

Blue Cross Blue Shield of Massechusetts is an Independent Licenses of the Blue Cross and Blue Shield Association

Medical Policy Extracranial Carotid Angioplasty and Stenting

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- Policy: Commercial
- Policy: Medicare
- <u>Authorization Information</u>
 - Policy Number: 219 BCBSA Reference Number: 7.01.68

Related Policies

None

Policy Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Coding Information

Description

Policy History

Carotid angioplasty with associated stenting and embolic protection may be <u>MEDICALLY NECESSARY</u> in patients who meet the following criteria:

- 50%-99% stenosis (NASCET measurement), AND
- Symptoms of focal cerebral ischemia (transient ischemic attack or monocular blindness) in previous 120 days, symptom duration less than 24 hours, or nondisabling stroke, AND
- Anatomic contraindication for carotid endarterectomy (such as prior radiation treatment or neck surgery, lesions surgically inaccessible, spinal immobility, or tracheostomy).

Carotid angioplasty with or without associated stenting and embolic protection is <u>INVESTIGATIONAL</u> for all other indications, including but not limited to, patients with carotid stenosis who are suitable candidates for CEA and patients with carotid artery dissection.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

BCBSMA covers carotid angioplasty with the placement of an FDA-approved carotid stent with embolic protection for the following indications for Medicare HMO Blue and Medicare PPO Blue members in accordance with CMS NCD:

- Patients who are at high risk for carotid endarterectomy (CEA) and who have symptomatic carotid artery stenosis >70%, or
- Patients who are at high risk for CEA and have symptomatic carotid artery stenosis between 50% and 70%, or
- Patients who are at high risk for CEA and have asymptomatic carotid artery stenosis >80%.

- Information Pertaining to All Policies
- References

Note: Patients at high risk for CEA are defined as 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, and
- Prior radiation treatment to the neck.

BCBSMA does not cover carotid angioplasty with the placement of an FDA-approved carotid stent for Medicare HMO Blue and Medicare PPO Blue members in accordance with CMS NCD when the deployment of the distal embolic protection device is not technically possible.

National Coverage Determination (NCD) for Percutaneous Transluminal Angioplasty (PTA) (20.7)

https://www.cms.gov/medicare-coverage-database/details/ncddetails.aspx?NCDId=201&ncdver=9&bc=AgAAgAAAAAA&

Prior Authorization Information

See below for situations where prior authorization may be required or may not be required. Yes indicates that prior authorization is required.

No indicates that prior authorization is not required.

	Outpatient	Inpatient
Commercial Managed Care (HMO and POS)	No	Yes
Commercial PPO and Indemnity	No	Yes
Medicare HMO Blue sm	No	Yes
Medicare PPO Blue SM	No	Yes

CPT Codes / HCPCS Codes / ICD-9 Codes

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

CPT codes:	Code Description
37215	Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; with distal embolic protection
37216	Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; without distal embolic protection
36221	Non-selective catheter placement, thoracic aorta, with angiography of the extracranial carotid, vertebral, and/or intracranial vessels, unilateral or bilateral, and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed
36222	Selective catheter placement, common carotid or innominate artery, unilateral, any approach, with angiography of the ipsilateral extracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed

36223	Selective catheter placement, common carotid or innominate artery, unilateral, any approach, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervicocerebral arch, when performed
36224	Selective catheter placement, internal carotid artery, unilateral, with angiography of the ipsilateral intracranial carotid circulation and all associated radiological supervision and interpretation, includes angiography of the extracranial carotid and cervicocerebral arch, when performed
36225	Selective catheter placement, subclavian or innominate artery, unilateral, with angiography of the ipsilateral vertebral circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed
36226	Selective catheter placement, vertebral artery, unilateral, with angiography of the ipsilateral vertebral circulation and all associated radiological supervision and interpretation, includes angiography of the cervicocerebral arch, when performed
36227	Selective catheter placement, external carotid artery, unilateral, with angiography of the ipsilateral external carotid circulation and all associated radiological supervision and interpretation (List separately in addition to code for primary procedure)
36228	Selective catheter placement, each intracranial branch of the internal carotid or vertebral arteries, unilateral, with angiography of the selected vessel circulation and all associated radiological supervision and interpretation (eg, middle cerebral artery, posterior inferior cerebellar artery) (List separately in addition to code for primary procedure)
37217	Transcatheter placement of an intravascular stent(s), intrathoracic common carotid artery or innominate artery by retrograde treatment, via open ipsilateral cervical carotid artery exposure, including angioplasty, when performed, and radiological supervision and interpretation
37238	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; initial vein
37239	Transcatheter placement of an intravascular stent(s), open or percutaneous, including radiological supervision and interpretation and including angioplasty within the same vessel, when performed; each additional vein (List separately in addition to code for primary procedure)
0075T	Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; initial vessel
0076T	Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous; each additional vessel (List separately in addition to code for primary procedure)

Description

Carotid artery angioplasty with stenting is a treatment for carotid stenosis that is intended to prevent future stroke. It is an alternative to medical therapy and a less-invasive alternative to carotid endarterectomy (CEA).

