



News Flash - News Flash – The Centers for Medicare & Medicaid Services (CMS) is pleased to announce that reporting for the 2007 PQRI on claims for dates of service as of July 1, 2007, has begun. Eligible professionals can now start participating in the PQRI by simply reporting the appropriate quality measure data on claims submitted to their Medicare claims processing contractor. Remember, all your informational needs can be met by visiting the PQRI website at <http://www.cms.hhs.gov/PQRI>. Here you will find educational resources, including the PQRI Tool Kit, and links to our most Frequently Asked Questions (FAQs).

MLN Matters Number: MM5660

Related Change Request (CR) #: 5660

Related CR Release Date: September 12, 2007

Effective Date: April 30, 2007

Related CR Transmittal #: R77NCD

Implementation Date: July 30, 2007

Percutaneous Transluminal Angioplasty (PTA)

Note: This article was revised on September 13, 2007, to reflect that CMS revised and re-issued CR5660. The CR release date, transmittal number, and the Web address for accessing CR5660 were changed. All other information remains the same.

Provider Types Affected

Physicians and hospitals who submit claims to Medicare contractors (Part A/B Medicare Administrative Contractors (A/B MACs), Fiscal Intermediaries (FI) or carriers) for PTA services provided to Medicare beneficiaries.

Provider Action Needed



STOP – Impact to You

On August 02, 2006, a request to reconsider the national coverage determination (NCD) for PTA and stenting of the carotid arteries initiated a national coverage analysis. Change request (CR) 5660 communicates the findings resulting from that analysis.

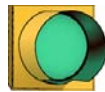
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**CAUTION – What You Need to Know**

Effective for dates of service performed on and after April 30, 2007, be aware of

- Clarifications regarding the use of PTA and stenting of the carotid arteries for patients at high risk for carotid endarterectomy (CEA) and
- Note the process that facilities must follow for certification and recertification that is specified in section 20.7 of Publication 100-03, the *Medicare National Coverage Determinations Manual*.

**GO – What You Need to Do**

If you are a provider of PTA and stenting of the carotid arteries services be aware that CMS has reviewed the evidence and determined that coverage for this NCD is unchanged and that facilities should follow the certification/recertification guidelines in CR5660. See the *Background and Additional Information* sections of this Medicare Modernization Act (MMA) update.

Background

On April 22, 2005, the Centers for Medicare & Medicaid Services (CMS) issued change request (CR) 3811 providing Medicare coverage for PTA of the carotid artery concurrent with placement of an FDA-approved carotid stent when beneficiaries are at high risk for carotid endarterectomy (CEA). This national coverage determination (NCD) is contained in section 20.7 of the *Medicare National Coverage Determinations Manual* and the changes in the NCD are listed below. To read more about this NCD, click on the article issued with this change request that may be found in the *Additional Information* section of this article.

PTA is covered when used under the following conditions:

- Treatment of Atherosclerotic Obstructive Lesions.
 - In the lower extremities, i.e. the iliac, femoral, and popliteal arteries.
 - In the upper extremities, i.e. the innominate, subclavian, axillary, and brachial arteries, but not head or neck vessels.
 - Of a single coronary artery.
- Concurrent with Carotid Stent Placement.

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- Food and Drug Administration (FDA)-Approved Category B Investigational Device Exemption (IDE) Clinical Trials Effective July 1, 2001.
- FDA-Approved Post Approval Studies--Effective October 12, 2004.
- Patients at High Risk for Carotid Endarterectomy (CEA)--Effective March 17, 2005.

NOTES: Coverage is limited to procedures performed using FDA approved carotid artery stents and embolic protection devices.

The use of a distal embolic protection device is required. If deployment of the distal embolic protection device is not technically possible, then the procedure should be aborted given the risks of carotid artery stenting (CAS) without distal embolic protection.

- Concurrent with Intracranial Stent Placement
 - FDA-Approved Category B IDE Clinical Trials--Effective November 6, 2006.

CAS for patients who are not at high risk for CEA remains covered only in FDA-approved Category B IDE clinical trials under 42 CFR 405.201.

CMS has determined that PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent is not reasonable and necessary for all other patients.

