CMS Manual System

Pub 100-04 Medicare Claims Processing

Transmittal 951

Department of Health & Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

Date: MAY 12, 2006

Change Request 5088

SUBJECT: Payment for Carotid Artery Stenting (CAS) Post-Approval Extension Studies

I. SUMMARY OF CHANGES: The Centers for Medicare and Medicaid Services (CMS) has determined that all extension studies must be reviewed by the Food and Drug Administration (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 extension study protocol, CMS will issue a letter to the study sponsor indicating that the study under review will be covered by Medicare.

NEW/REVISED MATERIAL

EFFECTIVE DATE: February 28, 2006

IMPLEMENTATION DATE: June 12, 2006

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	32/160/160.2.1/Carotid Artery Stenting (CAS) Post-Approval Extension Studies

III. FUNDING:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2006 operating budgets.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

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

Attachment – Business Requirements

Pub. 100-04	Transmittal: 951	Date: May 12, 2006	Change Request 5088

SUBJECT: Payment for Carotid Artery Stenting (CAS) Post-Approval Extension Studies

I. GENERAL INFORMATION

A. Background: On October 12, 2004, the Centers for Medicare and Medicaid Services (CMS) issued Change Request (CR) 3489, Transmittal 314 to provide contractors with instructions for processing claims for carotid artery stenting procedures performed in the 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. CMS has reviewed the extension requests and has determined that patients participating in post-approval extension studies are also included in the currently covered population of patients participating in FDA-approved post-approval studies (Pub. 100-3, Chapter 1, §20.7).

To grant approval for post-approval studies, the FDA reviews each study protocol. Once approval is granted, the FDA issues a formal approval letter to the study sponsor. Extensions of post-approval studies are not subject to approval by the FDA because they surpass the post-approval study requirements identified in the conditions of approval for post-approval studies. Since the FDA cannot approve these extension studies, individual Post-Market Approval (PMA) numbers cannot be issued to separately identify each study. Currently, in order to receive reimbursement for procedures performed as part of a carotid artery stenting post-approval study, providers must include the FDA-issued PMA number on each claim to indicate participation in a specific study.

B. Policy: CMS has determined that all 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 extension study protocol, CMS will issue a letter to the study sponsor indicating that the study under review will be covered by Medicare. Since an individual PMA number cannot be assigned by the FDA to each extension study, these studies will use the PMA number assigned to the original FDA-approved post-approval study (i.e., CAPTURE 2 shall use the PMA number assigned to CAPTURE 1).

In order to receive Medicare coverage for patients participating in post-approval extension studies, providers shall follow the process for informing contractors of their participation as established in CR 3489, Transmittal 314. 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.

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, Transmittal 314. Providers billing fiscal intermediaries (FIs) must bill using the most current ICD-9 CM procedure codes. For example, when billing a CAS extension study with dates of service July 1, 2006,

through July 15, 2006, the provider should bill ICD-9 CM procedure codes 00.61 and 00.63 (instead of the 39.50 and 39.90 procedure codes published in CR 3489).

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	
5088.1	Contractors shall educate providers via Medicare Learning Network (MLN) matters article that providers participating in the Capture 2 post-approval extension study must submit copies of 2 letters to their local contractor, i.e., an FDA acknowledgement letter and a CMS coverage letter.	X		X						
5088.2	After receiving the above letters contractors shall issue a letter to the provider assigning an effective date for participation in the extension study, i.e., Capture 2 post-approval extension study.	X		X						
5088.2.1	Contractors shall educate providers to bill for procedures performed in the extension study for dates of service on and after the assigned effective date.	X		X						
5088.3	Contractors shall not search their files to either retract payment for claims already paid or to retroactively pay claims. However, contractors shall adjust claims brought to their attention.	X		X						
5088.4	Contractors shall continue to follow the guidelines for processing post-approval study claims as directed in Change Request 3489, Transmittal 314, issued October 15, 2004. Providers billing FIs must bill using the most current ICD-9 CM procedure codes. For example, when billing a CAS extension study with dates of service July 1, 2006, through July 15, 2006, the provider should bill ICD-9 CM	X		X						

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	procedure codes 00.61 and 00.63.									

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	
5088.5	A provider education article related to this instruction will be available at 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 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 MLN 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: N/A

X-Ref Requirement #	Instructions

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*: February 28, 2006 **Implementation Date:** June 12, 2006 **Pre-Implementation Contact(s):** Sarah McClain, coverage, (410) 786-2994; Vera A. Dillard, Carriers claim processing, (410) 786-6149; Joe Bryson, FI claims processing, (410) 786-2986. **Post-Implementation Contact(s):** Regional Office	**No additional funding will be provided by CMS; contractor activities are to be carried out within their FY 2006 operating budgets.**

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Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

(Rev.951, 05-12-06)

160.2.1 – Carotid Artery Stenting (CAS) Post-Approval Extension Studies

160.2.1 – Carotid Artery Stenting (CAS) Post-Approval Extension Studies

(Rev.951, Issued: 05-12-06, Effective: 02-28-06, Implementation: 06-12-06)

A. Background

As explained above in §160.2, CMS issued Change Request (CR) 3489, Transmittal 314 to provide contractors with instructions for processing claims for carotid artery stenting 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. CMS has reviewed the extension requests and has determined that patients participating in post-approval extension studies are also included in the currently covered population of patients participating in FDA-approved post-approval studies.

B. Policy

To grant approval for post-approval studies, the FDA reviews each study protocol. Once approval is granted, the FDA issues a formal approval letter to the study sponsor. Extensions of post-approval studies are not subject to approval by the FDA because they surpass the post-approval study requirements identified in the conditions of approval for post-approval studies. Since the FDA cannot approve these extension studies, individual Post-Market Approval (PMA) numbers cannot be issued to separately identify each study. Currently, in order to receive reimbursement for procedures performed as part of a carotid artery stenting post-approval study, providers must include the FDA-issued PMA number on each claim to indicate participation in a specific study.

CMS has determined that all 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 extension study protocol, CMS will issue a letter to the study sponsor indicating that the study under review will be covered by Medicare. Since an individual PMA number cannot be assigned by the FDA to each extension study, these studies will use the PMA number assigned to the original FDA-approved post-approval study (i.e., CAPTURE 2 shall use the PMA number assigned to CAPTURE 1).

C. Billing

In order to receive Medicare coverage for patients participating in post-approval extension studies, providers shall follow the process for informing contractors of their participation as established in CR 3489, Transmittal 314. 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.

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, Transmittal 314. Providers billing FIs must bill using the most current ICD-9 CM procedure codes. For example, when billing a CAS extension study with dates of service July 1, 2006, through July 15, 2006, the provider should bill ICD-9 CM procedure codes 00.61 and 00.63 (instead of the 39.50 and 39.90 procedure codes published in CR 3489).