CMS Manual System

Pub. 100-04 Medicare Claims Processing

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

Transmittal 314 **Date: October 15, 2004**

CHANGE REQUEST 3489

NOTE: This Transmittal replaces Transmittal 307, dated October 1, 2004, which you were instructed to hold until further notice. Business Requirement 3489.5 was removed and Business Requirement 3489.4 was modified for clarity. In addition, we have changed the effective and implementation dates to October 12, 2004, to reflect the official posting of the National Coverage Determination. All other information remains the same. You may disseminate this instruction to the public as usual.

SUBJECT: Percutaneous Transluminal Angioplasty (PTA)

I. SUMMARY OF CHANGES: Medicare will cover PTA of the carotid artery concurrent with placement of an FDA-approved carotid stent for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing post-approval studies. The CMS determines that coverage of PTA of the carotid artery is considered reasonable and necessary under these circumstances.

Performance of PTA of the carotid artery concurrent with carotid stent placement when furnished outside of FDA-approved protocols governing both FDA-required post-approval studies and FDA Category B IDE clinical trials remains noncovered.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: October 12, 2004
IMPLEMENTATION DATE: October 12, 2004

(This revision to §20.7 of Pub. 100-03 is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, health maintenance organizations, competitive medical plans, and health care prepayment plans. Under 42 CFR 422.256(b), an NCD that expands coverage is also binding on a Medicare Advantage Organizations. In addition, an administrative law judge may not review an NCD. (See §1869(f)(1)(A)(i) of the Social Security Act.)

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. 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 not updated.*)

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

III. FUNDING: Medicare contractors shall implement these instructions within their current 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: 314	Date: October 15, 2004	Change Request 3489

SUBJECT: Percutaneous Transluminal Angioplasty (PTA) (Effective October 12, 2004)

I. GENERAL INFORMATION

A. Background: Effective July 1, 2001, Medicare covers 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. The 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

B. Policy: 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. CMS determines that coverage of PTA of the carotid artery is reasonable and necessary under these circumstances.

Post-approval numbers will have the same function as IDE numbers. The post-approval numbers will be the same as the pre-market approval (PMA) numbers assigned by the FDA. IDE numbers are preceded with a “G” and have six positions, i.e., G123456. PMA numbers are preceded with a “P” and have six positions, i.e., P123456. Just as contractors now receive FDA letters from site/sponsors with an IDE number, they will receive FDA letters from site/sponsors with a PMA number.

While the post-approval carotid stent is not "technically" an IDE, the device is still undergoing study to understand whether the results of earlier clinical trials used for FDA approval can be generalized to other populations, settings, treatment regimens, and outcomes. The QA modifier is still required by carriers and revenue code 0624 is still required by fiscal intermediaries.

C. Provider Education: A Medlearn Matters provider education article related to this instruction will be available at www.cms.hhs.gov/medlearn/matters **after the final national coverage decision has been posted to the CMS Web.** 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 must be included in your next regularly scheduled bulletin. 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.

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	
3489.1	Carriers shall accept claims with the QA modifier for PTA post-approval study device claims. The provider should place **no more than one** pre-market approval **(**PMA) number (that begins with a 'P') in one of the following claim formats: • Item 23 of the CMS-1500 paper claim form • 2300 INVESTIGATIONAL DEVICE EXEMPTION NUMBER REF Segment, data element REF02 (REF01 = LX) of the 837p NOTE: The FDA-approved carotid stents are currently being used in ongoing clinical investigations. The provider must still continue to use the QA modifier when billing for a post-approval study device.			X						
3489.2	Fiscal intermediaries shall accept claims with revenue code 0624 for PTA post-approval study devices. The provider should place **no more than one** PMA number (that begins with 'P') in one of the following claim formats: • Form Locator 43 of the CMS-1450 paper claim form • 2300 INVESTIGATIONAL DEVICE EXEMPTION NUMBER REF Segment, data element REF02 (REF01 = LX) of the 837i NOTE: The FDA-approved carotid stents are currently being used in ongoing clinical investigations. The provider must still continue to use revenue code 0624 when billing for a post-approval study device.	X								
3489.2.1	Fiscal intermediaries shall accept PTA post-	X								

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
	approval study device claims with revenue code 0624 in one of the following claim formats: • Form Locator 42 of the CMS-1450 paper claim form • 2400 INSTITUTIONAL SERVICE LINE SV201 Segment, data element 234 of the 837i									
3489.3	Contractors should follow the same claims processing criteria for processing post-approval study devices that are currently in place for Category B investigational device exemptions (IDEs). (For example, a letter of verification that the device is a post-approval study device should be sent to the contractor before the provider bills for the device.)	X		X						
3489.4	Contractors shall continue to load the IDE database that will now contain the PMA number (that begins with 'P').	X					X	X		
3489.5	Carriers shall instruct providers via a Medlearn Matters article to use the following unlisted procedure code when billing for this procedure: 37799: Unlisted Procedure, Vascular Surgery			X						
3489.6	Contractors shall instruct providers via a Medlearn Matters article to bill for the device using the following diagnosis code: 433.10	X		X						
3489.7	Fiscal intermediaries shall instruct providers via a Medlearn Matters article to bill for the device using the following inpatient procedure codes: • 39.50: Angioplasty or atherectomy of non-coronary vessel • 39.90: Insertion of non-coronary artery stent or stent(s)	X								

Requirement Number	Requirements	Responsibility ("X" indicates the columns that apply)								
		FI	RHHI	Carrier	DMERC	Shared System Maintainers				Other
						FISS	MCS	VMS	CWF	
3489.8	Contractors shall educate the provider community about 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 via a Medlearn Matters Article. However, the article **will not be posted** until the final national coverage determination is posted on the CMS Web site.	X		X						

III. 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

IV. SCHEDULE, CONTACTS, AND FUNDING

Effective Date*: October 12, 2004 **Implementation Date:** October 12, 2004 **Pre-Implementation Contact(s):**	**Medicare contractors shall implement these instructions within their current operating budgets**.

Rana Hogarth (coverage policy), rhogarth@cms.hhs.gov Vera Dillard (Part B claims processing), vdillard@cms.hhs.gov Joe Bryson (Part A claims processing), jbryson2@cms.hhs.gov **Post-Implementation Contact(s):** Regional office	

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