

Medical Coverage Policy



Endovascular Procedures (Angioplasty and/or Stenting) for Intracranial Arterial Disease (Atherosclerosis and Aneurysms)

Device/Equipment Drug Medical Surgery Test Other

Effective Date:	3/1/2009	Policy Last Updated:	4/16/2013
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Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

Prospective review is not required.

Description:

Patients with ischemic stroke or transient ischemic attack (TIA) are at high risk of recurrent events. Endovascular interventions have been used to treat patients with symptomatic intracranial stenoses who have failed medical therapy. Treatment options include balloon angioplasty, or balloon angioplasty with stenting.

It is estimated that intracranial atherosclerosis causes about 8% of all ischemic strokes. Intracranial stenosis may contribute to stroke in two ways: either due to embolism or low flow ischemia in the absence of collateral circulation. Recurrent annual stroke rates are estimated at 4–12% per year with atherosclerosis of the intracranial anterior circulation and 2.5–15% per year with lesions of the posterior (vertebrobasilar) circulation. Medical treatment typically includes either anticoagulant therapy (i.e., warfarin) or antiplatelet therapy (e.g., aspirin). However, medical therapy has been considered less than optimal. For example, in patients with persistent symptoms despite antithrombotic therapy, the subsequent rate of stroke or death has been extremely high, estimated in one study at 45%, with recurrent events occurring within 1 month of the initial recurrence. Surgical approaches have met with limited success. The widely quoted extracranial-intracranial (EC/IC) bypass study randomized 1,377 patients with symptomatic atherosclerosis of the internal carotid or middle cerebral arteries to medical care or EC/IC bypass. The outcomes in the two groups were similar, suggesting that the EC/IC bypass is ineffective in preventing cerebral ischemia. Due to inaccessibility, surgical options for the posterior circulation are even more limited.

Percutaneous transluminal angioplasty (PTA) has been approached cautiously for use in the intracranial circulation, due to technical difficulties in catheter and stent design and the risk of

embolism, which may result in devastating complications if occurring in the posterior fossa or brain stem. However, improvement in the ability to track catheterization, allowing catheterization of tortuous vessels, and the increased use of stents have created ongoing interest in exploring PTA as a minimally invasive treatment of this difficult-to-treat population. The majority of published studies of intracranial PTA has focused on the vertebrobasilar circulation.

BlueCHIP for Medicare covers PTA and stenting of intracranial arteries for the treatment of cerebral artery stenosis >50 % in patients with intracranial atherosclerotic disease when furnished in accordance with the FDA-approved protocols governing Category B IDE clinical trials. CMS determines that coverage of intracranial PTA and stenting is reasonable and necessary under these circumstances.

Intracranial stents are also being used in the treatment of cerebral aneurysms. Stent-assisted coiling began as an approach to treat fusiform or wide-neck aneurysms in which other surgical or endovascular treatment strategies may not be feasible. As experience grew, stenting was also used in smaller berry aneurysms as an approach to decrease the rate of retreatment needed in patients who receive coiling. A randomized trial has demonstrated that treatment of ruptured intracranial aneurysms with coiling leads to improved short-term outcome compared to surgical clipping; however, patients who receive coiling have a need for more repeat/follow-up procedures.

For elective treatment of symptomatic intracranial stenosis, endovascular procedures with or without stenting have not been shown to be superior to best medical care. One very small randomized controlled trial (RCT) did not report benefit and a larger RCT was terminated prematurely due to an excess of the primary outcome of death or stroke in the endovascular group. This evidence suggests that the adverse event rate with endovascular procedures is relatively high and may outweigh the benefit in preventing recurrent ischemic events. As a result, endovascular procedures with or without stenting are considered not medically necessary for the elective treatment of symptomatic intracranial stenosis as there is no proven efficacy.

For acute stroke, the evidence is very limited, consisting of only small case series. This evidence is insufficient to form conclusions about the effect of endovascular interventions in acute stroke, and as a result, endovascular interventions are considered not medically necessary for the treatment of acute stroke as there is no proven efficacy.

