

MLN Matters Number: MM3811

Related Change Request (CR) #: 3811

Related CR Release Date: April 22, 2005

Effective Date: March 17, 2005

Related CR Transmittal #: R33NCD and R531C

Implementation Date: July 5, 2005

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

**Note:** This article was revised on August 30, 2007, to add a reference to Change Request (CR) 5667 (<http://www.cms.hhs.gov/Transmittals/downloads/R1315CP.pdf>). CR5667 adds ICD-9-CM diagnosis code 433.11, occlusion of the carotid artery with infarct, to the list of payable claims for PTA to ensure all eligible Medicare beneficiaries are covered. The related MLN Matters article (MM5667) may be found at <http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM5667.pdf> on the CMS website. MM5667 also provides links to other related PTA articles.

### Provider Types Affected

Hospitals, physicians, and suppliers billing Medicare carriers or fiscal intermediaries (FIs) for Percutaneous Transluminal Angioplasty (PTA) services provided to Medicare beneficiaries

### Provider Action Needed



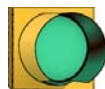
#### STOP – Impact to You

MM3811 and related CR3811 announce the expansion of Medicare coverage for PTA of the carotid artery.



#### CAUTION – What You Need to Know

Effective March 17, 2005, Medicare revised its coverage of PTA of the carotid artery as detailed in this article and CR 3811.



#### GO – What You Need to Do

If you are a provider of PTA services, be aware of the coverage changes and make certain that your billing staff is aware of the expanded national coverage allowed to Medicare beneficiaries receiving PTA services

#### Disclaimer

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## Background

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Medicare covers PTA of the carotid artery concurrent with carotid stent placement when all the requirements stipulated by the Food and Drug Administration (FDA)-approved policies for Category B Investigational Device Exemption (IDE) clinical trials are met, effective for dates of service on or after July 1, 2001.

PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent for an FDA-approved indication is covered, when all the requirements stipulated by the FDA-approved policies for post-approval studies are met, for dates of service on or after October 12, 2004.

### *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  $\geq 70\%$ . 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 to 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  $\geq 80\%$  (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).

### **Significant Comorbidities**

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. The significant comorbidities, include, but are not limited to, those listed in Section 20.7 of the Medicare NCD Manual as follows:

- Congestive heart failure (CHF) class III/IV;
- Left ventricular ejection fraction (LVEF)  $< 30\%$ ;
- Unstable angina;
- Contralateral carotid occlusion;

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- Recent myocardial infarction (MI);
- Previous CEA with recurrent stenosis ;
- Prior radiation treatment to the neck; and
- Other conditions that were used to determine patients at high risk for CEA in the prior CAS trials and studies, such as ARCHER, CABERNET, SAPPHIRE, BEACH, and MAVERIC II.

### **Carotid Artery Stenosis**

Symptoms of carotid artery stenosis include carotid transient ischemic attack (distinct focal neurologic dysfunction persisting less than 24 hours), focal cerebral ischemia producing a non-disabling stroke (modified Rankin scale < 3 with symptoms for 24 hours or more), and transient molecular blindness (amaurosis fugax). Patients who have had a disabling stroke (modified Rankin  $\geq$  3) would be excluded from coverage.

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.

The degree of carotid artery stenosis should be measured by duplex Doppler ultrasound or carotid artery angiography and recorded in the patient medical records. 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. If the stenosis is determined to be less than 70% by angiography, the CAS should not proceed.

- Carotid artery stenting with embolic protection is reasonable and necessary only if performed in facilities that have been determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes.
- All facilities must at least meet the minimum standards outlined in Pub 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.
- Advanced physiologic monitoring, including real time and archived physiologic, hemodynamic, and cardiac rhythm monitoring equipment, and associated support staff capable of interpreting findings and responding appropriately.
- Readily available emergency management equipment and systems, such as resuscitation equipment, a defibrillator, vasocative and antiarrhythmic drugs, endotracheal intubation capability, and anesthesia support.

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- A clearly delineated program for granting CAS privileges and for monitoring the quality of the individual interventionists and the program as a whole. The oversight committee for this program is encouraged to apply published standards from national specialty societies recognized by the American Board of Medical Specialties to determine appropriate physician qualifications.

Examples of standards and clinical competence guidelines include those published in the December 2004 edition of the *American Journal of Neuroradiology* and those published in the August 18, 2004, *Journal of the American College of Cardiology*.

- A data collection system maintained by the facility or its contractor on all CAS procedures done at that facility. The data must be analyzed routinely to ensure patient safety (to be determined by the facility but should not be less frequent than 6-month intervals), will be used in re-credentialing the facility, and must be made available to CMS upon request.

#### Written Documentation

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 a FDA-approved site that is participating and enrolling patients in ongoing CAS IDE trials, such as CREST;
- Is a 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. (Note that 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

**Note:** Performance of PTA to treat obstructive lesions of the vertebral and cerebral arteries remains non-covered. All other indications of PTA for which CMS has not specifically indicated coverage remain non-covered.

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## Additional Information

All providers should note that the following relate to services on or after March 17, 2005:

- FIs and carriers will only pay CAS claims from providers who are listed on the approved facility list which is at <http://www.cms.hhs.gov/MedicareApprovedFacilities/CASF/list.asp#TopOfPage> on the CMS website.
- Carriers will pay claims containing ICD-9 CM 433.10 and any of the following procedure codes: 37215, 37216, 0075T, or 0076T, for beneficiaries meeting the high risk criteria previously specified.
- FIs will pay claims containing ICD-9 CM 433.10 and both procedure codes 00.61 and 00.63.
- FIs will reject claims that do not have both procedure codes 00.61 and 00.63.
- FIs and carriers will deny CAS services for patients at high risk if the appropriate diagnosis code is not on the claim and use the appropriate Medicare Summary Notice (MSN) message and claim adjustment reason code in doing so.
- FIs and carriers will deny claims where the service was performed in an unapproved facility and use the appropriate MSN message and claim adjustment reason code in doing so.

**Note:** Providers must also bill V70.7 (Exam – clinical trial) as a secondary diagnosis for claims with “From” dates **before** October 1, 2005. Providers must bill V70.7 in order to avoid unintentional Medicare Code Editor (MCE) editing. For claims that have “From” dates **on or after** October 1, 2005, hospitals are not required to bill V70.7 as the unintentional MCE editing will be corrected.

### Coding for Carotid Artery Stents

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, in any diagnosis positions, on the same claim. Code 433.30 will identify the bilateral condition, while 433.10 will specifically identify the carotid vessel.

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You may also want to review the following MLN Matters article MM3489 and CR3489 for additional information relating to Medicare coverage of PTA. They are available at

<http://www.cms.hhs.gov/MLNMattersArticles/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. That site contains the NCD manual revision. 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/intermediary on their toll free number, which is available at

<http://www.cms.hhs.gov/MLNProducts/downloads/CallCenterTollNumDirectory.zip> on the CMS website.

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