Background

Combined with optimal medical management, carotid angioplasty with or without stenting has been evaluated as an alternative to CEA. Carotid angioplasty and stenting (CAS) involves the introduction of coaxial systems of catheters, microcatheters, balloons, and other devices. The procedure is most often performed through the femoral artery, but a transcervical approach can also be used to avoid traversing the aortic arch. The procedure typically takes 20 to 40 minutes. Interventionalists almost uniformly use an embolic protection device (EPD) designed to reduce the risk of stroke caused by thromboembolic material dislodged during CAS. EPDs can be deployed proximally (with flow reversal) or distally (using a filter). Carotid angioplasty rarely is performed without stent placement.

Proposed advantages of CAS over CEA include:

- General anesthesia is not used (although CEA can be performed under local/regional anesthesia)
- Cranial nerve palsies are infrequent sequelae (although almost all following CEA resolve over time)
- Simultaneous procedures may be performed on the coronary and carotid arteries

Examples of carotid stent systems for carotid angioplasty and stenting include ACCULINK[™] and RX ACCULINK[™] carotid stents from Guidant Corp., Xact® RX carotid stent system from Abbott Vascular Devices and Precise® nitinol carotid stent system from Cordis Corp, NexStent® carotid stent over-thewire and monorail delivery systems, Endotex Interventional Systems; and FilterWire EZ[™] embolic protection system, Boston Scientific Corp, ProtégéRx® and SpideRx®, ev3 Inc., Arterial Evolution Technology, Carotid Wallstent®, Boston Scientific Corp., GORE® Flow Reversal System, GORE® Embolic Filter , and Mo.Ma® Ultra Proximal Cerebral Protection Device, Invatec SPA. All carotid stent systems for carotid angioplasty and stenting are considered investigational regardless of the commercial name, the manufacturer or FDA approval status except as noted in the policy statement.

Summary

A substantial body of randomized controlled trial (RCT) evidence compares outcomes of carotid artery angioplasty with stenting (CAS) with carotid endarterectomy (CEA) for symptomatic and asymptomatic patients with carotid stenosis. The evidence does not support use of CAS in carotid artery disease for the average risk patient, because early adverse events are higher with CAS and long-term outcomes are not better. Data from RCTs and large database studies establish that the risk of CAS exceeds the threshold set to indicate overall benefit from the procedure. Therefore, for patients with carotid stenosis who are suitable candidates for CEA, CAS is considered investigational.

However, based on limited data, clinical input, an indirect chain of evidence, and unmet medical need, CAS may be considered a reasonable treatment option in recently symptomatic patients when CEA cannot be performed due to anatomic reasons. For this population, CAS may be considered medically necessary. It is considered investigational for all other indications, including carotid dissection.

Date	Action
5/2014	New references from BCBSA National medical policy.
	Added transcervical approach to background.
1/2014	Updated to add new CPT codes 37217, 37238 and 37239.
5/2013	New references from BCBSA National medical policy.
2/2013	BCBSA National medical policy review.
	Changes to policy statement. Effective 2/4/2013.
1/2013	Updated to add new CPT codes 36221-36228.
11/2011-	Medical policy ICD 10 remediation: Formatting, editing and coding updates.
4/2012	No changes to policy statements.
12/2011	BCBSA National medical policy review.
	No changes to policy statements.
4/2011	Reviewed - Medical Policy Group - Cardiology and Pulmonology.
	No changes to policy statements.
1/2011	Reviewed - Medical Policy Group - Neurology and Neurosurgery.
	No changes to policy statements.
8/1/2010	New policy, effective 8/1/2010, describing covered and non-covered indications.
8/2008	BCBSA National medical policy review.
	No changes to policy statements.
3/2008	Reviewed - Medical Policy Group - Allergy and ENT/Otolaryngology.
	No changes to policy statements.
7/2007	BCBSA National medical policy review.
	No changes to policy statements.

