

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 64	Date: JANUARY 5, 2007
	Change Request 5432

SUBJECT: Intracranial Percutaneous Transluminal Angioplasty (PTA) with Stenting

I. SUMMARY OF CHANGES: CMS has determined that PTA and stenting of intracranial arteries is reasonable and necessary for treatment of cerebral artery stenosis greater than or equal to 50% in patients with intracranial atherosclerotic disease when furnished in accordance with FDA-approved protocols governing Category B IDE clinical trials. All other indications for PTA with or without stenting to treat obstructive lesions of vertebral and cerebral arteries remain noncovered. This addition/revision of section 20.7 of Pub.100-03 is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, qualified independent contractors, the Medicare Appeals Council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

NEW/REVISED MATERIAL

EFFECTIVE DATE: NOVEMBER 6, 2006

IMPLEMENTATION DATE: February 5, 2007

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/revise information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

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)

III. FUNDING:

No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2007 operating budgets.

IV. ATTACHMENTS:

**Business Requirements
Manual Instruction**

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

Medicare National Coverage Determinations Manual

Chapter 1, Part 1 (Sections 10 – 80.12)

Coverage Determinations

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(Rev.64, 01-05-07)

20.7 – Percutaneous Transluminal Angioplasty (PTA)

20.7 – Percutaneous Transluminal Angioplasty (PTA)

(Rev.64, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

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 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 NCD Manual 310.1), or in accordance with the National Coverage Determination 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 National Coverage Determination 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 carotid artery stenting trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II.

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.

In addition, CMS has determined 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 carotid artery stenting 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.¹ Committees are encouraged to apply published standards from national specialty societies recognized by the American Board of Medical Specialties² 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 Neuroradiology³, and those published in the August 18, 2004 Journal of the American College of Cardiology.⁴

- To continue to receive Medicare payment for CAS under this decision, the facility or a contractor to the facility must collect data on all carotid artery stenting 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 has 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 SAPPHIRE, 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 certified 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.

¹ Facility guidelines based on Clinical Competence Statement on Carotid Stenting: Training and Credentialing for Carotid Stenting Multispecialty Consensus Recommendations 2004 Society for Cardiovascular Angiography and Interventions; Society for Vascular Medicine and Biology; and Society for Vascular Surgery.

² ABMS at <http://www.abms.org/approved.asp>.

³ Connors et al., 2004. "Training, Competency, and Credentialing Standards for Diagnostic Cervicocerebral Angiography, Carotid Stenting, and Cerebrovascular Intervention"

⁴ Creager et al., 2004.

5. *Effective November 6, 2006, Medicare covers PTA and stenting of intracranial arteries for the treatment of cerebral artery stenosis $\geq 50\%$ in patients with intracranial atherosclerotic disease when furnished in accordance with the Food and Drug Administration (FDA)-approved protocols governing Category B Investigational Device Exemption (IDE) clinical trials. CMS determines that coverage of intracranial PTA and stenting is reasonable and necessary under these circumstances.*

C. Nationally Noncovered Indications

All other indications for PTA *with or without stenting* to treat obstructive lesions of the vertebral and cerebral arteries remain 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 *November 2006*.)