Program Memorandum Intermediaries/Carriers

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

Transmittal AB-01-74 **Date: MAY 3, 2001**

CHANGE REQUEST 1660

SUBJECT: Claims Processing Instructions for Clinical Trials on Carotid Stenting With Category B Investigational Device Exemptions (IDEs)

The purpose of this Program Memorandum (PM) is to provide carriers and intermediaries with claims processing instructions on the processing of claims for clinical trials that utilize a Category B IDE for carotid stenting. Carriers and intermediaries must direct providers who submit these claims to follow the claims processing currently being utilized to process IDE claims. The claims processing instructions for the processing of routine care claims for clinical trial claims is not to be used in conjunction with our IDE claims processing requirements.

Background

Section 50-32 of the Coverage Issues Manual has been revised to reflect that effective July 1, 2001, Medicare will cover PTA of the carotid artery concurrent with carotid stent placement when furnished in accordance with the Food and Drug Administration approved protocols governing Category B IDE clinical trials.

Performance of PTA in the carotid artery when used to treat obstructive lesions outside of approved protocols governing Category B IDE clinical trials remains a noncovered service.

PTA of the vertebral and cerebral arteries remains noncovered.

Claims Processing Instructions for Carriers and Intermediaries

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.

Instructions for Both Carriers and Intermediaries

Contractors must review their local medical review policies to ensure that payment is provided for claims for PTA in a FDA approved clinical trial and deny any claims for services for PTA of the carotid artery when provided outside of a FDA approved clinical trial. Whenever a provider submits a claim for this service that lacks any of the required information for submitting an IDE claim, use the following messages:

MSN 16.10

Medicare does not pay for this item or service.

Medicare no paga por este articulo o servico.

Remittance Message B22

This claim/service is denied/reduced based on the diagnosis.

Carrier Claims Processing Instructions

Providers must bill these services following the claims processing instructions for Category B IDEs. These instructions require that the IDE claim be identified with the QA modifier and the IDE number assigned by the FDA.

You must issue a bulletin to providers notifying them how to submit these claims i.e., with the QA modifier and the location of the IDE on the claim form (both electronic and paper).

Intermediary Claims Processing Instructions

Follow the general bill review instructions in §3604 of the Medicare Intermediary Manual, Part 3. Providers must bill these services following the claims processing instructions for Category B IDEs. Hospitals bill you on Form HCFA-1450 or electronic equivalent using bill type 11x.

Intermediary Claims Processing Instructions for Hospital Outpatient Services

PTA of the carotid artery concurrent with carotid stent placement may not be performed in a hospital outpatient setting.

Intermediary Claims Processing Instructions for Hospital Inpatient Services

Principal diagnosis:	ICD-9-CM 433.10 or 433.11
Procedure codes:	39.50 Angioplasty or atherectomy of non-coronary vessel
	39.90 Insertion of non-coronary artery stent or stent(s)

Intermediaries must not install edits to ensure that both of these diagnosis codes are present on the claim as it is appropriate to bill these diagnosis codes separately.

You should notify your providers of the information contained in this PM.

The effective date for this PM is July 1, 2001.

The implementation date for this PM is July 1, 2001.

These instructions should be implemented within your current operating budget.

This PM may be discarded after July 1, 2002.

If you have any questions regarding this PM, you may contact your regional office.