

BACKGROUND

- This guide reviews coverage criteria and possible coding options for carotid stenting procedures for both Medicare and non-Medicare patients.
- All payment amounts are Medicare national averages; actual payments will vary by numerous factors.

COVERAGE: NON-MEDICARE, PRIVATE PAYERS or MEDICARE

Patients Insured by Non-Medicare, Private Payers:

Coverage for percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with carotid stent placement may vary by non-Medicare, private payer. As such, it is best to determine the coverage for each patient prior to rendering medical services. The most effective way to determine whether carotid stenting will be covered for your non-Medicare patients is to inquire whether the payer has a coverage policy for carotid stenting and, if so, to request a copy of the coverage policy. It may be necessary to seek prior authorization (physicians) or pre-certification (hospitals) for carotid stenting procedures. Please request a copy of Boston Scientific's Carotid Stenting Procedures Reimbursement Guide or visit www.carotid.com for additional information on the prior authorization process.

Medicare Beneficiaries:

Medicare has outlined specific coverage criteria for PTA with concurrent carotid stenting for its beneficiaries¹

1. For Beneficiaries NOT PARTICIPATING in FDA-approved Category B Investigational Device Exemption (IDE) Clinical Trials, Post- Approval Studies, or Other Qualifying Clinical Trials:
 - Coverage for PTA of the carotid artery concurrent with carotid stent placement will be considered only if all of the following criteria are met:
 - Patient is at high risk for carotid endarterectomy (CEA); AND
 - Patient has symptomatic carotid artery stenosis $\geq 70\%$; AND
 - Procedure is performed using an FDA-approved carotid artery stenting system and embolic protection device.

¹CMS Manual System. National Coverage Determinations, Publication 100-3, Section 20.7, Transmittal 77, September 12,, 2007 <http://www.cms.hhs.gov/transmittals/downloads/R77NCD.pdf>

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2. For Beneficiaries PARTICIPATING in FDA-approved Category B Investigational Device Exemption (IDE) Clinical Trials, Post-Approval Studies, or Other Qualifying Clinical Trials:
 - Coverage for PTA of the carotid artery concurrent with carotid stent placement will be considered when furnished in accordance with the Food and Drug Administration (FDA)-approved protocols governing Category B Investigational Device Exemption (IDE) clinical trials (including embolic protection)
 - Coverage for PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent for an FDA-approved indication will be considered when furnished in accordance with FDA-approved protocols governing post-approval studies (including embolic protection)
 - Carotid stenting coverage will also be considered for:
 - Those at high risk for carotid endarterectomy (CEA) 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.
 - Those at high risk for CEA who have symptomatic carotid artery stenosis between 50% and 69%, per 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 310.1), or per the NCD on carotid artery stenting (CAS) post-approval studies (Medicare NCD Manual 20.7)
 - Those at high risk for CEA who have asymptomatic carotid artery stenosis $\geq 80\%$, per 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 per the NCD on CAS post-approval studies (Medicare NCD Manual 20.7)
 - Carotid stenting coverage for patients who are not at high risk for CEA is only considered by Medicare when the patient is participating in an FDA-approved Category B Investigational Device Exemption (IDE) clinical trial for this patient population.
 - Medicare does not cover carotid stenting procedures if an embolic protection device is not deployed, even if deployment is attempted and fails.
 - The following flowchart is designed to help you determine whether a Medicare beneficiary is likely to be eligible for coverage for a carotid stenting procedure:

