CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-04 Medicare Claims Processing	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 2113	**Date: December 10, 2010**
	Change Request 7249

SUBJECT: Payment for 510k Post-Approval Extension Studies Using 510k-Cleared Embolic Protection Devices during Carotid Artery Stenting (CAS) Procedures

I. SUMMARY OF CHANGES: Effective October 22, 2010, CMS has determined that all 510k post-approval extension studies must be reviewed by the FDA via its pre-IDE process. The FDA will issue an acknowledgement letter stating that the extension study is scientifically valid and will generate clinically relevant post-market data. Upon receipt of this letter and review of the 510k post-approval extension study protocol, CMS will issue a letter to the study sponsor indicating that the study under review will be covered by Medicare. These studies will be identified by the presence of a dedicated, 6-digit pre-IDE number, preceded by the letter "I" (i.e., I123456).

EFFECTIVE DATE: October 22, 2010
IMPLEMENTATION DATE: January 12, 2011

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-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
N	32/160/4/Table of Contents/510k Post-Approval Studies using 510k-Cleared Embolic Protection Devices during Carotid Artery Stenting (CAS) Procedures
N	32/160/4/510k Post-Approval Studies using 510k-Cleared Embolic Protection Devices during Carotid Artery Stenting (CAS) Procedures

III. FUNDING:
For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs):
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: 2113	Date: January 12, 2011	Change Request: 7249

SUBJECT: Payment for 510k Post-Approval Extension Studies Using 510k-Cleared Embolic Protection Devices during Carotid Artery Stenting (CAS) Procedures

Effective Date: October 22, 2010

Implementation Date: January 12, 2011

I. GENERAL INFORMATION

A. Background: On October 12, 2004, the Centers for Medicare and Medicaid Services (CMS) issued Change Request (CR) 3489, Transmittal (TR) 314, to provide contractors with instructions for processing claims for carotid artery stenting (CAS) procedures performed in Food and Drug Administration (FDA)-approved post-approval studies. As the post-approval studies began to end, CMS received requests to extend coverage for the post-approval studies. On May 12, 2006, CMS issued CR 5088, TR 951, announcing that patients participating in post-approval extension studies are also included in the covered population of patients participating in FDA-approved post-approval studies (see the national coverage determination (NCD) at Pub. 100-03, chapter 1, section 20.7).

Recently, the FDA issued 510k approvals for proximal embolic protection devices (EPDs), which are utilized in CAS procedures. Utilization of an EPD is required in the NCD, however, the 510k process does not involve a post-approval study requirement, as traditional FDA marketing approvals require. CMS received requests to include patients participating in studies following the FDA 510k approval of these devices, under the current coverage policy. The CMS has determined that these patients, similar to patients covered in traditional post-approval extension studies as discussed above, are eligible for coverage under the current coverage policy (NCD 20.7). The FDA does not require devices approved through the 510k process to undergo further study following clearance. As such, 510k post-approval extension studies are neither required by the FDA or subject to FDA approval. However, for the purposes of study review, the FDA evaluates traditional post approval extension studies and 510k post-approval extension studies via the Pre-Investigational Device Exemption (IDE) process. As a result of the Pre-IDE process, each study is assigned and identified by a single, 6-digit number preceded by the letter 'I' (i.e. I123456).

B. Policy: Effective October 22, 2010, CMS determined that all 510k post-approval extension studies must be reviewed by the FDA. The FDA will issue an acknowledgement letter stating that the extension study is scientifically valid and will generate clinically relevant post-market data. Upon receipt of this letter and review of the 510k post-approval extension study protocol, CMS will issue a letter to the study sponsor indicating that the study under review will be covered by Medicare. Since the FDA evaluates these studies via the Pre-IDE process, each 510k post-approval extension study will be identified by the "I" number assigned to the study when submitted to the FDA for review (i.e., the FREEDOM study, examining the 510k-cleared Gore Flow Reversal System, was assigned I090962, and will be identified on all claims as such).

In order to receive Medicare coverage for patients participating in 510k post-approval extension studies, providers shall follow the process for informing contractors of their participation as established in CR 3489. Providers shall submit both the FDA acknowledgement letter and the CMS letter providing coverage for the extension study to their contractor. Additionally, providers shall submit any other materials contractors would require for FDA-approved post-approval studies or post-approval extension studies.

In response, contractors will issue a letter assigning an effective date for each facility's participation in the extension study. Providers may bill for procedures performed in the extension study for dates of service on and after the assigned effective date. Providers shall follow the billing instructions from CR 3489, replacing the QA modifier with Q0. Providers billing fiscal intermediaries must bill using the most current ICD-9-CM procedure codes.

