

# Information Related to Initial Application and Recertification of Eligibility for Medicare Reimbursement for Carotid Artery Stenting (CAS) and List of Eligible Facilities

In order to receive Medicare reimbursement for Carotid Artery Stenting procedures, facilities have to meet Medicare's minimum facility standards for performing carotid artery stenting for high risk patients. Once approved for reimbursement by Medicare, facilities need to recertify every two years to maintain eligibility for reimbursement.

This document offers information for your consideration related to completion of:

- A) The initial application for payment eligibility; and
- B) Recertification following initial application.

## **A) Initial Application**

The Centers for Medicare and Medicaid Services (CMS) requires written documentation from the facility outlining at least one of the following:

1. Facility's clinical trial experience (past or current) as defined by one or more of the following:
  - Whether the facility was an FDA-approved site that enrolled patients in a prior carotid artery stenting; and/or
  - Whether the facility is an FDA-approved site that is participating in a current CAS IDE clinical trial; and/or
  - Whether the facility participated (or is participating) in one or more FDA post-approval clinical studies.
2. Facility's ability to meet minimum standards listed in the CAS coverage policy:
  - The facility must provide a written affidavit to CMS attesting that the facility meets the minimum facility standards outlined below.

## **Facility Qualification Requirements for Medicare Coverage of Carotid Artery Stenting<sup>1</sup>**

CMS developed a list of minimum facility standards for performing carotid artery stenting in high risk patients. These standards were modeled in part on professional society statements on competency. In order to receive coverage for CAS performed in high risk patients, CMS requires that sites at least meet all the following five standards:

1. Facilities must have necessary imaging equipment, device inventory, staffing, and infrastructure to support a dedicated carotid stent program. Specifically, high-quality X-ray imaging equipment is a critical component of any carotid interventional suite, such as high resolution digital imaging systems with the capability of subtraction, magnification, road mapping, and orthogonal angulation.
2. Advanced physiologic monitoring must be available in the interventional suite. This includes real time and archived physiologic, hemodynamic, and cardiac rhythm monitoring equipment, as well as support staff who are capable of interpreting the findings and responding appropriately.

<sup>1</sup>Source: Medicare National Coverage Determination for Percutaneous Transluminal Angioplasty [20.7], Pub. No. 100-3. <http://www.cms.hhs.gov/transmittals/downloads/R77NCD.pdf>

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## Facility Qualification Requirements Continued

3. Emergency management equipment and systems must be readily available in the interventional suite such as resuscitation equipment, a defibrillator, vasoactive and antiarrhythmic drugs, endotracheal intubation capability, and anesthesia support.
4. Each institution should have a clearly delineated program for granting carotid stenting privileges and for monitoring the quality of the individual interventionalists and the program as a whole. The oversight committee for this program should be empowered to identify the minimum case volume for an operator to maintain privileges, as well as the (risk-adjusted) threshold for complications that the institution will allow before suspending privileges or instituting measures for remediation. Committees are 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*.
5. To continue to receive Medicare payment for CAS under this decision, the facility or a contractor to the facility must collect data on all CAS procedures done at that particular facility. This data must be analyzed routinely to ensure patient safety, and will also be used in the process of re-credentialing the facility. This data must be made available to CMS upon request. The interval for data analysis will be determined by the facility but should not be less frequent than every 6 months.

## Template forms are provided for your consideration in drafting your own correspondence related to initial Medicare eligibility for CAS Reimbursement.

- **If your facility has CAS clinical trial experience**, please refer to the following template letter requesting inclusion on the list of facilities eligible for Medicare reimbursement for CAS procedures: Please refer to the “Template Letter for Facilities with Prior Clinical Trial Experience” (located in reimbursement section on [www.carotid.com](http://www.carotid.com) and on [www.bostonscientific.com](http://www.bostonscientific.com) (Link for Interventional Radiology reimbursement library)
- **If your facility does not have CAS clinical trial experience**, but meets the minimum standards for facilities eligible for reimbursement for CAS procedures, as outlined in the CMS National Coverage Determination (NCD) for Percutaneous Transluminal Angioplasty (PTA) and CAS, please refer to the following template letter requesting inclusion on the list of Medicare-approved CAS facilities: Please refer to the “Template Letter for Facilities with No Clinical Trial Experience” (located in reimbursement section on [www.carotid.com](http://www.carotid.com) and [www.bostonscientific.com](http://www.bostonscientific.com) (Link for Interventional Radiology reimbursement library)

## CMS has provided that written documentation should be sent to:

Director, Coverage and Analysis Group  
7500 Security Boulevard, Mailstop C1-09-06  
Baltimore, MD 21244

See important information about the uses and limitations of this document, page 1.

