CHANGE REQUEST 1425

This transmittal revises Transmittal 1683, Change Request 1286, dated October 18, 2000.

**HEADER SECTION NUMBERS**  
4119 - 4120.2

**PAGES TO INSERT**  
4-33 - 4-36 (4 pp.)

**PAGES TO DELETE**  
4-33 - 4-36 (4 pp.)

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

Section 4119, Durable Medical Equipment Regional Carrier (DMERC) Instructions for Denying Claims for Prescription Drugs Billed and/or Paid to Suppliers Not Licensed to Dispense Prescription Drugs, is revised to create different Medicare Summary Notice (MSN) messages for assigned and non-assigned claims. HCFA needs to change the section so that beneficiaries who submit unassigned claims do not get a message telling them that they are not liable for payment when a pharmacy does not have a license to dispense drugs, when, in fact, the beneficiary will be held liable. The supplier remains liable for assigned claims.

These instructions should be implemented within your current operating budget.

**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.
1. Carriers should conduct post-payment reviews of x-rays on a sample basis. Prepayment review should be undertaken in all questionable cases.

2. It is the responsibility of the treating chiropractor to make the documenting x-ray(s) available to the carrier's review staff. If x-rays are not made available, or suggest a pattern in failing to demonstrate subluxation for any reason, including unacceptable technical quality, the carrier should conduct prepayment review of x-rays in 100 percent of the subsequent claims for treatments by the practitioner involved until satisfied that the deficiency will no longer occur. Where there is no x-ray documentation of subluxation on prepayment review, the claims, of course, should be denied. (The last sentence of this paragraph only refers to claims with dates of service prior to January 1, 2000.)

3. The x-ray film(s) must have been taken at a time reasonably proximate to the initiation of the course of treatment and must demonstrate a subluxation at the level of the spine specified by the treating chiropractor on the claim. (See §2251.2B.)

4. An x-ray obtained by the chiropractor for his own diagnostic purposes before commencing treatment should suffice for claims documentation purposes. However, when subluxation was for treatment purposes diagnosed by some other means and x-rays are taken to satisfy Medicare's documentation requirement, carriers should ask chiropractors to cone in on the site of the subluxation in producing x-rays. Such a practice would not only minimize the exposure of the patient but also should result in a film more clearly portraying the subluxation.

5. An x-ray will be considered of acceptable technical quality if any individual trained in the reading of x-rays could recognize a subluxation if present.

6. When claims have been denied because the x-ray(s) initially offered failed to document the existence of a subluxation requiring treatment, no review of these decisions should be undertaken on the basis of x-ray(s) subsequently taken. Permitting such reviews could be an inducement to excessive exposure of patients to radiation in cases where the decision to treat was made despite x-rays that did not show a subluxation.

4119. DURABLE MEDICAL EQUIPMENT REGIONAL CARRIER (DMERC) INSTRUCTIONS FOR DENYING CLAIMS FOR PRESCRIPTION DRUGS BILLED AND/OR PAID TO SUPPLIERS NOT LICENSED TO DISPENSE PRESCRIPTION DRUGS

A drug used as a supply with DME or a prosthetic device is not covered by Medicare if the drug is dispensed by an entity that is not licensed to dispense the drug. The drug is not considered to be reasonable and necessary because HCFA cannot be assured of its safety and effectiveness unless it is dispensed by an entity that has a State license that qualifies it to dispense the drug. The equipment used with the drugs dispensed by a non-licensed entity is also considered to be not reasonable and necessary because of the related safety and efficacy concerns. Physicians are considered to have been “deemed” the right to dispense prescription drugs, and therefore do not require a pharmacy license.

DMERCs should deny claims for a prescription drug (and related equipment when billed on the same claim as the drug) when the National Supplier Clearinghouse’s (NSC’s) files show the supplier is or was not licensed to dispense the drugs on the date of service (DOS).

An exception to this general policy is oxygen claims.

Messages
Assigned Claims:

Rev. 1688 4-33
4120 CLAIMS REVIEW AND ADJUDICATION PROCEDURES 12-00

EOMB: “Medicare cannot pay for this drug/equipment because our records do not show your supplier is licensed to dispense prescription drugs, and, therefore, cannot assure the safety and effectiveness of the drug/equipment. You are not financially liable for any amount for this drug/equipment unless your supplier gave you a written notice in advance that Medicare would not pay for it and you agreed to pay.” (EOMB message #8.98; MSN #8.50.)

Remittance for Drugs: “This service/procedure is denied/reduced when performed/billed by this type of provider, in this type of facility, or by a provider of this specialty.” (Remittance advice code B6, with group code CO—the provider may not bill the beneficiary.)

Additionally, remark code M143: “We have no record that you are licensed to dispense drugs by the State in which you are located.” Should appear on supplier remittance notices.

