CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 1925	**Date: March 5, 2010**
	Change Request 6839

SUBJECT: Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting

I. SUMMARY OF CHANGES: Effective for claims with dates of service on and after December 9, 2009, contractors shall be aware that percutaneous transluminal angioplasty (PTA) concurrent with carotid artery stenting (CAS) system placement in Food and Drug Administration-Approved post-approval studies, and PTA Concurrent with CAS system placement in patients at high risk for carotid endarterectomy includes revised language specific to embolic protection devices. See Pub. 100-03, Medicare National Coverage Determination Manual, section 20.7 for detailed information in this regard.

EFFECTIVE DATE: December 9, 2009
IMPLEMENTATION DATE: April 5, 2010

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	32/160.1/Category B Investigational Device Exemption (IDE) Study Coverage
R	32/160.2/Post-Approval Study Coverage
R	32/160.3/Carotid Artery Stenting (CAS) With Embolic Protection Coverage

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:
No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

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

Pub. 100-04	Transmittal: 1925	Date: March 5, 2010	Change Request: 6839

SUBJECT: Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting

Effective Date: December 9, 2009
Implementation Date: April 5, 2010

I. GENERAL INFORMATION

A. Background: Under the current national coverage determination (NCD) policy, patients at high risk for carotid endarterectomy (CEA) who have symptomatic carotid artery stenosis≥70% are covered for procedures performed using Food and Drug Administration (FDA)-approved carotid artery stenting (CAS) systems with embolic protection devices (EPDs) in facilities approved by the Centers for Medicare & Medicaid Services (CMS) to perform CAS procedures. In addition, patients at high risk for CEA with symptomatic carotid artery stenosis between 50% and 70% and patients at high risk for CEA with asymptomatic carotid artery stenosis ≥80% are covered in accordance with the Category B Investigational Device Exemption (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 20.7B). If deployment of the EPD is not technically possible, then the procedure should be aborted given the risks of CAS without distal embolic protection.

B. Policy: CMS internally generated a reconsideration of section 20.7B4 of the Medicare NCD Manual. CMS made no changes in the covered patient groups for percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with stenting, but slightly revised language regarding EPDs. In the final decision, effective December 9, 2009, CMS retained existing coverage for the following with a slight revision to the language regarding EPDs:

- Patients who are at high risk for CEA and who also have symptomatic carotid artery stenosis ≥70%. Coverage is limited to procedures performed using FDA-approved CAS systems and FDA-approved or -cleared EPDs;

- 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 NCD on CAS post-approval studies (Medicare NCD Manual 20.7B). Coverage is limited to procedures performed using FDA-approved CAS systems and FDA-approved or -cleared EPDs. (If deployment of the EPD is not technically possible, and not performed, then the procedure is not covered.);

- 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 20.7B). Coverage is limited to procedures performed using FDA-approved CAS systems and FDA-approved or -cleared EPDs.

The use of an FDA-approved or cleared EPD is required. If deployment of the EPD is not technically possible, and not performed, then the procedure is not covered by Medicare.

NOTE: This CR does not require new or revised claims processing instructions.

II. BUSINESS REQUIREMENTS TABLE

Use"Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6839.1	Effective for claims with dates of service on and after December 9, 2009, contractors shall be aware that PTA concurrent with CAS system placement in FDA-Approved Post-Approval Studies, and PTA Concurrent with CAS system placement in patients at high risk for CEA, includes revised language specific to EPDs. See Pub. 100-03, section 20.7, and Pub. 100-04, chapter 32, section 160, for detailed information in this regard.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A/B MAC	DME MAC	FI	CARRIER	RHHI	Shared-System Maintainers				OTHER
							FISS	MCS	VMS	CWF	
6839.2	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles shortly after the CR is released. You will receive notification of the article release via the established "MLN 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 one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X	X						

IV. SUPPORTING INFORMATION

A. For any recommendations and supporting information associated with listed requirements, use the box below:

X-Ref Requirement Number	Recommendations or other supporting information:
N/A	

B. For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

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Post-Implementation Contact(s): CMS ROs

VI. FUNDING

A. For *Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs),* and/or *Carriers*:

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

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.

160.1 – Category B *Investigational Device Exemption (*IDE*)* Study Coverage
(Rev. 1925; Issued: 03-05-10; Effective Date: 12-09-09; Implementation Date: 04-05-10)

Effective July 1, 2001, Medicare covers *percutaneous transluminal angioplasty (*PTA) of the carotid artery concurrent with stent placement when furnished in accordance with the *Food and Drug Administration (*FDA*)* protocols governing Category B Investigational Device Exemption (IDE) studies.

The billing for this procedure is based upon how the service is delivered. There are several CPT codes that may be billed depending upon how the procedure is performed. Contractor medical directors should consider what provider education information is needed to assist providers on the billing for this service.

Contractors must review their local *coverage determinations* to ensure that payment is provided for claims for PTA in a*n* FDA-approved clinical study and deny any claims for services for PTA of the carotid artery when provided outside of a*n* FDA-approved clinical study.

As a requirement for Category B IDE coverage, providers must bill a six-digit IDE Number that begins with a "G" (i.e., G123456). To identify the line as an IDE line, *institutional* providers must bill this IDE Number on a 0624 Revenue Code line while *practitioners* must bill this IDE Number along with a *Q0* modifier.

160.2 – Post-Approval Study Coverage
(Rev. 1925; Issued: 03-05-10; Effective Date: 12-09-09; Implementation Date: 04-05-10)

Effective October 12, 2004, Medicare covers PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent *and an FDA-approved or –cleared embolic protection device (effective December 9, 2009)* for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing post-approval studies. Billing *p*ost-*a*pproval *s*tudies is similar to normal Category B *IDE* billing procedures, except that under *p*ost-*a*pproval coverage, providers must bill the Pre-Market Approval (PMA) number assigned to the stent system by the FDA. PMA numbers are like typical IDE Numbers in that they have six-digits, but they begin with a "P" (i.e., P123456) instead of *a* "G."

160.3 – Carotid Artery Stenting (CAS) With Embolic Protection Coverage
(Rev. 1925; Issued: 03-05-10; Effective Date: 12-09-09; Implementation Date: 04-05-10)

Effective March 17, 2005, Medicare covers PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent *with embolic protection* under specific patient indications found in *Pub. 100-03, Medicare* National Coverage Determinations Manual, part 1, section 20.7. *Coverage is limited to procedures performed using FDA-approved CAS systems and FDA-approved or –cleared (effective December 9, 2009) embolic protection devices (EPDs). If deployment of the EPD is not technically possible, and not performed, then the procedure is not covered.*

In addition to the specific patient indications, CMS 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. *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 recertify every 2 years in order to maintain coverage of CAS procedures.*