

---

# Medicare Coverage Issues Manual

---

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

Transmittal 159

Date: SEPTEMBER 27, 2002

---

CHANGE REQUEST 2232

<u>HEADER SECTION NUMBERS</u>	<u>PAGES TO INSERT</u>	<u>PAGES TO DELETE</u>
Table of Contents	2 pp.	2 pp.
50 – 58 (Cont.)	2 pp.	2 pp.

**NEW/REVISED MATERIAL--*EFFECTIVE DATE: January 1, 2003***  
***IMPLEMENTATION DATE: January 1, 2003***

Section 50-59, Percutaneous Image-Guided Breast Biopsy, is a new section that implements a new policy that covers percutaneous image-guided breast biopsy.

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 Social Security Act).

**These instructions shall 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.**

## COVERAGE ISSUES

Endothelial Cell Photography	50-38
Telephone Transmission of Electroencephalograms	50-39
Ambulatory Electroencephalographic (EEG) Monitoring	50-39.1
Stereotaxic Depth Electrode Implantation	50-40
Human Tumor Stem Cell Drug Sensitivity Assays	50-41
Ambulatory Blood Pressure Monitoring	50-42
Digital Subtraction Angiography	50-43
Bone (Mineral) Density Study	50-44
Lymphocyte Mitogen Response Assays	50-45
Transillumination Light Scanning, or Diaphanography	50-46
Cardiointegram (CIG) as an Alternative to Stress Test or Thallium Stress Test	50-47
Portable Hand-Held X-Ray Instrument	50-48
Computer Enhanced Perimetry	50-49
Displacement Cardiography	50-50
Diagnostic Breath Analyses	50-51
Serologic Testing for Acquired Immunodeficiency Syndrome (AIDS)	50-52
Food Allergy Testing and Treatment	50-53
Cardiac Output Monitoring by Electrical Bioimpedance	50-54
Prostate Cancer Screening Tests	50-55
Home Prothrombin Time International Normalized Ratio (INR) Monitoring for Anticoagulation Management	50-56
Current Perception Threshold/Sensory Nerve Conduction Threshold Test (sNCT)	50-57
Single Photon Emission Tomography - Covered	50-58
<b>Percutaneous Image-Guided Breast Biopsy</b>	<b>50-59</b>

### Dialysis Equipment

Water Purification and Softening Systems Used In Conjunction With Home Dialysis	55-1
Peridex CAPD Filter Set	55-2
Ultrafiltration Monitor	55-3

### Durable Medical Equipment

White Cane for Use by a Blind Person	60-3
Home Use of Oxygen	60-4
Power-Operated Vehicles That May Be Used as Wheelchairs	60-5
Specially Sized Wheelchairs	60-6
Self-Contained Pacemaker Monitors	60-7
Seat Lift	60-8
Durable Medical Equipment Reference List	60-9
Home Blood Glucose Monitors	60-11
Infusion Pumps	60-14
Safety Roller	60-15
Lymphedema Pumps	60-16
Continuous Positive Airway Pressure (CPAP)	60-17
Hospital Beds	60-18
Air-Fluidized Bed	60-19
Transcutaneous Electrical Nerve Stimulators (TENS)	60-20
Intrapulmonary Percussive Ventilator (IPV)	60-21
Vagus Nerve Stimulation for Treatment of Seizures	60-22
Speech Generating Devices	60-23
Non-Implantable Pelvic Floor Electrical Stimulator	60-24

## COVERAGE ISSUES

Noncontact Normothermic Wound Therapy (NNWT) 60-25

### Prosthetic Devices

Hydrophilic Contact Lenses	65-1
Electrical Continence Aid	65-2
Scleral Shell	65-3
Carotid Sinus Nerve Stimulator	65-4
Electronic Speech Aids	65-5
Cardiac Pacemakers	65-6
Intraocular Lenses (IOLs)	65-7
Electrical Nerve Stimulators	65-8
Incontinence Control Devices	65-9
Enteral and Parenteral Nutritional Therapy Covered as Prosthetic Device	65-10
Parenteral Nutrition Therapy	65-10.1
Enteral Nutrition Therapy	65-10.2
Nutritional Supplementation	65-10.3
Bladder Stimulators (Pacemakers)	65-11
Phrenic Nerve Stimulator	65-13
Cochlear Implantation	65-14
Artificial Hearts and Related Devices	65-15
Tracheostomy Speaking Valve	65-16
Urinary Drainage Bags	65-17
Sacral Nerve Stimulation For Urinary Incontinence	65-18