Policy History

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information: <u>Medical Policy Terms of Use</u> <u>Managed Care Guidelines</u> <u>Indemnity/PPO Guidelines</u> <u>Clinical Exception Process</u> <u>Medical Technology Assessment Guidelines</u>

References

- Beneficial effect of carotid endarterectomy in symptomatic patients with high-grade carotid stenosis. North American Symptomatic Carotid Endarterectomy Trial Collaborators. N Engl J Med 1991; 325(7):445-53.
- MRC European Carotid Surgery Trial: interim results for symptomatic patients with severe (70-99%) or with mild (0-29%) carotid stenosis. European Carotid Surgery Trialists' Collaborative Group. Lancet 1991; 337(8752):1235-43.
- 3. Mayberg MR, Wilson SE, Yatsu F et al. Carotid endarterectomy and prevention of cerebral ischemia in symptomatic carotid stenosis. Veterans Affairs Cooperative Studies Program 309 Trialist Group. JAMA 1991; 266(23):3289-94.
- 4. Endarterectomy for asymptomatic carotid artery stenosis. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. JAMA 1995; 273(18):1421-8.
- 5. Randomised trial of endarterectomy for recently symptomatic carotid stenosis: final results of the MRC European Carotid Surgery Trial (ECST). Lancet 1998; 351(9113):1379-87.
- 6. Barnett HJ, Taylor DW, Eliasziw M et al. Benefit of carotid endarterectomy in patients with symptomatic moderate or severe stenosis. North American Symptomatic Carotid Endarterectomy Trial Collaborators. N Engl J Med 1998; 339(20):1415-25.
- Halliday A, Mansfield A, Marro J et al. Prevention of disabling and fatal strokes by successful carotid endarterectomy in patients without recent neurological symptoms: randomised controlled trial. Lancet 2004; 363(9420):1491-502.
- 8. Arazi HC, Capparelli FJ, Linetzky B et al. Carotid endarterectomy in asymptomatic carotid stenosis: a decision analysis. Clin Neurol Neurosurg 2008; 110(5):472-9.
- Marquardt L, Geraghty OC, Mehta Z et al. Low Risk of Ipsilateral Stroke in Patients With Asymptomatic Carotid Stenosis on Best Medical Treatment. A Prospective, Population-Based Study. Stroke 2009.
- 10. Naylor AR, Bell PRF. Treatment of Asymptomatic Carotid Disease with Stenting: Con. Semin Vasc Surg 2008; 21:101-07.
- 11. Brott TG, Hobson RW, 2nd, Howard G et al. Stenting versus endarterectomy for treatment of carotid-artery stenosis. N Engl J Med 2010; 363(1):11-23.
- 12. De Rango P, Brown MM, Leys D et al. Management of carotid stenosis in women: consensus document. Neurology 2013; 80(24):2258-68.
- 13. Jordan WD, Jr., Voellinger DC, Fisher WS et al. A comparison of carotid angioplasty with stenting versus endarterectomy with regional anesthesia. J Vasc Surg 1998; 28(3):397-402; discussion 02-3.
- 14. Lewis SC, Warlow CP, Bodenham AR et al. General anaesthesia versus local anaesthesia for carotid surgery (GALA): a multicentre, randomised controlled trial. Lancet 2008; 372(9656):2132-42.
- 15. Yadav JS, Wholey MH, Kuntz RE et al. Protected carotid-artery stenting versus endarterectomy in high-risk patients. N Engl J Med 2004; 351(15):1493-501.
- 16. Gurm HS, Yadav JS, Fayad P et al. Long-term results of carotid stenting versus endarterectomy in high-risk patients. N Engl J Med 2008; 358(15):1572-9.
- 17. Eckstein HH, Ringleb P, Allenberg JR et al. Results of the Stent-Protected Angioplasty versus Carotid Endarterectomy (SPACE) study to treat symptomatic stenoses at 2 years: a multinational, prospective, randomised trial. Lancet Neurol 2008; 7(10):893-902.
- Mas JL, Trinquart L, Leys D et al. Endarterectomy Versus Angioplasty in Patients with Symptomatic Severe Carotid Stenosis (EVA-3S) trial: results up to 4 years from a randomised, multicentre trial. Lancet Neurol 2008; 7(10):885-92.

