Medicare Coverage Issues Manual

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

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HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
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NEW/REVISED MATERIAL--*EFFECTIVE DATE: July 1, 2002*
IMPLEMENTATION DATE: July 1, 2002

Section 50-8.1, Services Provided for the Diagnosis and Treatment of Diabetic Sensory Neuropathy With Loss of Protective Sensation (aka Diabetic Peripheral Neuropathy), is added to delineate the coverage policy for foot care related to diabetic peripheral neuropathy with loss of protective sensation. This service is covered as a physician service under section 1861(s)(1) of the Social Security Act (the Act).

This section of the Coverage Issues Manual is a national coverage decision (NCD). NCDs are binding on all Medicare carriers, intermediaries, peer review organizations, Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans. Under 42 CFR 422.256 (b), an NCD that expands coverage is also binding on a Medicare+Choice Organization. In addition, an administrative law judge may not review an NCD. (See §1869 (f)(1)(A)(i) of the Act.).

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.

Supplies - Drugs

Diagnostic Services

50-8 CONSULTATION SERVICES RENDERED BY A PODIATRIST IN A SKILLED NURSING FACILITY

Consultation services rendered by a podiatrist in a skilled nursing facility are covered if the services are reasonable and necessary and do not come within any of the specific statutory exclusions. Section l862(a)(13) of the Act excludes payment for the treatment of flat foot conditions, the treatment of subluxations of the foot, and routine foot care. To determine whether the consultation comes within the foot care exclusions, apply the same rule as for initial diagnostic examinations, i.e., where services are performed in connection with specific symptoms or complaints which suggest the need for covered services, the services are covered regardless of the resulting diagnosis. The exclusion of routine physician examinations is also pertinent and would generally exclude podiatric consultation performed on all patients in a skilled nursing facility on a routine basis for screening purposes, except in those cases where a specific foot ailment is involved. Section l862(a)(7) of the Act excludes payment for routine physical checkups.

Cross-refer: Intermediary Manual, §§3157, 3158; Carriers Manual, §2323

50-8.1 SERVICES PROVIDED FOR THE DIAGNOSIS AND TREATMENT OF DIABETIC SENSORY NEUROPATHY WITH LOSS OF PROTECTIVE SENSATION (AKA DIABETIC PERIPHERAL NEUROPATHY)

Presently, peripheral neuropathy, or diabetic sensory neuropathy, is the most common factor leading to amputation in people with diabetes. In diabetes, sensory neuropathy is an anatomically diffuse process primarily affecting sensory and autonomic fibers; however, distal motor findings may be present in advanced cases. Long nerves are affected first, with symptoms typically beginning insidiously in the toes and then advancing proximally. This leads to loss of protective sensation (LOPS), whereby a person is unable to feel minor trauma from mechanical, thermal, or chemical sources. When foot lesions are present, the reduction in autonomic nerve functions may also inhibit wound healing.

Diabetic sensory neuropathy with LOPS is a localized illness of the feet and falls within the regulation's exception to the general exclusionary rule [see 42 C.F.R. § 411.15 (l)(1)(i)]. Foot exams for people with diabetic sensory neuropathy with LOPS are reasonable and necessary to allow for early intervention in serious complications that typically afflict diabetics with the disease.

Effective for services furnished on or after July 1, 2002, Medicare covers, as a physician service, an evaluation (examination and treatment) of the feet no more often than every six months for individuals with a documented diagnosis of diabetic sensory neuropathy and LOPS, as long as the beneficiary has not seen a foot care specialist for some other reason in the interim. LOPS shall be diagnosed through sensory testing with the 5.07 monofilament using established guidelines, such as those developed by the National Institute of Diabetes and Digestive and Kidney Diseases guidelines. Five sites should be tested on the plantar surface of each foot, according to the National Institute of Diabetes and Digestive and Kidney Diseases guidelines. The areas must be tested randomly since the loss of protective sensation may be patchy in distribution, and the patient may get clues if the test is done rhythmically. Heavily callused areas should be avoided. As suggested by the American Podiatric Medicine Association, an absence of sensation at two or more sites out of 5 tested on either foot when tested with the 5.07 Semmes-Weinstein monofilament must be present and documented to diagnose peripheral neuropathy with loss of protective sensation.