CMS has provided that your correspondence must include the following information:

- Facility's name and complete address
- Facility's Medicare provider number
- Point-of-contact for questions with telephone number
- Discussion as to whether and how each standard has been met by the hospital
- Mechanism of data collection for CAS procedures performed in the hospital
- Signature of a senior facility administrative official

## **B) Recertification**

In order to maintain eligibility for Medicare reimbursement, CMS requires facilities to recertify every two years after initial approval. Below is the language as put forth by Medicare on how to recertify. This information can also be accessed at <http://www.cms.hhs.gov/transmittals/downloads/R77NCD.pdf> .

Recertification requires a facility to document and describe whether and how it continues to meet the CMS standards. CMS has suggested that facilities adhere to the following process for recertification:

1. At 23 months after initial certification:

- Submission of a letter to CMS stating whether and how the facility continues to meet the minimum facility standards as listed above.

2. 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.
- Data elements for each patient should include:
  - a. Medicare identification number if a Medicare beneficiary;
  - b. Date of birth;
  - c. Date of procedure;
  - d. Determination of whether the patient met any of the high surgical risk criteria defined below
    - Age  $\geq$ 80;
    - Recent (< 30 days) Myocardial Infarction (MI);
    - Left Ventricle Ejection Fraction (LVEF) < 30%;
    - Contralateral carotid occlusion;

**See important information about the uses and limitations of this document, page 1.**

- 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.
- e. Determination of whether the patient met the definition of symptomatic as 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.
- f. Modified Rankin Scale score if the patient experienced a stroke.
- g. Percent stenosis of stented lesion(s) by angiography.
- h. Determination of whether embolic protection was used
- i. Determination of whether any of the following complications occurred during hospitalization
- All stroke: an ischemic neurologic deficit that persisted more than 24 hours;
  - Myocardial Infarction
  - All death.

Once granted, recertification should remain effective for two (2) years during which facilities will be required to submit the requested data elements every April 1 and October 1.

CMS has provided that it 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. CMS has provided the specific standards for CMS approval listed below under the National Registries heading. Facilities enrolled in a CMS approved national carotid artery stenting registry should likely 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.

### ***National Registries***

As noted above, CMS will consider approval for national registries developed by professional societies and other organizations which would allow these entities to collect and submit data to CMS on behalf of participating facilities to meet facility certification and recertification requirements. CMS has provided that 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 HIPPA;
3. Collect the required CMS data elements as listed in the above section;
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.

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CMS has required registries wishing to receive this designation from CMS to submit evidence that they meet or exceed CMS standards. Though the registry requirements pertain to CAS, CMS strongly encourages all national registries to establish a similar mechanism to collect and comparable data on CEA. Having both CAS and CEA data will help CMS answer questions about carotid revascularization, in general, about the Medicare population.

Information provided above and in this document is taken from Medicare National Coverage Determination for Percutaneous Transluminal Angioplasty [20.7], Pub. No. 100-3.  
<http://www.cms.hhs.gov/transmittals/downloads/R77NCD.pdf>

## List of CMS Eligible Facilities

Please see <http://www.cms.hhs.gov/MedicareApprovedFacilities/CASF/list.asp#TopOfPage/carotid-stentfacilities> for a list of facilities meeting CMS's minimum facility standards for performing carotid artery stenting for high risk patients. *Note, sites not on CMS' list of approved facilities are not eligible for Medicare reimbursement under any circumstance.*

See important information about the uses and limitations of this document, page 1.



Boston Scientific Corporation  
One Boston Scientific Place  
Natick, MA 01760-1537  
[www.bostonscientific.com](http://www.bostonscientific.com)

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