For the treatment of intracranial aneurysms, there are no RCTs of stent-assisted coiling with coiling alone. Non-randomized comparative studies report occlusion rates that are similar to coiling alone, and recurrence rates that may be lower than for coiling alone. Results of clinical vetting indicated strong support for treatment of aneurysms that are not amenable to surgery or simple coiling. Comparative trials with and without stenting for this clinical situation are unlikely. As a result, use of stent-assisted coiling for the treatment of intracranial aneurysms

may be considered medically necessary when surgical treatment is not appropriate and standard endovascular techniques do not allow for complete isolation of the aneurysm.

Medical Criteria:

None.

Policy:

Intracranial stent placement:

For All Products:

Intracranial stent placement may be considered **medically necessary** as part of the endovascular treatment of intracranial aneurysms for patients when surgical treatment is not appropriate and standard endovascular techniques do not allow for complete isolation of the aneurysm, e.g., wide-neck aneurysm (4 mm or more) or sack-to-neck ratio less than 2:1. All other indications are considered not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

Intracranial percutaneous transluminal angioplasty:

Commercial:

Intracranial percutaneous transluminal angioplasty with or without stenting is considered **not medically necessary** in the treatment of atherosclerotic cerebrovascular disease as there is insufficient peer-reviewed scientific literature that demonstrates that the procedure/service is effective.

BlueCHiP for Medicare:

BlueCHiP for Medicare covers Intracranial percutaneous transluminal angioplasty (PTA) and stenting of intracranial arteries for the treatment of cerebral artery stenosis >50 % in patients with intracranial atherosclerotic disease when furnished in accordance with the FDA-approved protocols governing Category B IDE clinical trials.

Medicare policy is developed separately from BCBSRI policy. Medicare policy incorporates consideration of governmental regulations from CMS (Centers for Medicare and Medicaid Services), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than does BCBSRI. Medicare and BCBSRI policies may differ. However, BlueCHiP for Medicare members must be offered, at least, the same services as Medicare offers.

Coverage:

Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage, subscriber agreement for the applicable surgery coverage/benefits.

Coding:**61630, 61635**

If occlusion of a vascular malformation is performed as part of the treatment of an aneurysm, code **61624** would be used.

Related topics:

None

Also know as:

Cerebral stenoses

Wingspan™

Neurolink System®

Atherosclerotic

References:

- I. Levy EI, Rahman M, Khalessi AA et al. Midterm clinical and angiographic follow-up for the first Food and Drug Administration-approved prospective, Single-Arm Trial of Primary Stenting for Stroke: SARIS (Stent-Assisted Recanalization for Acute Ischemic Stroke). *Neurosurgery* 2011; 69(4):915-20; discussion 20.
- II. Piotin M, Blanc R, Spelle L et al. Stent-assisted coiling of intracranial aneurysms: clinical and angiographic results in 216 consecutive aneurysms. *Stroke* 2010; 41(1):110-5.
- III. Bodily KD, Cloft HJ, Lanzino G et al. Stent-assisted coiling in acutely ruptured intracranial aneurysms: a qualitative, systematic review of the literature. *AJNR Am J Neuroradiol* 2011; 32(7):1232-6.
- IV. Meyers PM, Schumacher HC, Higashida RT et al. Indications for the performance of intracranial endovascular neurointerventional procedures: a scientific statement from the American Heart Association Council on Cardiovascular Radiology and Intervention, Stroke Council, Council on Cardiovascular Surgery and Anesthesia, Interdisciplinary Council on Peripheral Vascular Disease, and Interdisciplinary Council on Quality of Care and Outcomes Research. *Circulation* 2009; 119(16):2235-49.
- V. Decision Memo for Intracranial Stenting and Angioplasty (CAG-00085R5). Centers for Medicare and Medicaid Services. Available online at: <http://www.cms.gov/medicare-coverage-database/details/nca-proposed-decision-memo.aspx?NCAId=214&fromdb=true>.

Published:

Provider Update, July 2013

Provider Update, May 2012

Provider Update, May 2011

Provider Update, Jan 2011

Provider Update, Jan 2010

Provider Update, Feb 2009

History:

March 2013 - Annual Review

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