--*EFFECTIVE DATE: 4/1/01*
IMPLEMENTATION DATE: 4/1/01

Section 4105.1, Home Use of Durable Medical Equipment (DME), added to define the use of Durable Medical Equipment in the home.

Section 4105.2, Evidence of Medical Necessity, added to define what information is required to on a physician order and/or a CMN.

Section 4105.3, Incurred Expenses for DME and Orthotic and Prosthetic Devices, added to describe billing requirements for orthotics and prosthetics.

Section 4105.4, Evidence of Medical Necessity Oxygen Claims, added to define what medical information is required for billing for oxygen.

***** MCM 4105.4 supercedes PIM Chapter 5.6.***

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

These instructions should be implemented within your current operating budget.

CHAPTER IV
CLAIMS REVIEW AND ADJUDICATION PROCEDURES

Section

Line Review - Form HCFA-l490S

Line Review - Health Insurance Claim Form

Items and Services Having Special Review Considerations

Section

Items and Services Having
Special Review Considerations

4105. DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS AND SUPPLIES

4105.l Home Use of Durabale Medical Equipment (DME).--If a claim shows a nursing home or hospital address as the beneficiary's residence, or if the place of service code indicates that the beneficiary is an inpatient of a hospital or nursing home, develop for the date of admission and determine whether payment is possible (See §4105.3.) If a hospital is a participating hospital, an emergency hospital, or a hospital which meets the requirements of §1861(e)(l) of the law, it does not qualify as the patient's home.

Medicare law limits Part B payment for DME to that which is used in the beneficiary’s home. Hospitals and nursing homes cannot be considered a beneficiary’s home for DME purposes.

The following screening guides apply when the individual is in an SNF:

- If the facility meets the definition specified in §1819 (a)(1) of the Act, regardless of whether the facility participates in Medicare, the facility cannot be considered the beneficiary’s home.

- If the facility has a part which meets the §l819 (a) (l) definition, and a part that does not meet the §l819 (a) (l) definition, identify the part in which the beneficiary was physically located during the use period. The institution may be considered the individual's home only if he/she was in the part which does not meet §l819 (a) (l). See §23l2.l if an item of equipment is furnished or used outside the U.S.

- If a DME rental start date coincides with the beneficiary's discharge date from an institution not classified as a "home”, pay for medically necessary DME.

These rules apply only to DME claims. Orthotic and prosthetic devices are not subject to the "home use" requirement for coverage and payment purposes.

4105.2 Evidence of Medical Necessity.--A physician order and/or a CMN, if required, which has been signed and dated by the treating physician must be kept on file by the supplier for all durable medical equipment, prosthetics, orthotics and supplies (DMEPOS). The order or CMN must include:

- Beneficiary’s name and full address;

- Physician’s original signature (not a stamped signature);

- Date physician signed order;

- Description of the items including all options or additional features which will be billed separately or will require an upgraded code;

- Start date of order (if appropriate); and

- Diagnosis - On a freestanding order, either a narrative diagnosis or, an ICD-9 code may be used. However if the item is the subject of a local medical review policy or national coverag policy, then an ICD-9 code must be entered. On a CMN, an ICD-9 code must be entered. The diagnosis must be entered by the treating physician.

It should also include where appropriate:

- o Length of medical necessity (for rental items that do not have a Certificate of Medical Necessity (CMN) or supplies with ongoing use); and

- o Explanation of how item(s) is/are to be used.

For certain items of DME (as described in §3312), a CMN is required to be submitted with the claim. Carriers must regularly notify suppliers which items require a CMN and which items need only an order filed with the claim. If the CMN contains information otherwise contained on the order, it can also satisfy the order requirement.

If replacement supplies are needed for the therapeutic use of purchased DMEPOS, the treating physician must specify on the order, or on the CMN, the type of supplies needed and the frequency with which they must be replaced, used, or consumed. Evaluate supply utilization information as part of your medical necessity determination for DMEPOS. Do not accept "PRN" or "as needed" utilization estimates for supply replacement, use, or consumption.

When an order for DMEPOS is renewed or revised, supply utilization information must be specified or updated by the physician. Assess the continuing medical necessity.

Establish procedures for monitoring the utilization of replacement supplies. Suppliers must provide information documenting the medical necessity of the billed utilization with the claim where indicated in published policy or make it available to the DMERC on request.

