CMS Manual System

Pub 100-04 Medicare Claims Processing

Transmittal 1042

Department of Health & Human Services (DHHS)

Centers for Medicare & Medicaid Services (CMS)

Date: AUGUST 25, 2006

Change Request 5022

NOTE: Transmittal 911, dated April 21, 2006 is rescinded and replaced with Transmittal 1042, dated August 25, 2006. The correction is in the manual text under section 160.1, last paragraph, which changed the last sentence from CA modifier to QA modifier. All other information remains the same

SUBJECT: Clarification on Billing Requirements for Percutaneous Transluminal Angioplasty (PTA) Concurrent With the Placement of an Investigational or FDA-Approved Carotid Stent

I. SUMMARY OF CHANGES: This CR provides instructions to: 1) modify the date driver in reason code 32087 to apply if the claim statement through date is 'less than 10/1/04,' instead of 'less than 3/17/05,' 2) modify the 'approval' facility edit to not apply to Category B IDE and post-approval trial claims, and 3) remove procedure code 37216 from the list of covered procedure codes for CAS with embolic protection.

NEW/REVISED MATERIAL

EFFECTIVE DATE: March 17, 2005

IMPLEMENTATION DATE: October 2, 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:

R = REVISED, N = NEW, D = DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	32/Table of Contents
N	32/160/PTA for Implanting the Carotid Stent
N	32/160.1/Category B IDE Trial Coverage
N	32/160.2/Post Approval Study Coverage

N	32/160.3/Carotid Artery Stenting (CAS) With Embolic Protection Coverage

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: 1042	Date: August 25, 2006	Change Request 5022

NOTE: Transmittal 911, dated April 21, 2006 is rescinded and replaced with Transmittal 1042, dated August 25, 2006. The correction is in the manual text under section 160.1, last paragraph, which changed the last sentence from CA modifier to QA modifier. All other information remains the same.

SUBJECT: Clarification on Billing Requirements for Percutaneous Transluminal Angioplasty (PTA) Concurrent With the Placement of an FDA-Approved Carotid Stent

I. GENERAL INFORMATION

A. **Background:** CR 1660 (Effective July 1, 2001) – Category B IDE Study coverage

Medicare covers PTA of the carotid artery concurrent with stent placement when furnished in accordance with the FDA protocols governing Category B Investigational Device Exemption (IDE) studies. As a requirement for Category B IDE coverage, providers must bill a six-digit IDE Number that begins with a "G" (i.e. G123456).

CR 3489 (Effective October 12, 2004) – Post-Approval Study coverage

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. As a requirement for Category B IDE post-approval coverage, providers must bill the Pre-Market Approval (PMA) number assigned to the stent system by the FDA. PMA numbers are similar to six-digit IDE Numbers, except they begin with a "P" (i.e. P123456).

CR 3811 (Effective March 17, 2005) – CAS with Embolic Protection coverage

Medicare covers PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent under specific patient indications. In addition to the specific patient indications, CMS determined that CAS with embolic protection is reasonable and necessary only if performed in facilities meeting specified facility requirements and are, therefore, determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. Facilities meeting facility standards for coverage are deemed "approved" for receiving Medicare payment for CAS with embolic protection and are viewable on the following web site: http://www.cms.hhs.gov/MedicareApprovedFacilitie/CASF/list.asp.

Issues

Per CR 3489, hospitals were instructed to bill the carotid stenting post-approval studies using procedure codes 39.50 and 39.90. Immediately prior to the release of CR 3489, The ICD-9 CM Coding Guidelines updated the aforementioned codes to 00.61 and 00.63. Since standard coding practice requires coders to

use the most updated codes available, providers began billing the post-approval studies with the 00.61 and 00.63 procedure codes, even though CR 3489 instructed them to use 39.50 and 39.90.