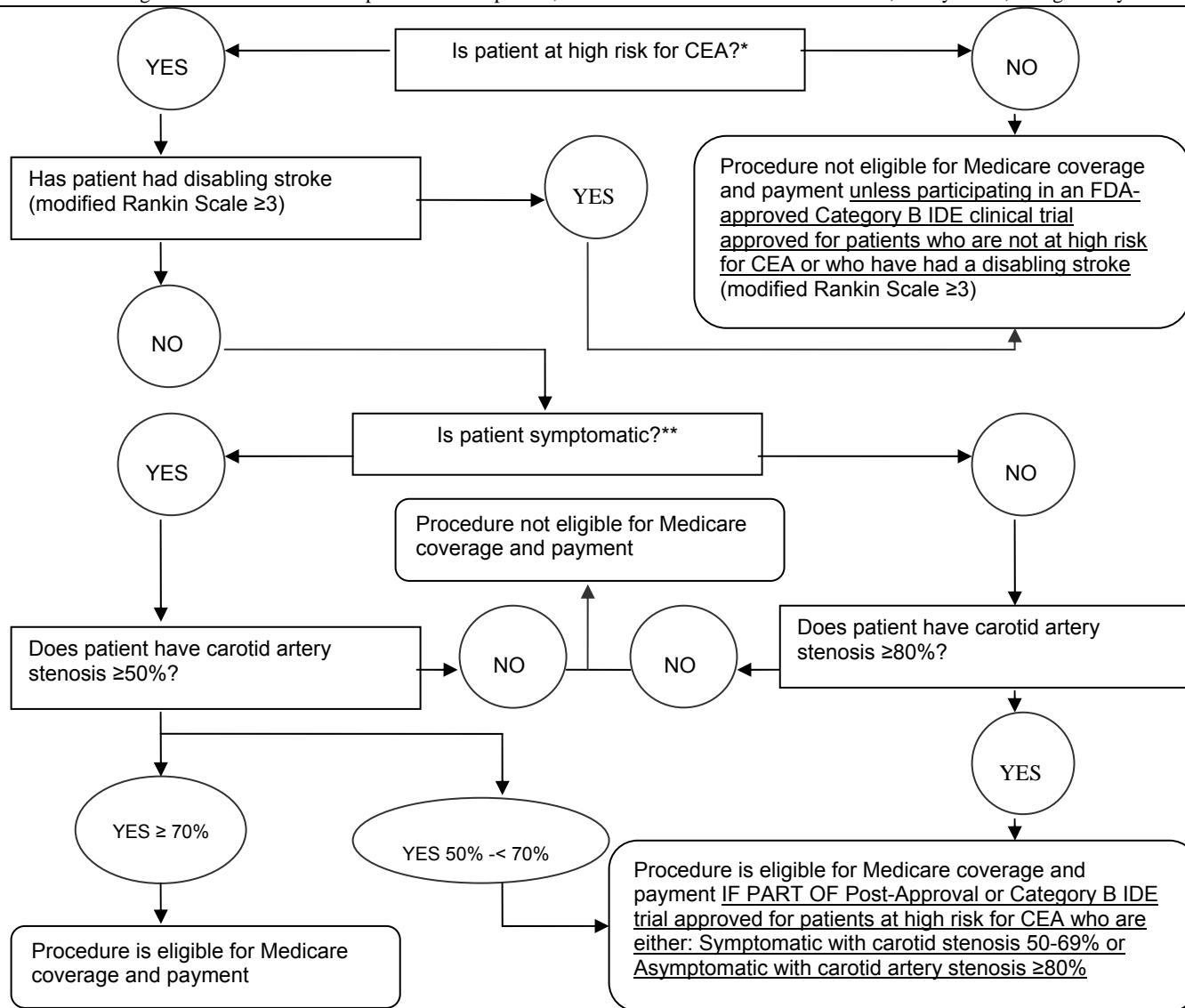
(See flow chart on page 3).

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

2009 Carotid Artery Stenting (CAS): Coverage, Coding and Payment Quick Reference

MEDICARE BENEFICIARY PAYMENT ELIGIBILITY FOR CAROTID STENTING PROCEDURES

Please note: This chart is; A) intended as a simplified tool to demonstrate typical Medicare coverage considerations for carotid artery stenting procedures, B) assumes facility approval by CMS and all other applicable non-referenced eligibility requirements are met, and C) because coverage determinations are complex and case specific, is not intended and should not be seen, in any event, as a guaranty of coverage



Below is Medicare's definition of high risk patients and symptoms of Carotid Artery Disease. This information can be found at <http://www.cms.hhs.gov/transmittals/downloads/R77NCD.pdf>

* High Risk patients are defined as those having significant comorbidities and/or anatomic risk factors (i.e., recurrent stenosis and/or previous radical neck dissection), and would be poor candidates for CEA in the opinion of a surgeon. Significant comorbid conditions include but are not limited to: congestive heart failure (CHF) class III/IV; left ventricular ejection fraction (LVEF) <30%; unstable angina; contralateral carotid occlusion; 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, SAPHIRE, BEACH, and MAVERIC II.

** 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 monocular blindness (amaurosis fugax).

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2009 Carotid Artery Stenting (CAS): Coverage, Coding and Payment Quick Reference

PHYSICIAN CODING AND PAYMENT

ICD-9-CM Diagnosis Code ²	CPT ^{®3} Code	Code Description	2009 MD In-Facility National Average Transitional Payment ⁴
433.10: Occlusion and stenosis of precerebral arteries; carotid artery without mention of cerebral infarction (Where applicable, this code should be reported, as primary diagnosis for Medicare patients. Failure to report this code for Medicare patients, where appropriate, may result in claim denial)	37215	Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; with distal embolic protection	\$1,101
433.30: Occlusion and stenosis of precerebral arteries; multiple and bilateral, without mention of cerebral infarction (For Medicare patients with bilateral stenosis, where applicable, this code should be reported, as a secondary diagnosis and report 433.10 as the primary diagnosis.) ⁵	37216	Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; without distal embolic protection	\$1,010
433.31: Occlusion and stenosis of precerebral arteries; multiple and bilateral, with cerebral infarction			

*** PLEASE NOTE:**

• It is important to document the existence of conditions or comorbidities when they define a patient as being at high risk for CEA, as defined by Medicare or non-Medicare, private payers. Where applicable, the ICD-9-CM diagnosis codes for such conditions or comorbidities should be listed as secondary diagnoses.

