

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 98	Date: December 24, 2008
	Change Request 6301

SUBJECT: Percutaneous Transluminal Angioplasty of the Carotid Artery Concurrent With Stenting

I. SUMMARY OF CHANGES: The Centers for Medicare and Medicaid Services (CMS) has decided to make no changes to the national coverage determination (NCD) for percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stenting. The NCD for PTA of the carotid artery concurrent with stenting continues to provide coverage for the certain patient populations under specific conditions.

This revision is an 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: OCTOBER 14, 2008

IMPLEMENTATION DATE: January 26, 2009

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: (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) (Various Effective Dates Below)

III. FUNDING:

SECTION A: For Fiscal Intermediaries and Carriers:

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

SECTION B: For Medicare Administrative Contractors (MACs):

The Medicare administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the contracting officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question

and immediately notify the contracting officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment - Business Requirements

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SUBJECT: Percutaneous Transluminal Angioplasty of the Carotid Artery Concurrent With Stenting

Effective Date: October 14, 2008

Implementation Date: January 26, 2009

I. GENERAL INFORMATION

A. Background: The Centers for Medicare & Medicaid Services (CMS) received a request to revise its current policy on carotid artery stenting (CAS) to cover patients at high risk for carotid endarterectomy (CEA) due to defined anatomic factors, and who have either symptomatic carotid artery stenosis of 50-69% (or greater) or asymptomatic carotid artery stenosis of greater than 80%.

Under the current policy, patients at high risk for CEA who have symptomatic carotid artery stenosis $\geq 70\%$ are covered for procedures performed using Food and Drug Administration-approved CAS systems with embolic protection devices in facilities approved by CMS to perform CAS procedures. In addition, patients at high risk for CEA with asymptomatic carotid artery stenosis between 50% and 70% and patients at high risk for CEA with asymptomatic carotid artery stenosis $\geq 80\%$ are covered in accordance with the Category B Investigational Device Exemption 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 CAS post-approval studies (Medicare NCD Manual 20.7, B.3).

B. Policy: Effective October 14, 2008, CMS decided to make no changes to the NCD for percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stenting. The NCD for PTA of the carotid artery concurrent with stenting continues to provide coverage for certain patient populations under specific conditions.

II. BUSINESS REQUIREMENTS TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A	D	F	C	R	Shared-System Maintainers				OTHER
		/	M	I	A	H	F	M	V	C	
		B	E		R	I	I	C	M	S	
		M	M		I		S	S	S	W	
		A	A		E					F	
		C	C		R						
6301.1	Effective October 14, 2008, contractors shall be aware that the current NCD policy on PTA of the carotid artery concurrent with stenting remains unchanged. See Pub. 100-03, section 20.7, for the complete instruction.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A	D	F	C	R	Shared-System Maintainers				OTHER
		/	M	I	A	H	F	M	V	C	
		B	E		R	I	I	C	M	S	
		M	M		I		S	S	S	W	
		A	A		E					F	
		C	C		R						

Medicare National Coverage Determinations Manual

Chapter 1, Part 1 (Sections 10 – 80.12) Coverage Determinations

Table of Contents *(Rev. 98, 12-24-08)*

20.7 – Percutaneous Transluminal Angioplasty (PTA) *(Various Effective Dates
Below)*

20.7 - Percutaneous Transluminal Angioplasty (PTA) (*Various Effective Dates Below*)

(Rev.98, Issued: 12-24-08, Effective: 10-14-08, Implementation: 01-26-09)

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.

Indications and Limitations of Coverage

B. Nationally Covered Indications

The PTA is covered when used under the following conditions:

1. Treatment of 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:

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. Concurrent with Carotid Stent Placement in Food and Drug Administration (FDA)-Approved Category B Investigational Device Exemption (IDE) Clinical Trials

Effective July 1, 2001, Medicare covers PTA of the carotid artery concurrent with carotid stent placement when furnished in accordance with the FDA-approved protocols governing Category B 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. Concurrent With Carotid Stent Placement in FDA-Approved Post-Approval Studies

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. Concurrent With Carotid Stent Placement in Patients at High Risk for Carotid Endarterectomy (CEA)

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 CEA and who also have symptomatic carotid artery stenosis >70 percent. 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 percent and 70 percent, 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 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 >80 percent, 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).

Coverage is limited to procedures performed using FDA approved carotid artery stents and embolic protection devices.

The use of a distal embolic protection device is required. If deployment of the distal embolic protection device is not technically possible, then the procedure should be aborted given the risks of CAS without distal embolic protection.

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. Significant comorbid conditions include but are not limited to:

- Congestive heart failure (CHF) class III/IV;
- Left ventricular ejection fraction (LVEF) < 30 percent;
- 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.

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

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

The degree of carotid artery stenosis shall be measured by duplex Doppler ultrasound or carotid artery angiography and recorded in the patient's 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 percent by angiography, then CAS should not proceed.

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 include specific physician training standards, facility support requirements and data collection to evaluate outcomes during a required reevaluation.