It appeared that this procedure code update did not have any affect on the processing of carotid stenting claims. However, because contractors could not distinguish between claims billed under the post-approval study (CR 3489) with claims billed under the coverage for CAS with embolic protection (CR 3811), edits created per CR 3811 began to be applied erroneously to post-approval study claims (Note: Because the same procedure codes are used in the Category B IDE study (per CR 1660), the post-approval study (per CR 3489), and the CAS with embolic protection performed outside of these studies (per CR 3811); contractors could not distinguish between the various trials/studies. Thus, edits intended for only one particular study has the potential of unintentionally being applied to all carotid stenting studies). This caused the following two issues:

1) Some Category B IDE study and Post-approval study claims were being rejected with either Reason Code 32087 or Reason Code 32811 when billed with procedure codes 00.61 and 00.63 with dates of service before March 17, 2005.

2) Some Category B IDE study claims and post-approval study claims billed, after the implementation of CR 3811, by providers who were not yet listed as an "approved facility" for CAS with embolic protection coverage, were being unintentionally rejected due to the "approved facility" edit (that would only pay for covered CAS with embolic protection services to facilities who are deemed "approved" and, thus, viewable on the following web site: http://www.cms.hhs.gov/MedicareApprovedFacilitie/CASF/list.asp) created in CR 3811.

NOTE: ICD-9 CM Coding Guidelines updated procedure codes 39.50 and 39.90 with procedure codes 00.61 and 00.63, effective 10/1/04. CR 3489 did not list the updated procedure codes in the instruction. Modifying the Reason Code 32087 and Reason Code 32811 (as shown in attachment 1) will prevent post-approval study claims from being erroneously rejected due to the fact they are correctly billing the updated procedure codes, 00.61 and 00.63.

Lastly, confusion arose when procedure code 37216 was on the list of covered procedure codes for CAS with embolic protection. Because 37216 is the procedure code for "transcatheter placement of intravascular stent(s) without distal embolic protection," it should not be on the list of covered procedure codes within CR 3811.

B. **Policy:** Claims that are being billed for Category B IDE studies and post-approval studies, per CR 1660 and CR 3489, respectively, are not subject to the same billing requirements as indicated in CR 3811.

This CR provides instructions to 1) modify the date drivers in Reason Code 32087 and 32811 2) modify the "approval" facility edit to not apply to Category B IDE and post-approval study claims, and 3) remove procedure code 37216 from the list of covered procedure codes for CAS with embolic protection.

C. 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	
5022.1	FISS shall modify reason code 32087, reason code 32812 and reason code 32811, as shown in attachment 1. Modifications in attachment 1 will update the reason codes to correspond to previous ICD-9 coding changes as well as prevent unintentional editing on a previous CAS study.					X				
5022.2	Effective for dates of service on or after March 17, 2005, contractors shall only pay CAS with embolic protection (CR 3811) claims from facilities who are listed on the approved list available at: http://www.cms.hhs.gov/MedicareApprovedFacilitie/CASF/list.asp.	X		X		X				
5022.2.1	Effective for dates of service on or after March 17, 2005, contractors shall ensure an edit for the approved facility is not applied to CAS claims billed under a Category B IDE study or post-approval study, identifiable through the use of an IDE or PMA number. Note: IDE numbers are preceded by a "G" (i.e. G123456) while PMA numbers are preceded by "P" (i.e. P123456).			X		X				
5022.2.2	If determined necessary, contractors should revise the disposition from a "deny" to a "reject" on any edits that currently deny claims from "unapproved" facilities trying to bill claims for CAS with embolic protection (per CR 3811).	X								

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
5022.3	Contractors shall adjust any Category B IDE study claims (per CR 1660) brought to their attention that had been previously denied due to the unintended application of the "approved" facility edit created per CR 3811.	X								
5022.4	Contractors shall adjust any post-approval study claims (per CR 3489) brought to their attention that had been previously denied due to the unintended application of the "approved" facility edit created per CR 3811.	X								
5022.5	Effective for dates of service on or after March 17, 2005, contractors shall not pay CAS with embolic protection claims that have procedure code 37216 (transcatheter placement of intravascular stent(s) without distal embolic protection). Note to Carriers: The CPT code 37216 will be included in the April 2006 quarterly update change request making it non-covered retroactively to March 17, 2005.			X			X			
5022.6	Contractors need not search their files to retract payment for claims already paid that contained CPT code 37216. However, contractors shall adjust claims brought to their attention.			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	
5022.7	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 "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: 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*: March 17, 2005 **Implementation Date:** October 2, 2006 **Pre-Implementation Contact(s):** **FIs:** Joe Bryson at joseph.bryson@cms.hhs.gov **Carriers:** Vera Dillard at vera.dillard@cms.hhs.gov **Coverage:** Sarah McClain at sarah.mcclain@cms.hhs.gov **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.**

