

MedStar Health, Inc.

POLICY AND PROCEDURE MANUAL

Policy Number: PA.046.MH
Last Review Date: 09/10/2015
Effective Date: 01/01/2016
Renewal Date: 01/01/2017

PA.046.MH – Extracranial Carotid Angioplasty with Stenting

This policy applies to the following lines of business:

- ✓ MedStar Employee (Select)
- ✓ MedStar MA – DSNP – CSNP
- ✓ MedStar CareFirst PPO

MedStar Health considers an Extracranial Carotid Angioplasty with Stenting (CAS) medically necessary for the following indications:

1. Members requiring carotid revascularization using FDA approved CAS and embolic protection systems/devices who have documented high risk for adverse events from Carotid Endarterectomy (CEA) and meet one of the following criteria:
 - a. Members with hemispheric neurological symptoms in the ipsilateral carotid artery distribution and $\geq 50\%$ stenosis of the common or internal carotid artery confirmed by angiographic measurement using North American Symptomatic Carotid Endarterectomy Trial (NASCET) methodology
 - b. Members without neurological symptoms who are at high surgical risk and $\geq 80\%$ stenosis of the common or internal carotid artery confirmed by angiographic measurement using the NASCET methodology

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. 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;
- Severe chronic lung disease;
- Documentation in the member's medical records; and
- Other conditions that were used to determine patients at high risk for CEA in the prior carotid artery stenting trials and studies

PA.046.MH – Extracranial Carotid Angioplasty with Stenting

Policy Number: PA.046.MH

Last Review Date: 09/10/2015

Effective Date: 01/01/2016

Renewal Date: 01/01/2017

2. The procedure is performed concurrent with the FDA-approved protocols governing Category B - Investigational Device Exemption (IDE) Clinical Trials (coverage of routine care only will be according to PA.078.MH Clinical Trials- Coverage of Routine Care Costs)
3. The procedure is performed concurrent with FDA Approved Post Approval Study and the member meets one of the following criteria:
 - Members who are at high risk and with neurologic symptoms and carotid artery stenosis between 50 and 80%.
 - Members who are at high risk with/without neurological symptoms and $\geq 80\%$ stenosis of the common or internal carotid artery by ultrasound or angiogram; The member has carotid lesions that, due to their anatomic location, are difficult to approach surgically.

Limitations:

1. Members who have had a disabling stroke (modified Rankin scale ≥ 3) shall be excluded from coverage.
2. If the use of an embolic protection device is not possible during an attempted CAS procedure, the procedure should be abandoned due to the risk of adverse events without embolic protection.
3. Carotid angioplasty with stenting must be performed by a physician with training and experience in this technology and facilities at which this procedure is performed must have written FDA approvals for Clinical trials or must have written affidavits approved by Centers for Medicare and Medicaid Services (CMS) attesting that they have met the minimum facility standards.
(Refer to PA.078.MH Clinical Trials- Coverage for Routine Care Costs)

Exclusion: Vertebral artery angioplasty with/without stenting is not covered. The safety and efficacy of this procedure is not yet established.

See Also:

PA.078.MH Clinical Trials- Coverage of Routine Care Costs

PA.079.MH Experimental and Investigational Services

Background

Cerebrovascular disease is the third leading cause of death in the United States.^{1,2} Approximately 750 000 people have a stroke annually, and carotid stenosis accounts for about 25% of these strokes. Risk factors for stroke include advanced age, male gender, hypertension, history of stroke or TIA (transient ischemic attack), atrial fibrillation,

PA.046.MH – Extracranial Carotid Angioplasty with Stenting

Policy Number: PA.046.MH
Last Review Date: 09/10/2015
Effective Date: 01/01/2016
Renewal Date: 01/01/2017

valvular heart disease, diabetes mellitus, carotid artery stenosis, hypercoagulable conditions, and cigarette smoking.

Prevention of stroke remains important and includes among others, treatment of hypertension and diabetes mellitus; smoking cessation; limiting alcohol intake; control of diet and obesity; antiplatelet drugs or anticoagulants for atrial fibrillation and appropriate acute myocardial infarctions; antiplatelet drugs for symptomatic carotid or vertebrobasilar atherosclerosis; and carotid endarterectomy (CEA) for specifically defined populations of patients with symptomatic carotid artery stenosis

Carotid artery stenting (CAS) is performed with a catheter, usually inserted through the femoral artery, and threaded up to the carotid artery beyond the area of narrowing. A distal embolic protection device or filter is usually placed first to catch emboli or debris that may dislodge during the procedure. A self-expandable or balloon-expandable, metal mesh stent is then placed to widen the stenosis and the protection device is removed.

