

CMS Manual System

Pub 100-03 Medicare National Coverage Determinations

Transmittal 33

Department of Health &
Human Services

Center for Medicare and &
Medicaid Services

Date: APRIL 22, 2005

CHANGE REQUEST 3811

SUBJECT: Percutaneous Transluminal Angioplasty (PTA)

I. SUMMARY OF CHANGES: This change request provides instructions for billing PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent. Effective March 17, 2005, Medicare covers PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent with embolic protection for the following:

- Patients who are at high risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis $\geq 70\%$. Coverage is limited to procedures performed using FDA-approved carotid artery stenting systems and embolic protection devices;

In addition, CMS determines that CAS with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. Standards to determine competency will include specific physician training standards, facility support requirements, and data collection to evaluate outcomes during a required reevaluation. CMS created a list of minimum standards modeled in part on professional society statements on competency. All facilities must at least meet CMS's standards as outlined in Pub. 100-03, section 20.7, of the NCD Manual. Coverage is limited to procedures performed using FDA-approved carotid artery stenting systems and embolic protection devices.

The CMS also determined that carotid artery stenting with embolic protection is reasonable and necessary for the following:

- Patients who are at high risk for CEA and have symptomatic carotid artery stenosis between 50% and 70%, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare National Coverage Determination (NCD) Manual 310.1), or in accordance with the NCD on carotid artery stenting (CAS) post-approval studies (Medicare NCD Manual 20.7)
- Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis $\geq 80\%$, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1), or in accordance with the NCD on CAS post- approval studies (Medicare NCD Manual 20.7).

This revision to Pub. 100-03, section 20.7, is a national coverage determination (NCD) made under section 1862(a)(1) of the Social Security Act. NCDs are binding on all carriers, fiscal

intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, health care prepayment plans, the Medicare Appeals Council, and administrative law judges (see 42 CFR sections 405.732, 405.860). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an administrative law judge may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.

NEW/REVISED MATERIAL :

EFFECTIVE DATE : March 17, 2005

IMPLEMENTATION DATE : July 5, 2005

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS:

R = REVISED, N = NEW, D = DELETED

R/N/D	Chapter / Section / SubSection / Title
R	1/Table of Contents
R	1/20.7/Percutaneous Transluminal Angioplasty (PTA) (Effective March 17, 2005)

III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2005 operating budgets.

IV. ATTACHMENTS:

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Medicare National Coverage Determinations Manual

Chapter 1 - Coverage Determinations

Table of Contents

(Rev.33, 04-22-05)

20.7 - Percutaneous Transluminal Angioplasty (PTA) (Effective March 17, 2005)

**20.7 - Percutaneous Transluminal Angioplasty (PTA) (Effective March 17, 2005)
(Rev.33, Issued: 04-22-05, Effective: 03-17-05, Implementation: 07-05-05)**

A. General

This procedure involves inserting a balloon catheter into a narrow or occluded blood vessel to recanalize and dilate the vessel by inflating the balloon. The objective of PTA is to improve the blood flow through the diseased segment of a vessel so that vessel patency is increased and embolization is decreased. With the development and use of balloon angioplasty for treatment of atherosclerotic and other vascular stenoses, PTA (with and without the placement of a stent) is a widely used technique for dilating lesions of peripheral, renal, and coronary arteries.

B. Nationally Covered Indications

PTA is covered to treat the following indications:

1. 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.

Of arteriovenous dialysis fistulas and grafts when performed through either a venous or arterial approach.

2. Effective July 1, 2001, Medicare covers 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 when provided in the context of such a clinical trial.

3. Effective October 12, 2004, Medicare covers PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing post-approval studies. CMS determines that coverage of PTA of the carotid artery is reasonable and necessary under these circumstances.

4. *Effective March 17, 2005, Medicare covers PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent with embolic protection for the following:*

- *Patients who are at high risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis $\geq 70\%$. Coverage is limited to procedures performed using FDA-approved carotid artery stenting systems and embolic protection devices;*
- *Patients who are at high risk for CEA and have symptomatic carotid artery stenosis between 50% and 70%, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare National Coverage Determinations Manual (NCD), 310.1), or in accordance with the NCD on carotid artery stenting (CAS) post-approval studies (Medicare NCD Manual 20.7);*
- *Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis $\geq 80\%$, in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1), or in accordance with the NCD on CAS post-approval studies (Medicare NCD Manual 20.7).*

Patients at high risk for CEA are defined as having significant comorbidities and/or anatomic risk factors (i.e., recurrent stenosis and/or previous radical neck dissection), and would be poor candidates for CEA in the opinion of a surgeon.