If necessary or appropriate for your medical necessity determination, ask the supplier to obtain documentation from the treating physician, establishing the severity of the beneficiary's condition and the immediate and long term need for the equipment and the therapeutic benefits the patient is expected to realize from its use. Do not accept a claim of therapeutic effectiveness or benefit based on speculation or theory alone. When restoration of function is cited as a reason for use of DMEPOS, the exact nature of the deformity or medical problem should be clear from the medical evidence submitted. Also, the manner in which the equipment or device will restore or improve the bodily function should be explained by the treating physician.

If, after obtaining the requested information, a question of medical necessity remains, have your medical staff resolve the issue.

Note that orders or certifications signed by physicians who are under sanction are not valid.

A. Period of Medical Necessity.--Your file must be documented to show how the period of medical necessity was established. You need not develop the period of medical necessity in the case of inexpensive and routinely purchased equipment.

B. Safeguards in Making Monthly Payments.--Establish appropriate safeguards to assure that payments are not made beyond the last month of medical necessity. Develop appropriate safeguards to identify and investigate the following:

- o Multiple claims for rental of the same or similar equipment from the same supplier within the same rental month (e.g., rental claims with different start dates but within the same rental period.);

- Contraindicated items of rented or purchased equipment;

- Incompatible claims information (e.g., liquid oxygen contents billed for a purchased gas delivery system.);

- Medical equipment rentals or purchases after a beneficiary's death;

- Rental start dates on or after the purchase of the same or comparable equipment (absent evidence that the beneficiary has disposed of purchased equipment);

- Rental claims for the same or similar equipment from different suppliers for the same or overlapping rental months; and

- Equipment rental start dates within periods of confinement in an institution that cannot be considered a patient's home.

Resolve these situations on a prepayment basis. Development, if necessary, may be via written or telephone contact per §3311, subject to any other documentation or development guidelines specified in §4105.

To the extent possible, give beneficiaries and supplier-assignees advance notice of the date and reason that payments are scheduled to stop. (see §7012ff. for EOMB language.)

4105.3 Incurred Expenses for DME and Orthotic and Prosthetic Devices.--The first month's expense for rental is incurred on the date of delivery of the equipment. Expenses for subsequent months are incurred on the same date of the month. Where equipment is purchased, benefits are payable on the same basis. Suppliers may submit claims as of the date expenses are incurred. If the date of delivery is not specified on the bill, assume, in the absence of evidence to the contrary, that the date of purchase or rental was the date of delivery.

Generally, for DMEPOS that is not mail order, the supplier’s date of service (DOS) is the date of delivery to a beneficiary’s home. For DMEPOS provided to a beneficiary immediately subsequent to a hospital inpatient stay and/or DME immediately following a nursing home stay, the DOS is the date of final discharge to the beneficiary’s home. Generally, for mail order DMEPOS, the DOS on the claim is the shipping date. However, for mail order DMEPOS provided immediately subsequent to a hospital inpatient stay and/or DME immediately following a nursing home stay, the DOS is the later of the shipping date or the date of discharge. Under no circumstances can the DOS be earlier than the date of discharge.

No payment may be made for rental for any month throughout which the beneficiary is in an institution which does not qualify as his or her home (see §2100.3) or is outside the U.S. (See §2312.) If the beneficiary is at home as of the first day of a rental month and, for part of the same rental month, is in an institution which cannot qualify as his or her home, or is outside the U.S., payment may be made for the entire rental month. Similarly, if an item of rental equipment is returned to the supplier before the end of a payment month because the beneficiary died in that rental month or because the equipment became unnecessary in that month, payment may be made for the entire rental month. However, if the supplier charges for only part of a month, or you are aware that the supplier customarily follows such a practice, pay on a prorated basis.

Note that in the case of purchased equipment, §2312 requires that the beneficiary must have been in the United States when the item was delivered, and §1050 requires that the beneficiary must have had SMI coverage at the time the item was delivered. Therefore, where a purchased item of equipment was delivered to a beneficiary outside the United States or before his/her coverage period began (i.e., the effective date of his/her enrollment), the entire expense of the item is excluded from coverage whether it was paid for in its entirety at purchase or on a deferred or installment basis. Payment cannot be made in such cases even though the beneficiary uses the item inside the United States or after his/her coverage begins.