Modified Rankin Stroke Scale:

- 0 - No symptoms at all
- 1 - No significant disability despite symptoms; able to carry out all usual duties and activities
- 2 - Slight disability; unable to carry out all previous activities but able to look after own affairs without assistance
- 3 - Moderate disability; requiring some help, but able to walk without assistance
- 4 - Moderately severe disability: unable to walk without assistance, and unable to attend to own bodily needs without assistance
- 5 - Severe disability: bedridden, incontinent, and requiring constant nursing care and attention

Codes:

CPT Codes	
Code	Description
0075T	Transcatheter placement of extracranial vertebral or intrathoracic carotid artery stent(s), including radiologic supervision and interpretation, percutaneous, initial vessel (Sunset January 2020)
0076T	Each additional vessel (List separating in addition to code for primary procedure (Sunset January 2020)

PA.046.MH – Extracranial Carotid Angioplasty with Stenting

Policy Number: PA.046.MH
Last Review Date: 09/10/2015
Effective Date: 01/01/2016
Renewal Date: 01/01/2017

37215	Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; with distal embolic protection
-------	--

References

1. Bonati LH, Dobson J, Featherstone RL, et al. [for the International Carotid Stenting Study investigators]. Long-term outcomes after stenting versus endarterectomy for treatment of symptomatic carotid stenosis: the International Carotid Stenting Study (ICSS) randomised trial. *Lancet*. 2014 Oct 14. pii: S0140-6736(14)61184-3. doi: 10.1016/S0140-6736(14)61184-3. [Epub ahead of print]. <http://www.sciencedirect.com/science/article/pii/S0140673614611843>
2. Bonati LH, Lyrer P, Ederle J, et al. Percutaneous transluminal balloon angioplasty and stenting for carotid artery stenosis. *Cochrane Database Syst Rev*. 2012 Sep 12;9:CD000515. doi: 10.1002/14651858.CD000515.pub4 <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD000515.pub4/pdf>
3. Brott TG, Halperin JL, Abbara S, et al. 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: 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. Developed in collaboration with the American Academy of Neurology and Society of Cardiovascular Computed Tomography. January 2011. © 2011 by the American College of Cardiology Foundation and the American Heart Association, Inc. http://my.americanheart.org/idc/groups/ahamah-public/@wcm/@sop/@spub/documents/downloadable/ucm_430166.pdf
4. Centers for Medicare and Medicaid Services (CMS). Decision Memo for Carotid Artery Stenting (CAG-00085R). Published March 17, 2005. https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=157&NCDId=201&IsPopup=y&bc=AAAAAAAAAgAAAA%3D%3D&#P99_9757
5. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) No. 20.7 - Percutaneous Transluminal Angioplasty (PTA). Effective date of this version: 01/01/2013 <http://www.cms.gov/medicare->

PA.046.MH – Extracranial Carotid Angioplasty with Stenting

Policy Number: PA.046.MH
Last Review Date: 09/10/2015
Effective Date: 01/01/2016
Renewal Date: 01/01/2017

- [coverage-database/details/ncd-
details.aspx?NCDId=201&ncdver=10&bc=AAAAGAAAAAAAAA%3d%3d&](#)
6. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) No. 20.1 - Vertebral Artery Surgery: Longstanding NCD. [http://www.cms.gov/medicare-coverage-database/details/ncd-
details.aspx?NCDId=48&ncdver=1&bc=AAAAGAAAAAAAAA%3d%3d&](http://www.cms.gov/medicare-coverage-database/details/ncd-
details.aspx?NCDId=48&ncdver=1&bc=AAAAGAAAAAAAAA%3d%3d&)
 7. Centers for Medicare and Medicaid Services (CMS): Pub 100-04 Medicare Claims Processing Transmittal 1315- Subject: Clarification of percutaneous transluminal angioplasty (PTA) billing requirements issued in CR 3811. Date: August 10, 2007. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/R1315CP.pdf>
 8. Centers for Medicare and Medicaid Services (CMS): Medicare Learning Network (MLN) Matters MM3811- Expansion of coverage for percutaneous transluminal angioplasty (PTA). Effective date: March 17, 2005. Updated February 7, 2013. <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm3811.pdf>
 9. Centers for Medicare and Medicaid Services (CMS): Medicare Learning Network (MLN) Matters MM5667- Clarification of percutaneous transluminal angioplasty (PTA) billing requirements issued in CR 3811. Effective date; March 17, 2005. Updated June 15, 2013. <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/mm5667.pdf>
 10. Coward LJ, McCabe DJ, Ederle J, et.al: Long-term outcome after angioplasty and stenting for symptomatic vertebral artery stenosis compared with medical treatment in the carotid and vertebral artery transluminal angioplasty study (CAVATAS). American Heart Association, Stroke. 2007 May; 38:1526-1530.. <http://stroke.ahajournals.org/content/38/5/1526.full.pdf+html>
 11. ECRI Institute: CMS Seeks to Expand Coverage of Carotid Stenting to Higher Risk Group, Published 9/18/2009. <https://members2.ecri.org/Components/Forecast/Pages/11743.aspx>
 12. Furie KL, Kasner Se, Adams RJ, et al. Guidelines for the prevention of stroke in patients with stroke or transient ischemic attack: a guideline for healthcare professionals from the American Heart Association/American Stroke Association. Stroke. 2011 Jan; 42(1):227-276: originally published online 10/21/10. <http://stroke.ahajournals.org/content/42/1/227.full.pdf+html>
 13. Gray WA, Verta P: The impact of regulatory approval and Medicare coverage on outcomes of carotid stenting. Catheterization Cardiovasc Interv. 2014 Jun 1;83(7):1158-1166. doi: 10.1002/ccd.25283. Epub 2013 Dec 3. <http://onlinelibrary.wiley.com/doi/10.1002/ccd.25283/pdf>
 14. Gray WA, White HJ Jr, Barrett DM, et al. Carotid stenting and endarterectomy: a clinical and cost comparison of revascularization strategies. Stroke 2002 Apr; 33(4):1063-1070. <http://stroke.ahajournals.org/content/33/4/1063.full.pdf+html>