According to Medicare, "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 CAS without distal embolic protection." See information at <http://www.cms.hhs.gov/transmittals/downloads/R77NCD.pdf>

• **This Quick Reference Guide assumes that the physician intends to place a carotid stent prior to initiating the procedure, therefore PTA is not reported separately.** If the original intent of the procedure is to perform PTA and a stent is unexpectedly placed due to PTA failure or the need for a stent in a different area, the physician may report PTA separately and utilize modifier '-59' with CPT Code 37215 or 37216 to denote multiple procedures. If the '-59' modifier is reported for CPT Code 37215 or 37216, the PTA procedure will be subject to multiple procedure discounting and typically the payment will be 50% of the average Medicare allowance. The failure should be documented.

² The Educational Annotation of ICD-9-CM, Reno, NV; Channel Publishing Ltd. Copyright 2008. Craig D. Puckett, Fifth Edition.

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⁴ Source: November 19, 2008 Federal Register. MD payments calculated using the 2009 conversion factor of \$36.0666. MD rates are effective through December 31, 2009.

⁵ Medlearn Matters Number MM3811, updated February 8, 2006.

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

2009 Carotid Artery Stenting (CAS): Coverage, Coding and Payment Quick Reference

HOSPITAL INPATIENT CODING AND PAYMENT

Payments for hospital inpatient services under Medicare are determined by assignment to CMS' Medicare Severity Diagnosis Related Group (MS-DRGs). All DRG assignments described below are based only on reporting of the occlusion and stenosis diagnosis codes and the procedure codes for PTA and stenting of the carotid artery listed below. Final MS-DRG grouping may be impacted by the reporting of other ICD-9-CM diagnosis or procedure codes in addition to those provided below.

- MS-DRG payment amounts are Medicare national averages; actual payments will vary by numerous factors.
- A facility's ability to bill separately for carotid stent and embolic protection devices for patients insured by non-Medicare private payers using revenue code 0278 or other codes, will depend on the facility's contractual arrangements.

ICD-9-CM Diagnosis Code ⁶	ICD-9-CM Procedure Code ⁶	MS-DRG ⁷ (Primary Procedure)	2008 Medicare National Average Payment Rate ⁸ (Effective Oct 01, 2008 – Dec 31, 2009)
433.10: Occlusion and stenosis of precerebral arteries; carotid artery without mention of cerebral infarction (Where applicable, this code should be reported, for Medicare patients meeting eligibility criteria for coverage. Failure to report this code, where appropriate for Medicare patients, may result in claim denial)	00.61: Percutaneous angioplasty or atherectomy of precerebral (extracranial) vessel(s) (Note: Where applicable, both 00.61 and 00.63 should be reported for Medicare patients meeting eligibility for coverage. Failure to report both codes where appropriate for Medicare patients, may result in claim denial.)	MS-DRG 034 -Other vascular procedures with MCC*	\$17,891
		MS-DRG 035 -Other vascular procedures with CC*	\$11,231
433.11: Occlusion and stenosis of precerebral arteries; carotid artery with cerebral infarction	00.63: Percutaneous insertion of carotid artery stent(s) (Note: Where applicable, both 00.61 and 00.63 should be reported for Medicare patients meeting eligibility for coverage. Failure to report both codes where appropriate for Medicare patients, may result in claim denial.)	MS-DRG 036 -Other vascular procedures without CC/MCC*	\$8,702
433.30: Occlusion and stenosis of precerebral arteries; multiple and bilateral, without mention of cerebral infarction	one of the following to be listed to indicate the number of vessels: 00.40 Procedure on single vessel 00.41 Procedure on two vessels 00.42 Procedure on three vessels 00.43 Procedure on four or more vessels One of the following to should be listed to indicate the number of stents used: 00.45 Insertion of one vascular stent 00.46 Insertion of two vascular stents 00.47 Insertion of three vascular stents 00.48 Insertion of four or more vascular stents		
433.31: Occlusion and stenosis of precerebral arteries; multiple and bilateral, with cerebral infarction			

* PLEASE NOTE: It is important to document the existence of conditions or comorbidities when they define a patient as being at high risk for CEA, as defined by Medicare or non-Medicare, private payers. Where applicable the ICD-9-CM diagnosis codes for such conditions or comorbidities should be listed as secondary diagnoses.