### Braces - Trusses - Artificial Limbs and Eyes

Corset Used as Hernia Support	70-1
Sykes Hernia Control	70-2
Prosthetic Shoe	70-3

### Patient Education Programs

Institutional and Home Care Patient Education Programs	80-1
Diabetes Outpatient Self-Management Training	80-2
Medical Nutrition Therapy	80-3

### Nursing Services

Home Health Visits to a Blind Diabetic	90-1
Home Health Nurses' Visits to Patients Requiring Heparin Injections	90-2

**50-56 HOME PROTHROMBIN TIME INTERNATIONAL NORMALIZED RATIO (INR) MONITORING FOR ANTICOAGULATION MANAGEMENT**

Use of the International Normalized Ratio (INR) allows physicians to determine the level of anticoagulation in a patient independent of the laboratory reagents used. The INR is the ratio of the patient's prothrombin time compared to the mean prothrombin time for a group of normal individuals. Maintaining patients within the therapeutic range minimizes adverse events associated with inadequate or excessive anticoagulation such as serious bleeding or thromboembolic events. Patient self-testing and self-management through the use of a home INR monitor may be used to improve the time in therapeutic rate (TTR) for select groups of patients. Increased TTR leads to improved clinical outcomes and reductions in thromboembolic and hemorrhagic events.

Home prothrombin monitoring with the use of INR devices is covered only for patients with mechanical heart valves. The monitor and the home testing must be prescribed by a treating physician as provided at 42 C.F.R. 410.32 (a) and the following requirements must be met:

1. The patient must have been anticoagulated for at least three months prior to use of the home INR device;
2. The patient must undergo an educational program on anticoagulation management and the use of the device prior to its use in the home; and
3. Self-testing with the device should not occur more frequently than once a week.

**50-57.1 CURRENT PERCEPTION THRESHOLD/SENSORY NERVE CONDUCTION THRESHOLD TEST (sNCT) NONCOVERED**

The Current Perception Threshold/Sensory Nerve Conduction Threshold (sNCT) test is a diagnostic test used to diagnose sensory neuropathies. The device is a noninvasive test that uses transcutaneous electrical stimuli to evoke a sensation. There is insufficient scientific or clinical evidence to consider this device reasonable and necessary within the meaning of Section 1862(a)(1)(A) of the law and will not be covered by Medicare.

**50-58 SINGLE PHOTON EMISSION TOMOGRAPHY – COVERED**

Single-photon emission computed tomography (SPECT) acquires information on the concentration of radionuclides introduced into the patient's body. It is useful in the diagnosis of several clinical conditions including:

- stress fracture
- spondylosis
- infection (e.g., discitis)
- tumor (e.g., osteoid osteoma)
- analyze blood flow to an organ, as in the case of myocardial viability
- differentiate ischemic heart disease from dilated cardiomyopathy.

Frequency limitations: Contractor discretion.

In the case of myocardial viability, FDG PET may be used following a SPECT that was found to be inconclusive. However, SPECT may not be used following an inconclusive FDG PET performed to evaluate myocardial viability.

#### 50-59 PERCUTANEOUS IMAGE-GUIDED BREAST BIOPSY

Percutaneous image-guided breast biopsy is a method of obtaining a breast biopsy through a percutaneous incision by employing image guidance systems. Image guidance systems may be either ultrasound or stereotactic.

The Breast Imaging Reporting and Data System (or BIRADS system) employed by the American College of Radiology provides a standardized lexicon with which radiologists may report their interpretation of a mammogram. The BIRADS grading of mammograms is as follows: Grade I-Negative, Grade II-Benign finding, Grade III-Probably benign, Grade IV-Suspicious abnormality, and Grade V-Highly suggestive of malignant neoplasm.

##### A. Nonpalpable Breast Lesions.--

Effective January 1, 2003, Medicare covers percutaneous image-guided breast biopsy using stereotactic or ultrasound imaging for a radiographic abnormality that is nonpalpable and is graded as a BIRADS III, IV, or V.

##### B. Palpable Breast Lesions.--

Effective January 1, 2003, Medicare covers percutaneous image guided breast biopsy using stereotactic or ultrasound imaging for palpable lesions that are difficult to biopsy using palpation alone. Contractors have the discretion to decide what types of palpable lesions are difficult to biopsy using palpation.