Significant comorbid conditions include but are not limited to:

- *congestive heart failure (CHF) class III/IV;*
- *left ventricular ejection fraction (LVEF) $< 30\%$;*
- *unstable angina;*
- *contralateral carotid occlusion;*
- *recent myocardial infarction (MI);*
- *previous CEA with recurrent stenosis ;*
- *prior radiation treatment to the neck; and*
- *other conditions that were used to determine patients at high risk for CEA in the prior CAS trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II.*

Symptoms of carotid artery stenosis include carotid transient ischemic attack (distinct focal neurologic dysfunction persisting less than 24 hours), focal cerebral ischemia producing a nondisabling stroke (modified Rankin scale < 3 with symptoms for 24 hours or more),¹ and transient monocular blindness (amaurosis fugax). Patients who have had a disabling stroke (modified Rankin scale ≥ 3) would be excluded from coverage.

The determination that a patient is at high risk for CEA and the patient's symptoms of carotid artery stenosis should be available in the patient medical records prior to performing any procedure.

The degree of carotid artery stenosis should be measured by duplex Doppler ultrasound or carotid artery angiography and recorded in the patient medical records. If the stenosis is measured by ultrasound prior to the procedure, then the degree of stenosis must be confirmed by angiography at the start of the procedure. If the stenosis is determined to be less than 70% by angiography, then CAS should not proceed.

In addition, CMS determines that CAS with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. Standards to determine competency will include specific physician training standards, facility support requirements, and data collection to evaluate outcomes during a required reevaluation.

The CMS created a list of minimum standards modeled in part on professional society statements on competency. All facilities must at least meet CMS's standards in order to receive coverage for CAS for high risk patients.

- Facilities must have necessary imaging equipment, device inventory, staffing, and infrastructure to support a dedicated carotid stent program. Specifically, high-quality X-ray imaging equipment is a critical component of any carotid interventional suite, such as high resolution digital imaging systems with the capability of subtraction, magnification, road mapping, and orthogonal angulation.*
- Advanced physiologic monitoring must be available in the interventional suite. This includes real time and archived physiologic, hemodynamic, and cardiac rhythm monitoring equipment, as well as support staff who are capable of interpreting the findings and responding appropriately.*
- Emergency management equipment and systems must be readily available in the interventional suite such as resuscitation equipment, a defibrillator, vasoactive and antiarrhythmic drugs, endotracheal intubation capability, and anesthesia support.*
- Each institution should have a clearly delineated program for granting carotid stent privileges and for monitoring the quality of the individual interventionalists and the program as a whole. The oversight committee for this program should be empowered to identify the minimum case volume for an operator to maintain privileges, as well*

as the (risk-adjusted) threshold for complications that the institution will allow before suspending privileges or instituting measures for remediation. Committees are encouraged to apply published standards from national specialty societies recognized by the American Board of Medical Specialties to determine appropriate physician qualifications. Examples of standards and clinical competence guidelines include those published in the December 2004 edition of the American Journal of Neuroradiology, and those published in the August 18, 2004, Journal of the American College of Cardiology.

- *To continue to receive Medicare payment for CAS under this decision, the facility or a contractor to the facility must collect data on all CAS procedures done at that particular facility. This data must be analyzed routinely to ensure patient safety, and will also be used in the process of re-credentialing the facility. This data must be made available to CMS upon request. The interval for data analysis will be determined by the facility but should not be less frequent than every 6 months.*

Since there currently is no recognized entity that evaluates CAS facilities, CMS established a mechanism for evaluating facilities. Facilities must provide written documentation to CMS that the facility meets one of the following:

1. *The facility was an FDA-approved site that enrolled patients in prior CAS IDE trials, such as SAPHIRE, and ARCHER;*
2. *The facility is an FDA-approved site that is participating and enrolling patients in ongoing CAS IDE trials, such as CREST;*
3. *The facility is an FDA-approved site for one or more FDA post-approval studies;*
or,
4. *The facility has provided a written affidavit to CMS attesting that the facility has met the minimum facility standards. This should be sent to:*

*Director, Coverage and Analysis Group
7500 Security Boulevard, Mailstop C1-09-06
Baltimore, MD 21244.*

*The letter must include the following information:
Facility's name and complete address;
Facility's Medicare provider number;
Point-of-contact for questions with telephone number;
Mechanism of data collection of CAS procedures; and,
Signature of a senior facility administrative official.*

A list of approved facilities will be made available and viewable at <http://www.cms.hhs.gov/coverage/carotid-stent-facilities.asp>. In addition, CMS will publish a list of approved facilities in the Federal Register. A new affidavit is required every two years to ensure that facilities maintain high standards.

C. Nationally Noncovered Indications

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

D. Other

All other indications for PTA for which CMS has not specifically indicated coverage remain noncovered.

(This NCD last reviewed April 2005.)