4105.4 Evidence of Medical Necessity Oxygen Claims.--Oxygen coverage is determined by the results of an arterial blood gas or oximetry test. A CMN for oxygen equipment must include results of specific testing before coverage can be determined. (see CIM 60-4)

Suppliers that bill electronically may transmit initial, revised, and recertification CMNs by electronic media using HCFA-established standard formats. In initial claims for home oxygen therapy, the electronic version of the Form HCFA-484 must accompany the claim. Information transmitted from a revised or recertification Form HCFA-484 must accompany the first claim for monthly benefits submitted after the supplier has received the hard copy Form HCFA-484 from the certifying physician. If the supplier submits the Form HCFA-484 information to you electronically, the supplier must keep the paper certification readily available so that it may be promptly furnished to you if requested for purposes of audits of medical necessity documentation.

Blood Oxygen Testing

The medical necessity of home oxygen is documented by the results of a blood oxygen test. The blood oxygen test may be either an arterial blood gas or an oximetry test. The following timeliness requirements must be met.

Initial Certification:

Groups I and II: Must be tested within 30 days prior to the date of initial certification. If the oxygen is begun immediately following discharge from an acute care facility, the test must be within two days prior to discharge.

Systems Logic

System changes will be required to add front end EMC and online edits to compare the test date to the initial date.

Recertifications:

Group I or II: Must be tested between the 61st - 90th day after the date of initial certification.

Systems Logic

For recertification of initial oxygen CMN, systems changes will be required to calculate and plug the scheduled recert date to be the initial date + “xx” days (where “xx” days must be determined by the DMERCs) when the length of medical necessity if greater than 3 months. This calculation must be done to insure that recertification letters are generated at the correct intervals. Currently the DMEPOS system generates recertification letters 96 days in advance of the scheduled recertification date.

System changes will be required to add an edit to compare the blood oxygen test date to the recertification date if the length of medical necessity is less than lifetime (lifetime = 99 months) when a recertification CMN is being added. The edit will prompt when the ABG/saturation test date is no within 30 days of the recertification date.

System changes will be required to change the current DMEPOS CMN edit 1089 OXY RETEST 61-90 so that it will prompt when a recertification CMN is being added and the ABG/saturation test date is not between 61-90 days after the initial date of the CMN.

The blood gas values for Group III (ABG equal to or greater than 60 or blood oxygen saturation is at or above 90 percent) would be included in the system criteria for editing Group II (ABG between 56 to 59 or blood oxygen saturation is 89 percent). The DMEPOS system editing currently checks for the ABG/saturation test date to be between 61-90 days after the initial date of the CMN when the ABG is greater than 55 of the saturation is greater than 88. Logic for system change requirements described in the section above for Group I and II recertification editing. This editing change will encompass editing changes for Group III CMNS.

Revised Certifications

Group I and II: Must be tested within 30 days prior to the date of the revised certification if the initial certification specified a length of need that is less than lifetime.

Physician Evalution

Initial Certification:

Groups I and II: Must be seen and evaluated by the treating physician within 30 days prior to the date of initial certification

Recertifications:

Group I and II: Must be seen and re-evaluated by the treating physician within 90 days prior to any recertification date.

A. Initial Certifications.--In reviewing the claim and the supporting Form HCFA-484, compare certain items, especially pertinent dates of treatment. For example, the start date of home oxygen coverage cannot precede the date of prescription or the date of the test(s) whose results establish that the special coverage criteria are met. Once coverage is established, the estimated length of need in Section B on the Form HCFA-484, and the circumstances and the results of testing that established the medical necessity at the start of home oxygen therapy, determines the recertification schedule. (See §4105.4C.)

Definitions of “Group” based on blood gas values (see CIM §60-4 for more detailed explanations and further qualifications of the following definitions):

Group I - An arterial PO_2 at or below 55 mm Hg, or arterial oxygen saturation at or below 88 percent.

Group II - An arterial PO_2 is 56 to 59 mm Hg or whose arterial blood oxygen saturation is 89 percent.

Group III - An arterial PO_2 at or above 60 mm Hg, or arterial blood oxygen saturation at or above 90 percent.

When oxygen is prescribed in an institution, in order to establish medical necessity it is necessary that the institution would have to recheck the oxygen level no sooner than 2 days before discharge. Clinical documentation will be reviewed to confirm the fact that the prescribing of continued oxygen was based upon the "chronic stable state" (was done while the patient was in a chronic stable state i.e., not during a period of acute illness or an exacerbation of the patient's underlying disease) of the patient.

Verify that the information shown on or accompanying the Form HCFA-484 supports the need for oxygen as billed.

When both arterial blood gas (ABG) and oxygen saturation (oximetry) tests have recently been performed on the same day, instruct suppliers to report only the ABG result. That test is generally acknowledged as the more reliable indicator of hypoxemia.