The CMS has 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 shall 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 shall 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 carotid artery stenting ensure patient safety. This data must be made available to CMS upon request. The interval for data analysis will be determined by the facility but shall 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 national provider identifier (formerly referred to as the Medicare provider number);
- Point-of-contact for questions with telephone number;
- Discussion of how each standard has been met by the hospital;
- 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.

Facilities must recertify every two (2) years in order to maintain Medicare coverage of CAS procedures. Recertification will occur when the facility documents that and describes how it continues to meet the CMS standards.

The process for recertification is as follows:

1. At 23 months after initial certification
 - Submission of a letter to CMS stating how the facility continues to meet the minimum facility standards as listed above.
2. At 27 months after initial certification:
 - Submission of required data elements for all CAS procedures performed on patients during the previous two (2) years of certification.
 - Data elements:
 - a. Patients' Medicare identification number if a Medicare beneficiary;
 - b. Patients' date of birth;
 - c. Date of procedure;
 - d. Does the patient meet high surgical risk criteria (defined below)?
 - Age >80;
 - Recent (< 30 days) Myocardial Infarction (MI);
 - Left Ventricle Ejection Fraction (LVEF) < 30 percent;
 - Contralateral carotid occlusion;

- New York Heart Association (NYHA) Class III or IV congestive heart failure;
 - Unstable angina: Canadian Cardiovascular Society (CCS) Class III/IV;
 - Renal failure: end stage renal disease on dialysis;
 - Common Carotid Artery (CCA) lesion(s) below clavicle;
 - Severe chronic lung disease;
 - Previous neck radiation;
 - High cervical Internal Carotid Artery (ICA) lesion(s);
 - Restenosis of prior carotid endarterectomy (CEA);
 - Tracheostomy;
 - Contralateral laryngeal nerve palsy.
- e. Is the patient symptomatic (defined below)?
- Carotid Transient Ischemic Attack (TIA) persisting less than 24 hours;
 - Non-disabling stroke: Modified Rankin Scale
 - Transient monocular blindness: amaurosis fugax.
- f. Modified Rankin Scale score if the patient experienced a stroke.
- g. Percent stenosis of stented lesion(s) by angiography.
- h. Was embolic protection used?
- i. Were there any complications during hospitalization (defined below)?
- All stroke: an ischemic neurologic deficit that persisted more than 24 hours;
 - MI;
 - All death.

Recertification is effective for two (2) additional years during which facilities will be required to submit the requested data every April 1 and October 1.

The CMS will consider the approval of national carotid artery stenting registries that provide CMS with a comprehensive overview of the registry and its capabilities, and the manner in which the registry meets CMS data collection and evaluation requirements. Specific standards for CMS approval are listed below. Facilities enrolled in a CMS approved national carotid artery stenting registry will automatically meet the data collection standards required for initial and continued facility certification. Hospitals' contracts with an approved registry may include authority for the registry to submit required data to CMS for the hospital. A list of approved registries will be available on the CMS Coverage Web site.

National Registries

As noted above, CMS will approve national registries developed by professional societies and other organizations and allow these entities to collect and submit data to CMS on behalf of participating facilities to meet facility certification and recertification requirements. To be eligible to perform these functions and become a CMS approved registry, the national registry, at a minimum, must be able to:

1. Enroll facilities in every U.S. state and territory;
2. Assure data confidentiality and compliance with HIPPA;
3. Collect the required CMS data elements as listed in the above section;
4. Assure data quality and data completeness;
5. Address deficiencies in the facility data collection, quality, and submission;
6. Validate the data submitted by facilities as needed;
7. Track long term outcomes such as stroke and death;
8. Conduct data analyses and produce facility specific data reports and summaries;
9. Submit data to CMS on behalf of the individual facilities; and
10. Provide quarterly reports to CMS on facilities that do not meet or no longer meet the CMS facility certification and recertification requirements pertaining to data collection and analysis.

Registries wishing to receive this designation from CMS must submit evidence that they meet or exceed our standards. Though the registry requirements pertain to CAS, CMS strongly encourages all national registries to establish a similar mechanism to collect comparable data on CEA. Having both CAS and CEA data will help answer questions about carotid revascularization, in general, in the Medicare population.

The CAS for patients who are not at high risk for CEA remains covered only in FDA-approved Category B IDE clinical trials under 42 CFR 405.201.

The CMS has determined that PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent is not reasonable and necessary for all other patients.

5. Concurrent with Intracranial Stent Placement in FDA-Approved Category B IDE Clinical Trials

Effective November 6, 2006, Medicare covers PTA and stenting of intracranial arteries for the treatment of cerebral artery stenosis >50 percent in patients with intracranial atherosclerotic disease when furnished in accordance with the FDA-approved protocols governing Category B IDE clinical trials. CMS determines that coverage of intracranial PTA and stenting is reasonable and necessary under these circumstances.

C. Nationally Non-covered Indications

All other indications for PTA with or without stenting to treat obstructive lesions of the vertebral and cerebral arteries remain non-covered. The safety and efficacy of these procedures are not established.

All other indications for PTA without stenting for which CMS has not specifically indicated coverage remain non-covered.

D. Other

Coverage of PTA with stenting not specifically addressed or discussed in this NCD is at local Medicare contractor discretion.

(This NCD last reviewed *October 2008*.)