Medlearn Matters
Information for Medicare Providers

Related Change Request (CR) #: 3489
Related CR Release Date: October 15, 2004
Related CR Transmittal #: 314 and 25
Effective Date: October 12, 2004
Implementation Date: October 12, 2004

Medlearn Matters Number: MM3489

# *Percutaneous Transluminal Angioplasty (PTA)*

## Provider Types Affected

Hospitals, physicians, and suppliers.

## Provider Action Needed

Effective October 12, 2004, Medicare will expand its coverage to include PTA of the carotid artery concurrent with placement of an FDA-approved carotid stent. This must be for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing post-approval studies. This is an addition to coverage in the context of an FDA-designated Category B Investigational Device Exemption (IDE) clinical trial.

## Background

Percutaneous Transluminal Angioplasty involves inserting a balloon catheter into a narrow or occluded blood vessel to recanalize and dilate the vessel by inflating the balloon. The objective of PTA is to improve the blood flow through the diseased segment of a vessel so that vessel patency is increased and embolization is decreased. PTA (with and without the placement of a stent) is used for dilating lesions of peripheral, renal, and coronary arteries.

PTA is covered to treat atherosclerotic obstructive lesions:

- in the lower extremities, and the upper extremities not including head or neck vessels;
- in treatment of a single coronary artery for patients for whom the likely alternative treatment is coronary bypass surgery and who exhibit certain characteristics;
- of the renal arteries for patients in whom there is an inadequate response to a thorough medical management of symptoms and for whom surgery is the likely alternative; and
- of arteriovenous dialysis fistulas and grafts when performed through either a venous or arterial approach.

PTA treatments that are not covered include:

- in the carotid artery when used to treat obstructive lesions outside of FDA-approved protocols governing Category B IDE clinical trials and outside of FDA-required post approval studies;
- to treat obstructive lesions of the vertebral and cerebral arteries;
- for all other indications for which CMS has not specifically indicated coverage.

## Additional Information

All providers should note that Fiscal Intermediaries (FIs) and carriers will follow the same procedures for processing post-approval study devices that are currently in place for Category B IDEs. For example, a letter of verification that the device is a post-approval study device should be sent to the carrier or intermediary before billing for the device.

In addition, providers billing carriers:

- Place no more than one Pre-Market Approval (PMA) number (that begins with a "P") in either item 23 of the CMS-1500 paper claim format or in the 2300 Investigational Device Exemption (IDE) Number Ref Segment, data element REF02 (REF01=LX) of the 837p claim format
- Use the QA modifier to reflect PTA post-approval study devices claim
- Use 37799, unlisted procedure, vascular surgery, as the procedure code
- Use 433.10 as the diagnostic code

For providers billing FIs:

- Place no more than one PMA number (that begins with a "P") in form locator 43 of the CMS-1450 paper form or in 2300 IDE Number Ref Segment, data element REF02 (REF01=LX) of the 837i
- Use revenue code 0624 for post-approval study devices in form locator 42 of the CMS-1450 paper claim form or 2400 Institutional Service Line SV201 Segment, data element 234 of the 837i
- Use 433.10 as the diagnostic code
- Use the inpatient procedure codes of 39.50 (angioplasty or atherectomy of non-coronary vessel) and 39.90 (insertion of non-coronary artery stent or stents)

The official instruction issued to your carrier regarding this change may be found at:

http://www.cms.hhs.gov/manuals/transmittals.comm_date_dsc.asp.

From that web page, look for CR 3489 in the CR NUM column on the right, and click on the file for the desired CR. For additional information relating to this issue, please call your carrier/intermediary at their toll free number at:

http://www.cms.hhs.gov/medlearn/tollnums.asp.