- 19. Ringleb PA, Allenberg J, Bruckmann H et al. 30 day results from the SPACE trial of stent-protected angioplasty versus carotid endarterectomy in symptomatic patients: a randomised non-inferiority trial. Lancet 2006; 368(9543):1239-47.
- 20. Naylor AR. SPACE: not the final frontier. Lancet 2006; 368(9543):1215-6.
- 21. Furlan AJ. Carotid-artery stenting—case open or closed? N Engl J Med 2006; 355(16):1726-9.
- 22. Mas JL, Chatellier G, Beyssen B et al. Endarterectomy versus stenting in patients with symptomatic severe carotid stenosis. N Engl J Med 2006; 355(16):1660-71.
- 23. Arquizan C, Trinquart L, Touboul PJ et al. Restenosis is more frequent after carotid stenting than after endarterectomy: the EVA-3S study. Stroke 2011; 42(4):1015-20.
- 24. ICSS. Carotid artery stenting compared with endarterectomy in patients with symptomatic carotid stenosis (International Carotid Stenting Study): an interim analysis of a randomised controlled trial. Lancet 2010.
- Bonati LH, Jongen LM, Haller S et al. New ischaemic brain lesions on MRI after stenting or endarterectomy for symptomatic carotid stenosis: a substudy of the International Carotid Stenting Study (ICSS). Lancet neurology 2010; 9(4):353-62.
- 26. Rothwell PM. Carotid stenting: more risky than endarterectomy and often no better than medical treatment alone. Lancet 2010; 375(9719):957-9.
- 27. Hopkins LN, Roubin GS, Chakhtoura EY et al. The Carotid Revascularization Endarterectomy versus Stenting Trial: credentialing of interventionalists and final results of lead-in phase. J Stroke Cerebrovasc Dis 2010; 19(2):153-62.
- 28. Silver FL, Mackey A, Clark WM et al. Safety of Stenting and Endarterectomy by Symptomatic Status in the Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST). Stroke 2011.
- 29. Lal BK, Beach KW, Roubin GS et al. Restenosis after carotid artery stenting and endarterectomy: a secondary analysis of CREST, a randomised controlled trial. Lancet Neurol 2012; 11(9):755-63.
- 30. Roffi M, Sievert H, Gray WA et al. Carotid artery stenting versus surgery: adequate comparisons? Lancet Neurol 2010; 9(4):339-41; author reply 41-2.
- 31. Nallamothu BK, Gurm HS, Ting HH et al. Operator experience and carotid stenting outcomes in Medicare beneficiaries. JAMA 2011; 306(12):1338-43.
- 32. Gray WA. Carotid stenting or carotid surgery in average surgical-risk patients: interpreting the conflicting clinical trial data. Progress in cardiovascular diseases 2011; 54(1):14-21.
- 33. Endarterectomy for asymptomatic carotid artery stenosis. Executive Committee for the Asymptomatic Carotid Atherosclerosis Study. JAMA : the journal of the American Medical Association 1995; 273(18):1421-8.
- 34. Woo K, Garg J, Hye RJ et al. Contemporary results of carotid endarterectomy for asymptomatic carotid stenosis. Stroke 2010; 41(5):975-9.
- 35. Barnett HJ, Pelz DM, Lownie SP. Reflections by contrarians on the post-CREST evaluation of carotid stenting for stroke prevention. Int J Stroke 2010; 5(6):455-6.
- 36. Angioplasty and stenting of the cervical carotid artery with distal embolic protection of the cerebral circulation. Technol Eval Cent Asses Program Exec Summ 2005; 19(15):1-4.
- Ederle J, Featherstone RL, Brown MM. Randomized controlled trials comparing endarterectomy and endovascular treatment for carotid artery stenosis: a Cochrane systematic review. Stroke 2009; 40(4):1373-80.
- Bangalore S, Kumar S, Wetterslev J et al. Carotid artery stenting vs carotid endarterectomy: metaanalysis and diversity-adjusted trial sequential analysis of randomized trials. Arch Neurol 2011; 68(2):172-84.
- 39. Murad MH, Shahrour A, Shah ND et al. A systematic review and meta-analysis of randomized trials of carotid endarterectomy vs stenting. J Vasc Surg 2011; 53(3):792-7.
- 40. Economopoulos KP, Sergentanis TN, Tsivgoulis G et al. Carotid artery stenting versus carotid endarterectomy: a comprehensive meta-analysis of short-term and long-term outcomes. Stroke 2011; 42(3):687-92.
- 41. Touze E, Trinquart L, Chatellier G et al. Systematic review of the perioperative risks of stroke or death after carotid angioplasty and stenting. Stroke 2009; 40(12):e683-93.

