
Medicare Coverage Issues Manual

Department of Health and
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HEALTH CARE FINANCING
ADMINISTRATION (HCFA)

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REFER TO CHANGE REQUEST 1660

<u>HEADER SECTION NUMBERS</u>	<u>PAGES TO INSERT</u>	<u>PAGES TO DELETE</u>
50-32 – 50-35	3pp.	2pp.

NEW/REVISED MATERIAL--*EFFECTIVE DATE: July 1, 2001*
IMPLEMENTATION DATE: July 1, 2001

Section 50-32, Percutaneous Transluminal Angioplasty (PTA), is revised to allow coverage of PTA of the carotid artery concurrent with carotid stent placement when furnished in accordance with the Food and Drug Administration approved protocols governing Category B Investigational Device Exemption (IDE) clinical trials.

Performance of PTA in the carotid artery when used to treat obstructive lesions outside of approved protocols governing Category B IDE clinical trials remains a noncovered service.

PTA to treat obstructive lesions of the vertebral and cerebral arteries remains noncovered. The safety and efficacy of these procedures have not been established.

This revision is a national coverage decision (NCD) made under §1862 (a)(1) of the Social Security Act. NCDs are binding on all Medicare carriers, intermediaries, peer review organizations, and other contractors. 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 disregard, set aside, or otherwise review a NCD issued under §1862 (a)(1). (See 42 CFR 405.732 and 405.860.)

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 previous published in the manual and is only being reprinted.

50-32 PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA)

This procedure involves inserting a balloon catheter into a narrow or occluded blood vessel to recanalize and dilate the vessel by inflating the balloon.

PTA is covered to treat the following indications:

- o Atherosclerotic obstructive lesions:
 - In the lower extremities, i.e., the iliac, femoral, and popliteal arteries, or in the upper extremities, i.e., the innominate, subclavian, axillary, and brachial arteries. The upper extremities do not include head or neck vessels.
 - Of a single coronary artery for patients for whom the likely alternative treatment is coronary bypass surgery and who exhibit the following characteristics:
 - + Angina refractory to optimal medical management;
 - + Objective evidence of myocardial ischemia; and
 - + Lesions amenable to angioplasty;
 - Of the renal arteries for patients in whom there is an inadequate response to a thorough medical management of symptoms and for whom surgery is the likely alternative. PTA for this group of patients is an alternative to surgery, not simply an addition to medical management.
- o Obstructive lesions of arteriovenous dialysis fistulas and grafts when performed through either a venous or arterial approach.

PTA is not covered to treat obstructive lesions of the carotid artery except in the following circumstance:

o Effective July 1, 2001, Medicare will cover PTA of the carotid artery concurrent with carotid stent placement when furnished in accordance with the Food and Drug Administration (FDA) approved protocols governing Category B Investigational Device Exemption (IDE) clinical trials. PTA of the carotid artery, when provided solely for the purpose of carotid artery dilation concurrent with carotid stent placement, is considered to be a reasonable and necessary service only when provided in the context of such a clinical trial, and therefore is considered a covered service for the purposes of these trials. Performance of PTA in the carotid artery when used to treat obstructive lesions outside of approved protocols governing Category B IDE clinical trials remains a noncovered service.

PTA is not covered to treat obstructive lesions of the vertebral and cerebral arteries. The safety and efficacy of these procedures have not been established.

50-33 UROFLOWMETRIC EVALUATIONS (Effective for services performed on and after January 1, 1980)

Uroflowmetric evaluations (also referred to as urodynamic voiding or urodynamic flow studies) are covered under Medicare for diagnosing various urological dysfunctions, including bladder outlet obstructions.

50-34 OBSOLETE OR UNRELIABLE DIAGNOSTIC TESTS

A. Diagnostic Tests (Effective for services performed on or after May 15, 1980).--Do not routinely pay for the following diagnostic tests because they are obsolete and have been replaced by more advanced procedures. The listed tests may be paid for only if the medical need for the procedure is satisfactorily justified by the physician who performs it. When the services are subject to PRO review, the PRO is responsible for determining that satisfactory medical justification exists. When the services are not subject to PRO review, the intermediary or carrier is responsible for determining that satisfactory medical justification exists. This includes:

- o Amylase, blood isoenzymes, electrophoretic,
- o Chromium, blood,
- o Guanase, blood,
- o Zinc sulphate turbidity, blood,
- o Skin test, cat scratch fever,
- o Skin test, lymphopathia venereum,
- o Circulation time, one test,
- o Cephalin flocculation,
- o Congo red, blood,
- o Hormones, adrenocorticotropin quantitative animal tests,
- o Hormones, adrenocorticotropin quantitative bioassay,
- o Thymol turbidity, blood,
- o Skin test, actinomycosis,
- o Skin test, brucellosis,
- o Skin test, psittacosis,
- o Skin test, trichinosis,
- o Calcium, feces, 24-hour quantitative,
- o Starch, feces, screening,
- o Chymotrypsin, duodenal contents,
- o Gastric analysis, pepsin,
- o Gastric analysis, tubeless,
- o Calcium saturation clotting time,
- o Capillary fragility test (Rumpel-Leede),
- o Colloidal gold,
- o Bendien's test for cancer and tuberculosis,
- o Bolen's test for cancer,
- o Rehfuess test for gastric acidity, and
- o Serum seromucoid assay for cancer and other diseases.

B. Cardiovascular Tests (Effective for services performed on or after January 1, 1997).--Do not pay for the following phonocardiography and vectorcardiography diagnostic tests because they have been determined to be outmoded and of little clinical value. They include:

- o CPT code 93201, Phonocardiogram with or without ECG lead; with supervision during recording with interpretation and report (when equipment is supplied by the physician),

- o CPT code 93202, Phonocardiogram; tracing only, without interpretation and report (e.g., when equipment is supplied by the hospital, clinic),
- o CPT code 93204, Phonocardiogram; interpretation and report,
- o CPT code 93205, Phonocardiogram with ECG lead, with indirect carotid artery and/or jugular vein tracing, and/or apex cardiogram; with interpretation and report,
- o CPT code 93208, Phonocardiogram; without interpretation and report,
- o CPT code 93209, Phonocardiogram; interpretation and report only,
- o CPT code 93210, Intracardiac,
- o CPT code 93220, Vectorcardiogram (VCG), with or without ECG; with interpretation and report,
- o CPT code 93221, Vectorcardiogram; tracing only, without interpretation and report,
- o CPT code 93222, Vectorcardiogram; interpretation and report only.

50-35 SWEAT TEST

The sweat test is an important diagnostic tool in cystic fibrosis and may be covered when used for that purpose. Usage of the sweat test as a predictor of efficacy of sympathectomy in peripheral vascular disease is unproven and, therefore, is not covered.