CMS Manual System

Pub. 100-04 Medicare Claims Processing

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

Transmittal 531 **Date: APRIL 22, 2005**

CHANGE REQUEST 3811

SUBJECT: Percutaneous Transluminal Angioplasty (PTA) (Effective March 17, 2005)

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 ≥ 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 ≥ 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).

NEW/REVISED MATERIAL - EFFECTIVE DATE*: March 17, 2005
IMPLEMENTATION DATE: July 5, 2005

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
N/A	

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:

X	**Business Requirements**
	Manual Instruction
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

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

Attachment - Business Requirements

Pub. 100-04	Transmittal: 531	Date: April 22, 2005	Change Request 3811

SUBJECT: Percutaneous Transluminal Angioplasty (PTA) (Effective March 17, 2005)

I. GENERAL INFORMATION

A. Background: Effective July 1, 2001, Medicare covered 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

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.

B. **Policy** 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 ≥ 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 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 ≥ 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 $\geq$ 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 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 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 2 years to ensure that facilities maintain high standards.

II. BUSINESS REQUIREMENTS

"Shall" denotes a mandatory requirement
"Should" denotes an optional requirement

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3811.1	Effective for dates of service performed on and after March 17, 2005, contractors shall only pay carotid artery stenting (CAS) claims from facilities who are listed on the approved list which will be available at http://www.cms.hhs.gov/coverage/carotid-stent-facilities.asp NOTE: No payment for CAS shall be made for implantations performed before the date that the facility is added to the approved web site.	X		X						
3811.2	Effective for dates of service performed on and after March 17, 2005, carriers shall pay claims that contain the following for beneficiaries that meet the high risk criteria listed under the Policy section of this instruction and in the Pub 100-03, chapter 1, section 20.7. • ICD-9 CM 433.10 • Any of the following procedure codes: 37215 37216 0075T 0076T			X						
3811.3	Effective for dates of service performed on and after March 17, 2005, FIs shall pay claims that contain the following: • ICD-9 CM 433.10 • Procedure codes 00.61 and 00.63 Note: Provider must also bill V70.7 (Exam –	X								

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	clinical trial) as a secondary diagnosis for these claims with "From" dates before October 1, 2005. Providers must bill V70.7 in order to avoid unintentional Medicare Code Editor (MCE) editing. The unintentional edit will be corrected October 1, 2005. FIs shall not require V70.7 as basis for payment.									
3811.3.1	Effective for dates of service performed on and after March 17, 2005, FIs shall reject CAS claims that do not have both procedure code 00.61 AND procedure code 00.63.	X				X				
3811.4	Contractors shall deny claims where the service was performed in an unapproved facility.	X		X						
3811.4.1	Contractors shall use an appropriate Medicare Summary Message (MSN) and Claim Adjustment Reason code such as MSN #16.2 (This service cannot be paid when provided in this location/facility.) and Reason Code #58 (Payment adjusted because the treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service.).	X		X		X	X	X		
3811.5	Contractors shall deny CAS services for patients at high risk if the appropriate diagnosis is not on the claim.	X		X		X	X	X		
3811.5.1	Contractors shall use the appropriate MSN and claim adjustment reason codes such as: MSN #21.21 (This service was denied because Medicare only covers this service under certain circumstances.) and reason code #11 (The diagnosis is inconsistent with the procedure.)	X		X		X	X	X		

III. PROVIDER EDUCATION

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)

		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3811.1	A provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters shortly after the CR is released. You will receive notification of the article release via the established "medlearn matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within 1 week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin and incorporated into any educational events on this topic. Contractors are free to supplement Medlearn Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X						

IV. SUPPORTING INFORMATION AND POSSIBLE DESIGN CONSIDERATIONS

A. Other Instructions:

X-Ref Requirement #	Instructions
3811.3	FIs should accept CAS claims on either an 11X type of bill or 12X type of bill.

B. Design Considerations: N/A

X-Ref Requirement #	Recommendation for Medicare System Requirements

C. Interfaces: N/A

D. Contractor Financial Reporting /Workload Impact: N/A

E. Dependencies: N/A

F. Testing Considerations: N/A

V. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: March 17, 2005 **Implementation Date: July 5, 2005** **Pre-Implementation Contact(s): Rana Hogarth, rhogarth@cms.hhs.gov (coverage), Vera Dillard, vdillard@cms.hhs.gov (Part B), Joe Bryson, jbryson@cms.hhs.gov (Part A)** **Post-Implementation Contact(s):**	**Medicare contractors shall implement these instructions within their current operating budgets.**

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