⁶The Educational Annotation of ICD-9-CM, Reno, NV; Channel Publishing Ltd. Copyright 2007. Craig D. Puckett, Fifth Edition DHHS, CMS. 42 CFR Parts

⁷2008 DRG Expert. Ingenix: 2008

⁸ Source: October 3, 2008 Federal Register (update). National average (wage index greater than one) MS- DRG rates calculated using the national adjusted full update standardized labor, non-labor and capital amounts (\$5,552.58). (Actual reimbursement will vary for each provider and institution for a variety of reasons including geographic differences in labor and non-labor costs,) hospital teaching status, and/or proportion of low-income patients)

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FREQUENTLY ASKED QUESTIONS

1. Q. Does Medicare provide coverage for carotid stenting?

- A. Yes, for selected patients. Please refer to the flow chart on Medicare Beneficiary Eligibility for Carotid Stenting Procedures in this Quick Reference Guide for more details. It should be noted that Medicare does not currently cover carotid artery stenting in high risk, asymptomatic patients with stenosis <80% or in non-high risk patients unless the procedure is done as part of an FDA-approved IDE or post-approval clinical study.

2. Q. I have a non-Medicare patient. Does this procedure need prior authorization?

- A. Plan requirements vary. The patient's individual plan and guidelines should be consulted for appropriate prior authorization and referral requirements.

3. Q. If a percutaneous transluminal angioplasty (PTA) of the carotid artery is performed with carotid stent placement, should we code separately for both the PTA and stent placement procedures?

- A. If the physician's initial intent is to place a carotid stent, the PTA cannot be billed separately. Currently, there are two specific codes for carotid angioplasty and stenting:
- 37215 Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; with distal embolic protection; and
 - 37216 without distal embolic protection
- According to the American Medical Association's (AMA's) description of these procedures, pre-stent carotid angioplasty is included in the carotid stenting codes. Moreover, Medicare does not cover PTA of the carotid artery unless it is performed as part of a carotid stenting procedure.

4. Q. Is there existing guidance around how carotid stenosis and bilateral stenting procedures should be coded when performed during the same operative session?

- A. Medicare requires ICD-9-CM diagnosis code 433.10, occlusion and stenosis of precerebral arteries, carotid artery, without mention of cerebral infarction, to be listed as the primary diagnosis on claims for carotid stenting procedures. Therefore, ICD-9-CM diagnosis code 433.30, occlusion and stenosis of precerebral arteries, multiple and bilateral, without mention of cerebral infarction, should be listed as a secondary diagnosis code on Medicare physician and facility claims.⁹ Physicians performing bilateral carotid stenting procedures during the same operative session can also report modifier '-50' with CPT^{®10} Codes 37215 or 37216, to indicate that a bilateral procedure was performed.

⁹Medlearn Matters Number MM3811, updated February 8, 2006.

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FREQUENTLY ASKED QUESTIONS (continued)

- 5. Q. Will Medicare reimburse for a carotid stenting procedure if an embolic protection device is not deployed?**
- A.** No. Medicare does not cover carotid stenting procedures if an embolic protection device is not deployed, even if deployment is attempted and fails.
- 6. Q. What codes do I use if, after initiating a procedure, carotid stenting is not indicated?**
- A.** If carotid stenting is not indicated, the appropriate codes for carotid catheterization and imaging may be reported, if applicable, in lieu of 37215 and 37216.¹¹
- 7. Q. What should I do if the claim is denied?**
- A.** Boston Scientific recommends careful review of the Explanation of Benefits (EOB) form explaining the reason for the denial. If the EOB does not clearly explain the reason for denial, you can immediately contact your Medicare contractor or your patient's payer to ask for an explanation of the denied claim. In those cases where a clerical error was made on the claim form, you should consider confirming the appropriate codes to use and resubmit a corrected claim form. For non-Medicare payers, if the procedure received prior authorization, documentation indicating the prior authorization number, scope of the service authorized, the code(s) recommended, the date and time (if possible) and name of the person authorizing the services should be attached to your appeal. In other cases, contractors and payers may deny claims due to a perceived lack of medical necessity. In these cases, you can ask the claims processor to specify what additional materials are required to reverse

NOTE: Federal law prohibits fraudulent statements made on insurance claim submissions, and violations can result in both civil and criminal penalties. Boston Scientific strongly recommends that you consult your payers for local coverage and reimbursement policies, and follow all applicable federal, state, and local laws when billing for reimbursement.

If you have questions regarding the information contained in this document, please dial 1-800-553-5878 ext. 2801

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