



Related MLN Matters Article #: MM3489

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Related CR #: 3489

Percutaneous Transluminal Angioplasty (PTA)

Keywords

MM3489, CR3489, R314CP, R25NCD, Percutaneous, Transluminal, Angioplasty, PTA

Provider Types Affected

Hospitals, physicians and suppliers

Key Points

- The effective date of the instruction is October 12, 2004.
- The implementation date is October 12, 2004.
- Medicare will expand its coverage to include PTA of the carotid artery concurrent with placement of a Food and Drug Administration (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.
- 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; and

- For all other indications for which the Centers for Medicare & Medicaid Services (CMS) has not specifically indicated coverage.
- Fiscal intermediaries (FIs) and carriers will follow the procedures for processing post-approval study devices that are in place for Category B IDEs.
- There is additional billing and coding instructions for providers billing carriers and FIs on page 2 of MLN Matters article MM3489.

Important Links

The related MLN Matters article can be found at

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3489.pdf> on the CMS website.

The official instruction (CR3489) regarding this change may be viewed at

<http://www.cms.gov/Transmittals/downloads/R314CP.pdf> on the CMS website.

The Medicare *NCD Manual* revision may be viewed at

<http://www.cms.hhs.gov/Transmittals/downloads/R25NCD.pdf> on the CMS website.

For additional information relating to this issue, providers may contact their carrier/intermediary at their toll-free number at <http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.