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	
7249.1	Contractors shall continue to follow the guidelines for processing post-approval study claims as directed in CR 3489, TR 314, issued October 15, 2004. Please note that the QA clinical trial modifier should be replaced with modifier Q0.	X		X	X						
7249.2	Upon receiving the FDA acknowledgement letter and CMS coverage letter, contractors shall issue a letter to the provider assigning an effective date for participation in the 510k post-approval extension study.	X		X	X						
7249.3	Contractors shall continue to load the IDE database that will now contain the 510k post-approval extension study pre-IDE 6-digit number preceded by an 'I'.	X		X	X						
7249.4	Contractors are not required to adjust claims for dates of service October 22, 2010, until the implementation date of this CR. However, contractors may adjust claims that are brought to their attention.	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	
7249.5	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	X		X	X						

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	
	information that would benefit their provider community in billing and administering the Medicare program correctly.										

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements:
Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:
7249.1 7249.3	See CR 3489

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

V. CONTACTS

Pre-Implementation Contact(s): Coverage Policy: Eileen Pencek, eileen.pencek@cms.hhs.gov, Sarah McClain, sarah.mcclain@cms.hhs.gov, Practitioner Claims Processing: Cynthia Thomas, Cynthia.Thomas2@cms.hhs.gov, Chanelle Jones, Chanelle.Jones@cms.hhs.gov, Institutional Claims Processing: Sarah Shirey-Losso Sara.Shirey-Losso@cms.hhs.gov.

Post-Implementation Contact(s): Appropriate CMS Regional Office and/or appropriate project officer.

VI. FUNDING

Section A: ***For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs):*** 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.

Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

160.4 – 510k Post-Approval Extension Studies using 510k-Cleared Embolic Protection Devices during Carotid Artery Stenting (CAS) Procedures

160.4 – 510k Post-Approval Extension Studies using 510k-Cleared Embolic Protection Devices during Carotid Artery Stenting (CAS) Procedures
(Rev.)

A. Background

As explained above in section 160.2, the Centers for Medicare & Medicaid Services (CMS) issued instructions in 2004 for processing claims for carotid artery stenting (CAS) procedures performed in Food and Drug Administration (FDA)-approved post-approval studies. As the post-approval studies began to end, CMS received requests to extend coverage for the post-approval studies. As explained above in section 160.2.1, CMS reviewed the extension requests and determined that patients participating in post-approval extension studies were also included in the covered population of patients participating in FDA-approved post-approval studies.

Recently, the FDA issued 510k approvals for proximal embolic protection devices (EPDs) which are utilized in CAS procedures. Utilization of an EPD is required in the Percutaneous Transluminal Angioplasty (PTA) national coverage determination (NCD) at Pub. 100-03, chapter 1, section 20.7. However the 510k process does not involve a post-approval study requirement as traditional FDA marketing approvals require. CMS received requests to include patients participating in studies following the FDA 510k approval of these devices under NCD 20.7. CMS subsequently determined that these patients, similar to patients covered in traditional post-approval extension studies, are eligible for coverage under the current coverage policy at NCD 20.7.

The FDA does not require devices approved through the 510k process to undergo further study following clearance. As such, 510k post-approval extension studies are neither required by the FDA or subject to FDA approval. However, for the purposes of study review, the FDA evaluates traditional post-approval extension studies and 510k post-approval extension studies via the Pre-Investigational Device Exemption (IDE) process. As a result of the Pre-IDE process, each study is assigned and identified by a single, 6-digit pre-IDE number, preceded by the letter 'I' (i.e. I123456).

B. Policy

Effective October 22, 2010, CMS has determined that all 510k post-approval extension studies must be reviewed by the FDA. The FDA will issue an acknowledgement letter stating that the extension study is scientifically valid and will generate clinically relevant post-market data. Upon receipt of this letter and review of the 510k post-approval extension study protocol, CMS will issue a letter to the study sponsor indicating that the study under review will be covered by Medicare. Since the FDA evaluates these studies via the Pre-IDE process, each 510k post-approval extension study will be identified by the 'I' number assigned to the study when submitted to the FDA for review (i.e., the FREEDOM study examining the 510k-cleared Gore Flow Reversal System was assigned I090962 and will be identified as such on all claims).

C. Billing

In order to receive Medicare coverage for patients participating in 510k post-approval extension studies, providers shall follow the same processes as explained above in section 160.2.1 (CAS for Post-Approval Studies). The only difference is that providers must report 510k-cleared devices with a pre-IDE number beginning with an "I", instead of an IDE number beginning with a "P" (post-market approval).

Contractors will issue a letter assigning an effective date for each facility's participation in the extension study. Providers may bill for procedures performed in the extension study for dates of service on and after the assigned effective date utilizing the most current ICD-9-CM procedure codes.