Medicare
Carriers Manual
Part 3 - Claims Process

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

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CHANGE REQUEST 1426

THIS INSTRUCTION MANUALIZES PROGRAM MEMORANDA B-01-002 (CHANGE REQUEST 1426), B-01-017 (CHANGE REQUEST 1484), AND B-01-013 (CHANGE REQUEST 1531).

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
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4119 - 4121.2	4-33 - 4-38 (6 pp.)	4-33 - 4-38 (6 pp.)

MANUALIZATION--*EFFECTIVE DATE: Not Applicable*
IMPLEMENTATION DATE: Not Applicable

Section 4119, Durable Medical Equipment Regional Carrier (DMERC) Instructions For Denying Claims For Drugs Billed and/or Paid to Suppliers Not Licensed to Dispense Drugs, manualizes the three Program Memoranda noted above.

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.

CHAPTER IV
CLAIMS REVIEW AND ADJUDICATION PROCEDURES

Section

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 DRUGS BILLED AND/OR PAID TO SUPPLIERS NOT LICENSED TO DISPENSE DRUGS

Medicare does not cover a drug used as a supply with durable medical equipment (DME), or a prosthetic device, if the entity that dispensed the drug does not have a pharmacy license. Medicare does not consider such drugs to be reasonable and necessary because CMS cannot be assured of their safety and effectiveness. Medicare also does not consider the equipment beneficiaries use with such drugs to be reasonable and necessary, because of the related safety and efficacy concerns. CMS considers physicians as having been “deemed” the right to dispense prescription drugs. Therefore, physicians do not require a pharmacy license.

On October 11, 2000, CMS (then the Healthcare Financing Administration) published a final rule (65 FR 197) containing standards a supplier must meet in order to receive payment for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). The new regulations amend §424.57 of the Code of Federal Regulations (CFR), and are effective for all DMEPOS claims with dates of service (DOS) on or after December 11, 2000.

DMERCs must deny claims for a 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 DOS.

Exceptions

CMS has made an exception to this general policy for claims for oxygen and for EPO.

Messages

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. In the future, if you want Medicare to pay for this drug, you must obtain the drug from a licensed pharmacy." (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.)

Remittance for Related Equipment: "Claim/service denied because the related or qualifying claim/service was not paid or identified on the claim." (Remittance advice code #107, 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.

Appeals

Follow instructions in the Medicare Carriers Manual, Part 3-Claims Process, §12000.

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 the course of treatment to evaluate the status of the lesion and watch for complicating factors, and active treatment by one or a combination of the following modalities:

(1) surgical excision (avulsion) of the affected nail(s);
(2) mechanical debridement of the lesion;
(3) topical treatment; or
(4) systemic treatment.

With the appropriate advice from physicians who treat foot infections (e.g., dermatologists, podiatrists and surgeons), guidelines should be developed concerning accepted standards of medical practice with respect to appropriate utilization of the above types of services for different types of infectious conditions, taking into account such factors as the indications for various modalities of treatment, the required duration of different courses of therapy, and the required frequency of follow-up evaluation examinations. For example, when a physician prescribes a topical medication for an infection, patients are usually expected to perform most of the treatment by themselves at home (or if residing in nursing homes or skilled nursing facilities, etc., the staff of the facility is expected to perform most of the treatment), with perhaps occasional follow-up visits to (or by) the physician for evaluation of the status of the lesion. As part of the initial diagnostic and follow-up evaluation visits, the physician may cleanse the lesion and apply medication and these services would, of course, be covered where they are an accepted integral component of such visits; however, if the patient regularly comes to the physician to receive the care which he is expected to perform himself at home and there are no special medical circumstances relating to the infection warranting such special care, this would represent excessive utilization of physicians' services and should be excluded. Carriers' utilization guidelines should enable them to identify where a course of therapy involves more frequent follow-up visits than are the accepted standards of physician care for that modalityof therapy and to deny payment for such excessive visits unless there is documentation of special medical circumstances relating to the infection justifying the extra visits. For instance, in the case

of claims for patients whose initial course of treatment includes a medically necessary visit to the physician for mechanical debridement of a mycotic lesion of the toenail, carriers must use a 60-day claims processing screen for identifying excessive follow-up services for the patient (i.e., the presumption would be that only one follow-up visit is covered every 60 days following the end of the initial treatment period unless medical documentation is submitted that supports more frequent visits). Similarly, utilization guidelines should identify when visits extend beyond the period of follow-up evaluation which is the accepted standard for a particular course of treatment for an infection and to deny payment for visits beyond the period unless development reveals complications in the infectious condition necessitating more prolonged treatment.

4121. EXTRACORPOREAL IMMUNOADSORPTION (ECI) USING PROTEIN A COLUMNS

4121.1 Coverage Summary.--Extracorporeal immunoadsorption using Protein A columns has been developed for the purpose of selectively removing circulating immune complexes (CIC) and immunoglobulins (IgG) from patients in whom these substances are associated with their diseases. The technique involves pumping the patient's anticoagulated venous blood through a cell separator from which 1-3 liters of plasma are collected and perfused over adsorbent columns, after which the plasma rejoins the separated, unprocessed cells and is retransfused to the patient. Medicare covers this procedure for the conditions noted below.

A. For Claims with Dates of Service on or After May 6, 1991 Through December 31, 2000.--Medicare covers the use of Protein A columns only for the treatment of patients with idiopathic thrombocytopenia purpura (ITP) failing other treatments.

B. For Claims with Dates of Service on or After January 1, 2001.--Medicare continues to cover the use of Protein A columns for the treatment ITP failing other treatments. In addition, Medicare covers its use for the treatment of rheumatoid arthritis (RA) for patients having both of the following conditions:

1. Severe RA. Patient disease is active, having > 5 swollen joints, > 20 tender joints, and morning stiffness > 60 minutes.

2. Failed an adequate course of a minimum of 3 Disease Modifying Anti-Rheumatic Drugs (DMARDs). Failure does not include intolerance.

Other uses of these columns are currently considered to be investigational and/or experimental and, therefore, not reasonable and necessary under the Medicare law. (See §1862(a)(1)(A) of the Act; also refer to §35-90 of the Coverage Issues Manual.)

4121.2 Coding and Payment.--The following codes and payment methodology apply to claims for ECI using protein A columns. Deny claims lacking the appropriate procedure-diagnosis code combinations for the dates of service indicated.

A. For Claims with Dates of Service on or After January 1, 2000.--

Code		
CPT/Description (Short Descriptor)	ICD-9-CM/Description	Payment Methodology
36521/Therapeutic apheresis; plasma and/or cell exchange with extracorporeal affinity column adsorption and plasma reinfusion	287.3/Primary thrombocytopenia;	Refer to the Medicare Physician Fee Schedule Database.

B. For Claims with Dates of Service on or After January 1, 2001.--

Code		
CPT/Description (Short Descriptor)	ICD-9-CM/Description	Payment Methodology
36521/Therapeutic apheresis; plasma and/or cell exchange with extracorporeal affinity column adsorption and plasma reinfusion	287.3/Primary thrombocytopenia; 714.0/Rheumatoid arthritis 714.1/Felty's Syndrome 714.2/Other rheumatoid arthritis with visceral or systemic involvement 714.30, 714.31, 714.32, 714.33/Types of juvenile rheumatoid arthritis	Refer to the Medicare Physician Fee Schedule Database.

C. For Claims With Dates of Service From May 6, 1991 Through December 31, 1999.--
Use HCPCS code Q0068 (Extracorporeal plasmaphersis immunoadsorption with staphylococcal protein A columns) and ICD-9-CM 287.3.