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

Attachment

Explanation of Reason Code Modifications

Reason Code 32087

BEFORE implementation of CR 5022

- If procedure code 0061 exists on claim without procedure code 0063 or vice versa.
- If procedure code 0061 and 0063 exist on the claims and the type of bill does not equal 11X or 12X;
- If procedure codes 0061 and 0063 exist on the claim and the claim statement through dates is less than 03/17/2005.

UPON implementation of CR 5022

- If procedure code 0061 exists on claim without procedure code 0063 or vice versa.
- If procedure code 0061 and 0063 exist on the claim and the type of bill does not equal 11X or 12X;
- If procedure code 0061 and 0063 exist on the claim and the claim statement through date is less than **10/1/04**.

Reason Code 32812

BEFORE the implementation of CR 5022

If procedure codes 0061 and 0063 are present, then the PTA Indicator on the Provider File must equal a 'Y'.

UPON implementation of CR 5022

If procedure codes 0061 and 0063 are present, **and there is no Revenue Code 0624 on the claim,** then the PTA Indicator on the Provider File must equal a 'Y'.

Reason Code 32811

BEFORE the implementation of CR 5022

Procedure codes 0061 and 0063 are present and the claim statement through date is greater than or equal to 03/17/05, and diagnosis code 43310 is not present; and if 0061 and 0063 procedure codes are present and statement from date is less than 10/01/05 and diagnosis code V707 is not also on the claim.

UPON implementation of CR 5022

Procedure codes 0061 and 0063 are present and the claim statement through date is greater than or equal to **10/01/04**, and diagnosis code 43310 is not present; and if 0061 and 0063 procedure codes are present and statement from date is less than 10/01/05 and diagnosis code V707 is not also on the claim.

NOTE:: Modifications to reason codes are in bold font above.

Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

Table of Contents
(Rev.1042, 08-25-06)

160 – PTA for Implanting the Carotid Stent
(Rev.1042, Issued: 08-25-06, Effective: 03-17-05, Implementation: 10-02-06)

160.1 – Category B IDE Study Coverage
(Rev.1042, Issued: 08-25-06, Effective: 03-17-05, Implementation: 10-02-06)

CR 1660 (Effective July 1, 2001)

Medicare covers PTA of the carotid artery concurrent with stent placement when furnished in accordance with the 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 medical review policies to ensure that payment is provided for claims for PTA in a FDA approved clinical study and deny any claims for services for PTA of the carotid artery when provided outside of a 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, providers billing FIs must bill this IDE Number on a 0624 Revenue Code line while providers billing carriers must bill this IDE Number along with a QA modifier.

160.2 – Post Approval Study Coverage
(Rev.1042, Issued: 08-25-06, Effective: 03-17-05, Implementation: 10-02-06)

CR 3489 (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. Billing Post Approval Studies is similar to normal Category B IDEs billing procedures, except that under Post Approval 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 "G."

160.3 – Carotid Artery Stenting (CAS) With Embolic Protection Coverage
(Rev.1042, Issued: 08-25-06, Effective: 03-17-05, Implementation: 10-02-06)

CR 3811 (Effective March 17, 2005)

Medicare covers PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent under specific patient indications found in The National Coverage Determinations Manul, chapter 1, part 1, section 20.7. In addition to the specific patient indications, CMS determined that CAS with embolic protection is reasonable and necessary only if performed in facilities meeting specified facility requirements and are, therefore, determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. Facilities meeting facility standards for coverage are deemed "approved" for receiving Medicare payment for CAS with embolic protection and are viewable on the following Web site: http://www.cms.hhs.gov/MedicareApprovedFacilitie/CASF/list.asp.