
Medicare Coverage Issues Manual

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HEADER SECTION NUMBERS

50-41 - 50-44

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NEW/REVISED MATERIAL--*EFFECTIVE DATE: July 1, 2003*
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Section 50-42, Ambulatory Blood Pressure Monitoring, is revised to specify that a physician is required to perform the interpretation of the data obtained through ambulatory blood pressure monitoring, but that there are no requirements regarding the setting in which the **interpretation** is performed. Everything else in this national coverage determination remains unchanged.

This revision to the Coverage Issues Manual is a national coverage decision (NCD). The NCDs are binding on all Medicare carriers, intermediaries, peer review organizations, health maintenance organizations, competitive medical plans, and health 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.)

Provider Education: Contractors must publish the above information in their next regularly scheduled bulletin and place it on their Web sites within 2 weeks of receiving this instruction. If you have a list-serv that targets the affected provider community, you should use it to notify subscribers that information about a coverage decision for Ambulatory Blood Pressure Monitoring is available on your Web site.

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.

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 by the physician. 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.

(This NCD last reviewed January 16, 2003)

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 CMS 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.