PA.046.MH – Extracranial Carotid Angioplasty with Stenting

Policy Number: PA.046.MH

Last Review Date: 09/10/2015

Effective Date: 01/01/2016

Renewal Date: 01/01/2017

15. Eliasziw M, Fox AJ, Sharpe BL, et al. Carotid artery stenosis: external validity of the North American Symptomatic Carotid Endarterectomy Trial measurement method. *Radiology*. 1997 Jul; 204(1):229-233.
<http://pubs.rsna.org/doi/pdf/10.1148/radiology.204.1.9205252>
16. Higashida RT, Meyers PM, Pharoors MD, et al. Reporting Standards for Carotid Artery angioplasty and Stent Placement. *Stroke*. 2004; 35; e112-e134.
<http://stroke.ahajournals.org/content/35/5/e112.full>
17. Kernan, MW, Ovbiagele, B, Black, HR et al. Guidelines for the Prevention of Stroke in Patients with Stroke and Transient Ischemic Attack- A Guideline for Healthcare Professionals From the American Heart Association/ American Stroke Association. July 2014.
<http://stroke.ahajournals.org/content/early/2014/04/30/STR.0000000000000024.full.pdf+html>
18. Lin PH, Bush RL, Lumsden AB. Carotid artery stenting: current status and future directions. *Vasc Endovascular Surg*. 2003 Sep-Oct; 37(5): 315-322.
<http://ves.sagepub.com/content/37/5/315.long>
19. Matsumura JS, Gray W, Chaturvedi S, et al. Results of carotid artery stenting with distal embolic protection with improved systems: Protected Carotid Artery Stenting in Patients at High Risk for Carotid Endarterectomy (PROTECT) trial. *J Vasc Surg*. 2012 Apr;55(4):968-976.e5. doi: 10.1016/j.jvs.2011.10.120. Epub 2012 Jan 9.
<http://www.sciencedirect.com/science/article/pii/S074152141102595X>
20. National Heart, Lung, and Blood Institute: Health Topics: What Is Carotid Endarterectomy? Posted 12/1/2010. <http://www.nhlbi.nih.gov/health/health-topics/topics/carend/>
21. Neequaye SK, Halliday AW. National Institute for Health and Clinical Excellence (NICE) carotid artery stenting: a summary of the 2011 guidelines. *Heart*. 2011 Nov; online: doi: 10.1136/heartjnl-2011-301218
<http://heart.bmj.com/content/early/2011/11/29/heartjnl-2011-301218.full.pdf+html>
22. Taylor S, Alcocer F, Jordan WD Jr. Controversies in carotid stenting. *Vasc Endovascular Surg* 2003 Mar-Apr; 37(2):79-87.
<http://ves.sagepub.com/content/37/2/79.long>
23. Vilain KR, Magnuson EA, Li H, et al. Costs and cost-effectiveness of carotid stenting versus endarterectomy for patients at standard surgical risk: Results from the Carotid Revascularization Endarterectomy versus Stenting Trial (CREST). *Stroke*. 2012 Sept; 43(9): 2408-2416.
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3555501/pdf/nihms395625.pdf>
24. White CJ. Carotid artery stenting. *J Am Coll Cardiol*. 2014 Aug 19;64(7):722-731. doi: 10.1016/j.jacc.2014.04.069.
<http://www.sciencedirect.com/science/article/pii/S0735109714040960>

PA.046.MH – Extracranial Carotid Angioplasty with Stenting

Policy Number: PA.046.MH

Last Review Date: 09/10/2015

Effective Date: 01/01/2016

Renewal Date: 01/01/2017

25. Wholey MH, Al-Mubarek N, Wholey MH. Updated review of the global carotid artery stent registry. *Catheter Cardiovasc Interv* 2003 Oct; 60(2):259-266.

<http://onlinelibrary.wiley.com/doi/10.1002/ccd.10645/pdf>

Disclaimer:

MedStar Health medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.

These policies are the proprietary information of Evolent Health. Any sale, copying, or dissemination of said policies is prohibited.