- 42. Carotid Stenting Trialists Collaboration, Bonati LH, Dobson J et al. Short-term outcome after stenting versus endarterectomy for symptomatic carotid stenosis: a preplanned meta-analysis of individual patient data. Lancet 2010; 376(9746):1062-73.
- 43. Bangalore S, Kumar S, Wetterslev J et al. Carotid Artery Stenting vs Carotid Endarterectomy: Metaanalysis and Diversity-Adjusted Trial Sequential Analysis of Randomized Trials. Arch Neurol 2011; 68(2):172-84.
- 44. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Angioplasty and Stenting of the Cervical Carotid Artery with Embolic Protection of the Cerebral Circulation. TEC Assessments 2009; Volume 24, Tab 12.
- Gray WA, Chaturvedi K, Verta P. Thirty-Day Outcomes for Carotid Artery Stenting in 6320 Patients From 2 Prospective, Multicenter, High-Surgical-Risk Registries. Circ Cardiovasc Intervent 2009; 2:159-66.
- 46. White CJ, Iyer SS, Hopkins LN et al. Carotid stenting with distal protection in high surgical risk patients: the BEACH trial 30 day results. Catheter Cardiovasc Interv 2006; 67(4):503-12.
- 47. Lee VH, Brown RD, Jr., Mandrekar JN et al. Incidence and outcome of cervical artery dissection: a population-based study. Neurology 2006; 67(10):1809-12.
- 48. Schirmer CM, Atalay B, Malek AM. Endovascular recanalization of symptomatic flow-limiting cervical carotid dissection in an isolated hemisphere. Neurosurg Focus 2011; 30(6):E16.
- 49. Ohta H, Natarajan SK, Hauck EF et al. Endovascular stent therapy for extracranial and intracranial carotid artery dissection: single-center experience. J Neurosurg 2011; 115(1):91-100.
- 50. Hopkins LN, Myla S, Grube E et al. Carotid artery revascularization in high surgical risk patients with the NexStent and the Filterwire EX/EZ: 1-year results in the CABERNET trial. Catheter Cardiovasc Interv 2008; 71(7):950-60.
- Brott TG, Halperin JL, Abbara S et al. 2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS guideline on the management of patients with extracranial carotid and vertebral artery disease: executive summary. Stroke 2011; 42(8):e420-63.
- 52. Brott TG, Halperin JL, Abbara S et al. 2011 ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS Guideline on the Management of Patients With Extracranial Carotid and Vertebral Artery Disease. J Am Coll Cardiol 2011.
- 53. Brott TG, Halperin JL, Abbara S et al. 2011

ASA/ACCF/AHA/AANN/AANS/ACR/ASNR/CNS/SAIP/SCAI/SIR/SNIS/SVM/SVS Guideline on the Management of Patients With Extracranial Carotid and Vertebral Artery Disease: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines, and the American Stroke Association, American Association of Neuroscience Nurses, American Association of Neurological Surgeons, American College of Radiology, American Society of Neuroradiology, Congress of Neurological Surgeons, Society of Atherosclerosis Imaging and Prevention, Society for Cardiovascular Angiography and Interventions, Society of Interventional Radiology, Society of NeuroInterventional Surgery, Society for Vascular Medicine, and Society for Vascular Surgery. Circulation 2011.

- 54. Ricotta JJ, Aburahma A, Ascher E et al. Updated Society for Vascular Surgery guidelines for management of extracranial carotid disease. J Vasc Surg 2011; 54(3):e1-31.
- 55. Tendera M, Aboyans V, Bartelink ML et al. ESC Guidelines on the diagnosis and treatment of peripheral artery diseases: Document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteries: the Task Force on the Diagnosis and Treatment of Peripheral Artery Diseases of the European Society of Cardiology (ESC). Eur Heart J 2011; 32(22):2851-906.
- NICE. UK National Institute for Health and Clinical excellence carotid artery stent placement for asymptomatic carotid artery stenosis. 2011. 2011. Available online at: http://publications.nice.org.uk/carotid-artery-stent-placement-for-asymptomatic-extracranial-carotidstenosis-ipg388. Last accessed February 2014.
- 57. Guidelines for patient selection and performance of carotid artery stenting. Int Med J 2011; 41(4):344-7.

58. National Coverage Analysis (NCA) for Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting (CAG-00085N). Available online at: http://www.cms.gov/medicare-coverage-database/details/nca-

details.aspx?NCAId=62&ver=7&NcaName=Percutaneous+Transluminal+Angioplasty+(PTA)+of+the +Carotid+Artery+Concurrent+with+Stenting&CoverageSelection=National&KeyWord=angioplasty&K eyWordLookUp=Title&KeyWordLookUp=Title&KeyWordSearchType=And&KeyWordSearchType=A nd&bc=gAAAACAAAAA&. Last accessed February 2014.