Non-Assigned Claims:

MSN: “This item or service is not covered when performed or ordered by this provider.” (MSN #12.18)

Appeals


4120. FOOT CARE

4120.1 Application of Foot Care Exclusions to Physicians’ Services.--The exclusion of foot care is determined by the nature of the service (§2323). Thus, reimbursement for an excluded service should be denied whether performed by a podiatrist, osteopath, or a doctor of medicine, and without regard to the difficulty or complexity of the procedure.

When an itemized bill shows both covered services and noncovered services not integrally related to the covered service, the portion of charges attributable to the noncovered services should be denied. (For example, if an itemized bill shows surgery for an ingrown toenail and also removal of calluses not necessary for the performance of toe surgery, any additional charge attributable to removal of the calluses should be denied.)

In reviewing claims involving foot care, the carrier should be alert to the following exceptional situations:

1. Payment may be made for incidental noncovered services performed as a necessary and integral part of, and secondary to, a covered procedure. For example, if trimming of toenails is required for application of a cast to a fractured foot, the carrier need not allocate and deny a portion of the charge for the trimming of the nails. However, a separately itemized charge for such excluded service should be disallowed. When the primary procedure is covered the administration of anesthesia necessary for the performance of such procedure is also covered.

2. Payment may be made for initial diagnostic services performed in connection with a specific symptom or complaint if it seems likely that its treatment would be covered even though the resulting diagnosis may be one requiring only noncovered care.

3. Payment may be made for routine-type foot care such as cutting or removal of corns, calluses, or nails when the patient has a systemic disease of sufficient severity that unskilled performance of such procedure would be hazardous (§2323C).
a. Claims for such routine services would show in item 7D of the SSA-1490 the complicating systemic disease. Where these services were rendered by a podiatrist this item should also include the name of the M.D. or D.O. who diagnosed the complicating condition. In those cases where active care is required, the approximate date the beneficiary was last seen by such physician must also be indicated.

NOTE: Section 939 of P.L. 96-499 removed "warts" from the routine foot care exclusion effective July 1, 1981.

b. Relatively few claims for routine-type care are anticipated considering the severity of conditions contemplated as the basis for this exception. Claims for this type of foot care should not be paid in the absence of convincing evidence that nonprofessional performance of the service would have been hazardous for the beneficiary because of an underlying systemic disease. The mere statement of a diagnosis such as those mentioned in §2323C does not of itself indicate the severity of the condition. Where development is indicated to verify diagnosis and/or severity the carrier should follow existing claims processing practices which may include review of carrier's history and medical consultation as well as physician contacts.

c. A presumption of coverage may be made by the carrier where the claim or other evidence available discloses certain physical and/or clinical findings consistent with the diagnosis and indicative of severe peripheral involvement. For purposes of applying this presumption, the following findings are pertinent:

Class A Findings
- Nontraumatic amputation of foot or integral skeletal portion thereof

Class B Findings
- Absent posterior tibial pulse
- Advanced trophic changes as (three required): hair growth (decrease or absence); nail changes (thickening); pigmentary changes (discoloration); skin texture (thin, shiny); skin color (rubor or redness)
- Absent dorsalis pedis pulse

Class C Findings
- Claudication
- Temperature changes (e.g., cold feet)
- Edema
- Paresthesia (abnormal spontaneous sensations in the feet)
- Burning
The presumption of coverage may be applied when the physician rendering the routine foot care has identified: (1) a Class A finding; (2) two of the Class B findings; or (3) one Class B and two Class C findings. Case evidencing findings falling short of these alternatives may involve podiatric treatment that may constitute covered care and should be reviewed by the carrier’s medical staff and developed as necessary.
For purposes of applying the coverage presumption where the routine services have been rendered by a podiatrist, the carrier may deem the active care requirement met if the claim or other evidence available discloses that the patient has seen an M.D. or D.O. for treatment and/or evaluation of the complicating disease process during the 6-month period prior to the rendition of the routine-type service or had come under such care shortly after the services were furnished usually as a result of a referral.

4120.2 Application of the "Reasonable and Necessary" Limitation to Foot Care Services.--In evaluating claims for foot care services, in addition to determining whether any of the other statutory limitations apply, carriers should assure that payment is made only for services which are "reasonable and necessary" for diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member. (See §2303.) Determinations as to whether a foot care service is reasonable and necessary should be made on the same basis as all other such determinations—that is, with the advice of medical consultants and with reference to accepted standards of medical practice and the circumstances of the individual case. With appropriate professional consultation, guidelines should be established concerning the scope, frequency, and duration of services which would constitute reasonable and necessary utilization of services for various foot conditions; these guidelines should be used to screen out for denial, claims in which the services billed would clearly not be reasonable and necessary and to screen out questionable cases for special review or further development.

For example, infections of the feet and toenails which cause pain or deformity of sufficient degree to markedly limit ambulation, may require a variety of medical services such as physical examination, and laboratory tests for the purpose of diagnosing the existence and type of infectious condition (and differentiating it from other types of dermatoses), prescription of a regimen of treatment, periodic examinations throughout