A. The examination includes:

1) a patient history, and

2) a physical examination that must consist of *at least* the following elements:

a. visual inspection of forefoot and hindfoot (including toe web spaces);

b. evaluation of protective sensation;

c. evaluation of foot structure and biomechanics;

d. evaluation of vascular status and skin integrity;

e. evaluation of the need for special footwear; and

3) patient education.

A. Treatment includes, but is not limited to:

1) local care of superficial wounds;

2) debridement of corns and calluses; and

3) trimming and debridement of nails.

The diagnosis of diabetic sensory neuropathy with LOPS should be established and documented prior to coverage of foot care. Other causes of peripheral neuropathy should be considered and investigated by the primary care physician prior to initiating or referring for foot care for persons with LOPS.

50-9 GASTROPHOTOGRAPHY

Gastrophotography is an accepted procedure for diagnosis and treatment of gastrointestinal disorders. The photographic record provided by this procedure is often necessary for consultation and/or followup purposes and when required for such purposes, is more valuable than a conventional gastroscopic examination. Such a record facilitates the documentation and evaluation (healing or worsening) of lesions such as the gastric ulcer, facilitates consultation between physicians concerning difficult-to-interpret lesions, provides preoperative characterization for the surgeon, and permits better diagnosis of postoperative gastric bleeding to help determine whether there is a need for reoperation. Therefore, program reimbursement may be made for this procedure.

50-10 VABRA ASPIRATOR

The VABRA aspirator is a sterile, disposable, vacuum aspirator which is used to collect uterine tissue for study to detect endometrial carcinoma. The use of this device is indicated where the patient exhibits clinical symptoms or signs suggestive of endometrial disease, such as irregular or heavy vaginal bleeding.

Program payment cannot be made for the aspirator or the related diagnostic services when furnished in connection with the examination of an asymptomatic patient. Payment for routine physical checkups is precluded under the statute (§l862(a)(7) of the Act).

Cross-refer: Intermediary Manual, §3157; Carriers Manual §2320; §50-4

50-12 COMPUTERIZED TOMOGRAPHY

A. General.--Diagnostic examinations of the head (head scans) and of other parts of the body (body scans) performed by computerized tomography (CT) scanners are covered if you find that the medical and scientific literature and opinion support the effective use of a scan for the condition, and the scan is: (1) reasonable and necessary for the individual patient; and (2) performed on a model of CT equipment that meets the criteria in C below.

CT scans have become the primary diagnostic tool for many conditions and symptoms. CT scanning used as the primary diagnostic tool can be cost effective because it can eliminate the need for a series of other tests, is non-invasive and thus virtually eliminates complications, and does not require hospitalization.

B. Determining Whether a CT Scan Is Reasonable and Necessary.--Sufficient information must be provided with claims to differentiate CT scans from other radiology services and to make coverage determinations. Carefully review claims to insure that a scan is reasonable and necessary for the individual patient; i.e., the use must be found to be medically appropriate considering the patient's symptoms and preliminary diagnosis.

There is no general rule that requires other diagnostic tests to be tried before CT scanning is used. However, in an individual case the contractor's medical staff may determine that use of a CT scan as the initial diagnostic test was not reasonable and necessary because it was not supported by the patient's symptoms or complaints stated on the claim form; e.g., "periodic headaches."

Continue to review claims for CT scans for evidence of abuse which might include the absence of reasonable indications for the scans, an excessive number of scans or unnecessarily expensive types of scans considering the facts in the particular cases.

C. Approved Models of CT Equipment.--

1. Criteria for Approval.--In the absence of evidence to the contrary, you may assume that a CT scan for which payment is requested has been performed on equipment that meets the following criteria:

- The model must be known to the Food and Drug Administration, and
- Must be in the full market release phase of development.

Should it be necessary to confirm that those criteria are met, ask the manufacturer to submit the information in subsection C.2. If manufacturers inquire about obtaining Medicare approval for their equipment, inform them of the foregoing criteria.

