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## *Expansion of Coverage for Percutaneous Transluminal Angioplasty (PTA)*

### Key Words

MM3811, CR3811, PTA, coverage, percutaneous, Transluminal, angioplasty

### Provider Types Affected

Hospitals, physicians, and suppliers billing Medicare Carriers or Fiscal Intermediaries (FIs) for Percutaneous Transluminal angioplasty (PTA) services provided to Medicare beneficiaries

### Key Points

- The effective date of the instruction is March 17, 2005.
- The implementation date is July 5, 2005.
- This article was revised on November 23, 2005, to add the following important information regarding diagnostic coding:
  - In the American Hospital Association's (AHA's) publication *Coding Clinic for ICD-9-CM, First Quarter 2002*, page 10 (and corrected in *Second Quarter 2002*, page 19), there is a Q & A regarding coding of bilateral carotid artery stenosis. The answer said, "Assign only code 433.10, (Occlusion and stenosis of precerebral arteries, carotid artery, without mention of cerebral infarction) as the principal diagnosis."
  - The correction notice changed that advice to use code 433.30 (Occlusion and stenosis of precerebral arteries, multiple and bilateral, without mention of cerebral infarction) instead of 433.10.
  - **In an effort to reduce the confusion, CMS has decided to allow hospitals to be able to code both 433.30 and 433.10 on the SAME claim**, in either principal diagnosis or secondary diagnosis positions. Code 433.30 will identify the bilateral condition, while 433.10 will specifically identify the carotid vessel.

### Expanded Coverage

- Effective March 17, 2005, The Centers for Medicare & Medicaid Services (CMS) expanded the coverage of PTA of the carotid artery, concurrent with placement of an FDA-approved carotid stent with embolic protection for the following:

- Patients who are at high risk for carotid endarterectomy (CEA) and who also have symptomatic carotid artery stenosis equal to or greater than 70%. Coverage is limited to procedures performed using FDA-approved carotid artery stenting systems and embolic protection devices;
- Patients who are at high risk for CEA and have symptomatic carotid artery stenosis between 50% and 70% in accordance with the Category B IDE clinical trials regulation (42 CFR 405.201), as a routine cost under the clinical trials policy (Medicare National Coverage Determination (NCD) Manual, Section 310.1), or according to the NCD on carotid artery stenting (CAS) post-approval studies (Medicare NCD Manual, Section 20.7); and
- Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis equal to or greater than 80% (according to the Category B IDE clinical trials regulation (42 CFR 405.201)), as a routine cost under the clinical trials policy (Medicare NCD Manual 310.1), or according to the NCD on CAS post-approval studies (Medicare NCD Manual, Section 20.7).
- The appropriate documentation confirming that a patient is at high risk for CEA and records of the patient's symptoms of carotid artery stenosis should be available in the patient medical records prior to performing any procedure.
- CMS defines high risk patients as those having significant comorbidities and/or anatomic risk factors and are considered by a surgeon to be poor candidates for CEA.
- Symptoms of carotid artery stenosis include carotid transient ischemic attack, focal cerebral ischemia producing a non-disabling stroke, and transient molecular blindness. Patients who have a disabling stroke would be excluded from coverage.
- If the stenosis is measured by ultrasound prior to the procedure, then the degree of stenosis must be confirmed by angiography at the start of the procedure.
- The CAS should not proceed if the stenosis is determined to be less than 70% by angiography.
- All facilities in which PTA is performed must at least meet the minimum standards outlined in Publication 100-03, Section 20.7, of the *NCD Manual* in order to receive coverage for CAS for high-risk patients. Briefly, facilities must have high-quality X-ray imaging equipment, device inventory, staffing, and infrastructure to support a dedicated CAS program.
- For evaluation purposes, all facilities must provide written documentation to CMS indicating it meets one of the following criteria:
  - Was an FDA-approved site that enrolled patients in prior CAS IDE trials, such as SAPPHIRE, and ARCHER;
  - Is an FDA-approved site that is participating and enrolling patients in ongoing CAS IDE trials, such as CREST;
  - Is an FDA-approved site for one or more FDA post-approval studies; or
  - Has provided a written affidavit to CMS affirming that the facility meets the minimum facility standards. The affidavit must include the facility's name and complete address, Medicare provider number, point-of-contact name and telephone number, CAS procedure data collection mechanism, and a senior facility administrative official's signature.
- A new affidavit is required every two years.

- The affidavit should be sent to:  
Director, Coverage and Analysis Group  
7500 Security Boulevard, Mail-stop C1-09-06  
Baltimore, MD 21244

## Important Links

<http://www.cms.hhs.gov/MedlearnMattersArticles/downloads/MM3811.pdf>

Information relating to Medicare coverage of PTA is available at <http://www.cms.hhs.gov/MedlearnMattersArticles/downloads/MM3489.pdf> and <http://www.cms.hhs.gov/Transmittals/downloads/R314CP.pdf> on the CMS website.

The official instruction issued to your carrier/FI regarding this change may be found at <http://www.cms.hhs.gov/Transmittals/downloads/R33NCD.pdf> on the CMS website.

The changes to the *Medicare Claims Processing Manual* are at <http://www.cms.hhs.gov/Transmittals/downloads/R531CP.pdf> on the CMS website.

If you have questions regarding this issue, contact your carrier/FI on their toll free number, which is available at <http://www.cms.hhs.gov/apps/contacts/> on the CMS website.

The facilities that have met the CMS's minimum facility standards for performing CAS for high risk patients may be reviewed at <http://www.cms.hhs.gov/MedicareApprovedFacilitie/CASF/list.asp#TopOfPage> on the CMS website.