
Medicare Coverage Issues Manual

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<u>HEADER SECTION NUMBERS</u>	<u>PAGES TO INSERT</u>	<u>PAGES TO DELETE</u>
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NEW/REVISED MATERIAL--*EFFECTIVE DATE: April 1, 2002*
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Section 50-42, Ambulatory Blood Pressure Monitoring, is revised to change the coverage status from non-covered to covered and to clarify the conditions under which ambulatory blood pressure monitoring is covered.

This revision to 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 Social Security 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.

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50-37 NONINVASIVE TESTS OF CAROTID FUNCTION
(Effective for services performed on and after November 15, 1980)

Noninvasive tests of carotid function aid physicians in studying and diagnosing carotid disease. There are a variety of these tests which measure various anatomical and physiological aspects of carotid function, including pressure (systolic, diastolic, and pulse), flow, collateral circulation, and turbulence.

For operational purposes, it is useful to classify noninvasive tests of carotid function into direct and indirect tests. The direct tests examine the anatomy and physiology of the carotid artery, while the indirect tests examine hemodynamic changes in the distal beds of the carotid artery (the orbital and cerebral circulations).

It is important to note that the names of these tests are not standardized. Following are some of the acceptable tests, recognizing that this list is not inclusive and that determinations should be made by local medical consultants:

DIRECT TESTS

- Carotid Phonoangiography
- Direct Bruit Analysis
- Spectral Bruit Analysis
- Doppler Flow Velocity
- Ultrasound Imaging including Real Time B-Scan and Doppler Devices

INDIRECT TESTS

- Periorbital Directional Doppler Ultrasonography
- Oculoplethysmography
- Ophthalmodynamometry

50-38 ENDOTHELIAL CELL PHOTOGRAPHY
(Effective for services rendered on and after August 19, 1983)

Endothelial cell photography involves the use of a specular microscope to determine the endothelial cell count. It is used by ophthalmologists as a predictor of success of ocular surgery or certain other ocular procedures. Endothelial cell photography is a covered procedure under Medicare when reasonable and necessary for patients who meet one or more of the following criteria:

- o Have slit lamp evidence of endothelial dystrophy (cornea guttata),
- o Have slit lamp evidence of corneal edema (unilateral or bilateral),
- o Are about to undergo a secondary intraocular lens implantation,
- o Have had previous intraocular surgery and require cataract surgery,
- o Are about to undergo a surgical procedure associated with a higher risk to corneal endothelium; i.e., phacoemulsification, or refractive surgery (see §35-54 for excluded refractive procedures),
- o With evidence of posterior polymorphous dystrophy of the cornea or irido-corneal-endothelium syndrome, or
- o Are about to be fitted with extended wear contact lenses after intraocular surgery.

When a pre-surgical examination for cataract surgery is performed and the conditions of this section are met, if the only visual problem is cataracts, endothelial cell photography is covered as part of the presurgical comprehensive eye examination or combination brief/intermediate examination provided prior to cataract surgery, and not in addition to it. (See §35-44.)

50-39 TELEPHONE TRANSMISSION OF ELECTROENCEPHALOGRAMS

Telephone transmission of electroencephalograms (EEGs) is covered as a physician's service or as incident to a physician's service when reasonable and necessary for the individual patient, under appropriate circumstances. The service is safe, and may save time and cost in sending EEGs from remote areas without special competence in neurology, neurosurgery, and electroencephalography, by avoiding the need to transport patients to large medical centers for standard EEG testing.

Telephone transmission of EEGs has been most helpful in the following clinical situations:

- o Altered consciousness, such as stuporous, semicomatose, or comatose states;
- o Atypical seizure variants in patients experiencing bizarre, distressing symptoms as seen with "spike and wave stupor" or other forms of seizure disorders;
- o Diagnosis of a suspected intracranial tumor;
- o Head injury, where a subdural hematoma may be identified;
- o Headaches during the acute phase where, for instance, in migraine syndrome, abnormal responses may be seen.

Telephonically transmitted EEGs should not be used for determining electrical inactivity (i.e., brain death), because of unavoidable signal interference.

50-39.1 AMBULATORY ELECTROENCEPHALOGRAPHIC (EEG) MONITORING (Effective for services performed on or after June 12, 1984)

Ambulatory or 24-hour electroencephalographic (EEG) monitoring is accomplished by a cassette recorder that continuously records brain wave patterns during 24 hours of a patient's routine daily activities and sleep. The monitoring equipment consists of an electrode set, preamplifiers, and a cassette recorder. The electrodes attach to the scalp, and their leads are connected to a recorder, usually worn on a belt.

Ambulatory EEG monitoring is a diagnostic procedure for patients in whom a seizure diathesis is suspected but not defined by history, physical or resting EEG. Ambulatory EEG can be utilized in the differential diagnosis of syncope and transient ischemic attacks if not elucidated by conventional studies. Ambulatory EEG should always be preceded by a resting EEG.

Ambulatory EEG monitoring is considered an established technique and covered under Medicare for the above purposes.

50-40 STEREOTAXIC DEPTH ELECTRODE IMPLANTATION

Stereotaxic depth electrode implantation prior to surgical treatment of focal epilepsy for patients who are unresponsive to anticonvulsant medications has been found both safe and effective for diagnosing resectable seizure foci that may go undetected by conventional scalp electroencephalographs (EEGs).

The procedure employs thin wire electrodes which are implanted in the brain of the focal epileptic patient for EEG monitoring. By taking several readings during seizure activity, the location of the epileptic focus may be found, so that better informed decisions can be made regarding the surgical treatment of persons with intractable seizures.