Facilities Certification

Facilities must be certified for Medicare to cover the CAS procedures and must recertify every two (2) years in order to maintain Medicare coverage of CAS procedures. Recertification will occur when the facility documents that and describes how it continues to meet the CMS standards. The new recertification guidelines are as follows:

At 23 months after initial certification:

- Submission of a letter to CMS stating how the facility continues to meet the minimum facility standards as listed in Section 20.7 of the *Medicare National Coverage Determinations Manual*. (See the *Additional Information* section of this article for the Web link to the NCD within CR5660)

At 27 months after initial certification:

- Submission of required data elements for all CAS procedures performed on patients during the previous two (2) years of certification.
- Required data elements:
 - Patients' Medicare identification number if a Medicare beneficiary;

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Patients' date of birth;

Date of procedure;

Does the patient meet high surgical risk criteria (defined below)?

- Age ≥ 80 ;
- Recent (< 30 days) Myocardial Infarction (MI);
- Left Ventricle Ejection Fraction (LVEF) < 30%;
- Contralateral carotid occlusion;
- New York Heart Association (NYHA) Class III or IV congestive heart failure;
- Unstable angina: Canadian Cardiovascular Society (CCS) Class III/IV;
- Renal failure: end stage renal disease on dialysis;
- Common Carotid Artery (CCA) lesion(s) below clavicle;
- Severe chronic lung disease;
- Previous neck radiation;
- High cervical Internal Carotid Artery (ICA) lesion(s);
- Restenosis of prior carotid endarterectomy (CEA);
- Tracheostomy;
- Contralateral laryngeal nerve palsy.

Is the patient symptomatic (defined below)?

- Carotid Transient Ischemic Attack (TIA) persisting less than 24 hours;
- Non-disabling stroke: Modified Rankin Scale <3 with symptoms for 24 hours or more;
- Transient monocular blindness: amaurosis fugax;

Modified Rankin Scale score if the patient experienced a stroke;

Percent stenosis of stented lesion(s) by angiography;

Was embolic protection used?

Were there any complications during hospitalization (defined below)?

- Stroke: an ischemic neurologic deficit that persisted more than 24 hours
- MI
- Death

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Recertification is effective for two (2) additional years during which facilities will be required to submit the requested data every April 1 and October 1.

CMS will consider the approval of national carotid artery stenting registries that provide CMS with a comprehensive overview of the registry and its capabilities, and the manner in which the registry meets CMS data collection and evaluation requirements. Specific standards for CMS approval are listed below. Facilities enrolled in a CMS approved national CAS registry will automatically meet the data collection standards required for initial and continued facility certification. Hospitals' contracts with an approved registry may include authority for the registry to submit required data to CMS for the hospital. A list of approved registries will be made available on the CMS coverage website. In addition, CMS will publish a list of approved facilities in the Federal Register.

National Registries

As noted above, CMS will approve national registries developed by professional societies and other organizations and allow these entities to collect and submit data to CMS on behalf of participating facilities to meet facility certification and recertification requirements. To be eligible to perform these functions and become a CMS approved registry, the national registry, at a minimum, must be able to:

1. Enroll facilities in every US state and territory;
2. Assure data confidentiality and compliance with HIPAA;
3. Collect the required CMS data elements as listed above;
4. Assure data quality and data completeness;
5. Address deficiencies in the facility data collection, quality, and submission;
6. Validate the data submitted by facilities, as needed;
7. Track long term outcomes such as stroke and death;
8. Conduct data analyses and produce facility specific data reports and summaries;
9. Submit data to CMS on behalf of the individual facilities; and
10. Provide quarterly reports to CMS on facilities that do not meet or no longer meet the CMS facility certification and recertification requirements pertaining to data collection and analysis.

Registries wishing to receive this designation from CMS must submit evidence that they meet or exceed these 10 requirements. Though the registry requirements pertain to CAS, CMS strongly encourages all national registries to establish a similar mechanism to collect comparable data on CEA. Having both CAS and CEA

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data will help answer questions about carotid revascularization, in general, in the Medicare population.

Additional Information

For complete details regarding this Change Request (CR) please see the official instruction (CR5660) issued to your Medicare carrier, or A/B MAC. That instruction may be viewed by going to

<http://www.cms.hhs.gov/Transmittals/downloads/R77NCD.pdf> on the CMS website.

If you have questions, please contact your Medicare carrier, FI, or A/B MAC, at their toll-free number which may be found at:

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

The *MLN Matters* article related to CR3811, which is referenced in the *Background Section* of this article can be reviewed by clicking on the following link

<http://www.cms.hhs.gov/MLNMattersArticles/downloads/MM3811.pdf> on the CMS website.

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