Values in Group III establish a rebuttable presumption of non-coverage. The Form HCFA-484 certification must be supplemented by additional documentation from the treating physician designed to overcome this presumption and justify the oxygen order, including a summary of other, more conservative therapy that has not relieved the patient's condition. Refer a claim with such documentation to your medical director for the coverage determination.

Deny the following types of claims without further development:

o The claim where the only qualifying test results came from oximetry tests conducted by a supplier of DME other than a hospital;

o Claims lacking information necessary to justify coverage in accordance with guidelines in §60-4 of the Coverage Issues Manual;

o Hard copy claims where the Form HCFA-484 lacks the treating physician's signature; or

o Electronic claims where the Form HCFA-484 fails to indicate that the treating physician's handwritten signature is on file in the supplier's office.

An initial CMN is also required when there has been a break in medical necessity of 60 days plus whatever days remained in the rental month during which the oxygen was discontinued. (This indication does not apply if there was just a break in billing because the patient was in a hospital, nursing facility, hospice, or HMO, but the patient continued to use oxygen during that time.)

1. Medical Review.--Have your medical staff review all claims with initial certifications calling for oxygen flow rates of more than 4 liters per minute before payment is authorized.

2. Items Requiring Special Attention.--

a. Oxygen Delivery or Supply Prescribed.--If the treating physician has specified the oxygen equipment to be supplied, ensure that the equipment furnished is consistent with that prescribed.

b. Treating Physician Identification.--Ensure that the Form HCFA-484 has been signed by the treating physician. A stamped signature is unacceptable. The physician's identification number must be the Unique Physician Identification Number (UPIN).

B. Revised Certifications.--Encourage treating physicians to file timely, revised Form HCFA-484s through the supplier if their order for oxygen changes.

A revised CMN is necessary when:

1. The prescribed maximum flow rate changes from one of the following categories to another: (a) less than 1 LPM, (b) 1-4 LPM, (c) greater than 4 LPM. If the change is from category

(a) or (b) to category (c), a repeat blood gas study with the beneficiary on 4 LPM must be performed 30 days prior to the start of the greater than 4LPM flow.

2. Portable oxygen is added subsequent to initial certification of a stationary system. In this situation, there is no requirement for a repeat blood gas study unless the initial qualifying study was performed during sleep, in which case a repeat blood gas study must be performed while the patient is at rest (awake) or during exercise.

3. The intial certification specified an estimated length of need that is less than lifetime and the physician wants to extend the certification.

4. There is a new treating physician (no new testing is required).

Do not adjust payments on oxygen claims unless a revised certification documents the necessity for the change. Timely adjust payments, if necessary, for services since the oxygen prescription was changed.

C. Scheduling and Documenting Recertifications of Medical Necessity for Oxygen.--Recertification scheduling and documentation requirements depend on the date when home oxygen therapy began. Request the following information on all recertifications:

- Date and results of the most recent arterial blood gas or oximetry tests prior to the recertification date;
- Name of the provider conducting the most recent arterial blood gas or oximetry tests performed prior to the recertification date and the conditions under which this test were conducted; and
- Estimated length of need for oxygen (Section B on the Form HCFA-484).

Establish the schedule for recertifying the need for oxygen for patients beginning home oxygen therapy in accordance with the requirements below.

1. Recertifications.--If the oxygen test results on the initial certification were in either Group I or Group II, recertification must be performed within 90 days after the initial certification. In this situation, a repeat blood gas study must be performed between the 61st and 90th day of home oxygen therapy.

If recertification is due, do not pay the next month's claim if the test was not performed during the required time frame. If a qualifying test is not obtained between the 61st and 90th day of home oxygen therapy, but the patient continues to use oxygen and a test is obtained at a later date, instruct suppliers to use the date of the repeat test as the date of service on a subsequent claim, and if that test meets Group I or II criteria, resume payments from that point of time.

2. New Orders--In the following situation, a new order must be obtained and kept on file by the supplier, but neither a new CMN nor a repeat blood gas study are required:

o Prescribed maximum flow rate changes but remains within one of the following categories: (a) less than 1 LPM, (b) 1-4 LPM, (c) greater than 4 LPM;

In the following situation a new order must be obtained and kept on file by the supplier and a revised CMN is required:

o If the physician has initially specified a delivery system, and a change is made from one type of stationary system to another (i.e., concentrator, liquid, gaseous).