2. Evidence of Approval

a. The letter sent by the Bureau of Radiological Health, Food and Drug Administration (FDA), to the manufacturer acknowledging the FDA's receipt of information on the specific CT scanner system model submitted as required under Public Law 90-602, "The Radiation Control for Health and Safety Act of 1968."

b. A letter signed by the chief executive officer or other officer acting in a similar capacity for the manufacturer which:

(1) Furnishes the CT scanner system model number, all names that hospitals and physicians' offices may use to refer to the CT scanner system on claims, and the accession number assigned by FDA to the specific model;

(2) Specifies whether the scanner performs head scans only, body scans only (i.e., scans of parts of the body other than the head), or head and body scans;

(3) States that the company or corporation is satisfied with the results of the developmental stages that preceded the full market release phase of the equipment, that the equipment is in the full market release phase, and the date on which it was decided to put the product into the full market release phase.

D. Mobile CT Equipment.--CT scans performed on mobile units are subject to the same Medicare coverage requirements applicable to scans performed on stationary units, as well as certain health and safety requirements recommended by PHS. As with scans performed on stationary units, the scans must be determined medically necessary for the individual patient. The scans must be performed on types of CT scanning equipment that have been approved for use as stationary units (see C above), and must be in compliance with applicable State laws and regulations for control of radiation.

1. Hospital Setting.--The hospital must assume responsibility for the quality of the scan furnished to inpatients and outpatients and must assure that a radiologist or other qualified physician is in charge of the procedure. The radiologist or other physician (i.e., one who is with the mobile unit) who is responsible for the procedure must be approved by the hospital for similar privileges.

2. Ambulatory Setting.--If mobile CT scan services are furnished at an ambulatory health care facility other than a hospital-based facility, e.g., a freestanding physician-directed clinic, the diagnostic procedure must be performed by or under the direct personal supervision of a radiologist or other qualified physician. In addition, the facility must maintain a record of the attending physician's order for a scan performed on a mobile unit.

3. Billing for Mobile CT Scans.--Hospitals, hospital-associated radiologists, ambulatory health care facilities, and physician owner/operators of mobile units may bill for mobile scans as they would for scans performed on stationary equipment.

4. Claims Review.--Evidence of compliance with applicable State laws and regulations for control of radiation should be requested from owners of mobile CT scan units upon receipt of the first claims. All mobile scan claims should be reviewed very carefully in accordance with instructions applicable to scans performed on fixed units, with particular emphasis on the medical necessity for scans performed in an ambulatory setting.

E. Multiplanar Diagnostic Imaging (MPDI).--(Effective for services performed on or after 6-11-85.)

In usual computerized tomography (CT) scanning procedures, a series of transverse or axial images are reproduced. These transverse images are routinely translated into coronal and/or sagittal views. Multiplanar diagnostic imaging (MPDI) is a process which further translates the data produced by CT scanning by providing reconstructed oblique images which can contribute to diagnostic information. MPDI, also known as planar image reconstruction or reformatted imaging, is covered under Medicare when provided as a service to an entity performing a covered CT scan.

50-13 MAGNETIC RESONANCE IMAGING (Effective for services performed on or after 11-22-85.)

Magnetic resonance imaging (MRI), formerly called nuclear magnetic resonance (NMR), is covered under Medicare when furnished as described below for the types of covered conditions described in this instruction.

A. General

1. Method of Operation.--Magnetic resonance imaging is a noninvasive method of graphically representing the distribution of water and other hydrogen-rich molecules in the human body. In contrast to conventional radiographs or CT scans, in which the image is produced by X-ray beam attenuation by an object, MRI is capable of producing images by several techniques. In fact, various combinations of MR image production methods may be employed to emphasize particular characteristics of the tissue or body part being examined. The basic elements by which MRI produces an image are the density of hydrogen nuclei in the object being examined, their motion, and the relaxation times, the period of time required for the nuclei to return to their original states in the main, static magnetic field after being subjected to a brief additional magnetic field. These relaxation times reflect the physical-chemical properties of tissue and the molecular environment of its hydrogen nuclei. Only hydrogen atoms are present in human tissues in sufficient concentration for current use in clinical MRI.

2. General Clinical Utility.--Overall, MRI is a useful diagnostic imaging modality that is capable of demonstrating a wide variety of soft-tissue lesions with contrast resolution equal or superior to CT scanning in various parts of the body.