50-41 HUMAN TUMOR STEM CELL DRUG SENSITIVITY ASSAYS

Human tumor stem cell drug sensitivity assays involve exposure of human tumor stem cell colonies grown in tissue culture to anticancer drugs and observing for cytotoxic effects. Their purpose is to screen potential anticancer drugs and predict the effects of these drugs on tumors of individual patients, to allow the selection of the most effective drug or drugs for that patient. Human tumor drug sensitivity assays are considered experimental, and therefore, not covered under Medicare at this time.

The Fluorescent Cytoprint Assay, a miniaturized organ culture system for cancer chemosensitivity testing, allows for qualitative visual estimation of cell kill using low power microscopy and a noncytotoxic fluorescence probe for cell viability. The clinical application of the assay, based on testing in tumor microorgans rather than in clones derived from single cells, is considered experimental, and therefore, not covered under Medicare at this time.

50-42 AMBULATORY BLOOD PRESSURE MONITORING

Ambulatory blood pressure monitoring (ABPM) involves the use of a non-invasive device which is used to measure blood pressure in 24-hour cycles. These 24-hour measurements are stored in the device and are later interpreted at the physician's office. ABPM must be performed for at least 24 hours to meet coverage criteria.

ABPM is only covered for those patients with suspected white coat hypertension. Suspected white coat hypertension is defined as 1) office blood pressure >140/90 mm Hg on at least three separate clinic/office visits with two separate measurements made at each visit; 2) at least two documented blood pressure measurements taken outside the office which are <140/90 mm Hg; and 3) no evidence of end-organ damage. The information obtained by ABPM is necessary in order to determine the appropriate management of the patient. ABPM is not covered for any other uses. In the rare circumstance that ABPM needs to be performed more than once in a patient, the qualifying criteria described above must be met for each subsequent ABPM test.

For those patients that undergo ABPM and have an ambulatory blood pressure of <135/85 with no evidence of end-organ damage, it is likely that their cardiovascular risk is similar to that of normotensives. They should be followed over time. Patients for which ABPM demonstrates a blood pressure of >135/85 may be at increased cardiovascular risk, and a physician may wish to consider antihypertensive therapy.

50-43 DIGITAL SUBTRACTION ANGIOGRAPHY

Digital subtraction angiography (DSA) is a diagnostic imaging technique that applies computer technology to fluoroscopy for the purpose of visualizing the same vascular structures observable with conventional angiography. Since the radiographic contrast material can be injected into a vein rather than an artery, the procedure reduces the risk to patients, and can be done on an outpatient basis.

Contractors should be alert to possible increases in utilization of DSA over conventional angiographic procedures, as well as to the fact that ordinarily patients should not require inpatient hospitalization solely to perform the procedure.

Reimbursement for DSA should not exceed, and may be less than, that being paid for conventional angiographic techniques. (See HCFA Pub. 14-3, §5242 for reasonable charge instructions.)

50-44 BONE (MINERAL) DENSITY STUDIES--Effective for services rendered on or after March 4, 1983.

Bone (mineral) density studies are used to evaluate diseases of bone and/or the responses of bone diseases to treatment. The studies assess bone mass or density associated with such diseases as osteoporosis, osteomalacia, and renal osteodystrophy. Various single or combined methods of measurement may be required to: (a) diagnose bone disease, (b) monitor the course of bone changes with disease progression, or (c) monitor the course of bone changes with therapy. Bone density is usually studied by using photodensitometry, single or dual photon absorptiometry, or bone biopsy.

THE FOLLOWING BONE (MINERAL) DENSITY STUDIES ARE COVERED UNDER MEDICARE:

A. Single Photon Absorptiometry--A non-invasive radiological technique that measures absorption of a monochromatic photon beam by bone material. The device is placed directly on the patient, uses a low dose of radionuclide, and measures the mass absorption efficiency of the energy used. It provides a quantitative measurement of the bone mineral of cortical and trabecular bone, and is used in assessing an individual's treatment response at appropriate intervals.

Single photon absorptiometry is covered under Medicare when used in assessing changes in bone density of patients with osteodystrophy or osteoporosis when performed on the same individual at intervals of 6 to 12 months.

B. Bone Biopsy--A physiologic test which is a surgical, invasive procedure. A small sample of bone (usually from the ilium) is removed, generally by a biopsy needle. The biopsy sample is then examined histologically, and provides a qualitative measurement of the bone mineral of trabecular bone. This procedure is used in ascertaining a differential diagnosis of bone disorders and is used primarily to differentiate osteomalacia from osteoporosis.

Bone biopsy is covered under Medicare when used for the qualitative evaluation of bone no more than four times per patient, unless there is special justification given. When used more than four times on a patient, bone biopsy leaves a defect in the pelvis and may produce some patient discomfort.

C. Photodensitometry--(radiographic absorptiometry)--A noninvasive radiological procedure that attempts to assess bone mass by measuring the optical density of extremity radiographs with a photodensitometer, usually with a reference to a standard density wedge placed on the film at the time of exposure. This procedure provides a quantitative measurement of the bone mineral of cortical bone, and is used for monitoring gross bone change.

THE FOLLOWING BONE (MINERAL) DENSITY STUDY IS NOT COVERED UNDER MEDICARE:

Dual Photon Absorptiometry--A noninvasive radiological technique that measures absorption of a dichromatic beam by bone material. This procedure is not covered under Medicare because it is still considered to be in the investigational stage.