

**Medical Coverage Policy | Endovascular Procedures
(Angioplasty and/or Stenting) for Intracranial
Arterial Disease (Atherosclerosis and Aneurysms)**



EFFECTIVE DATE: 03|03|2015

POLICY LAST UPDATED: 04|19|2016

OVERVIEW

Cerebrovascular diseases include a range of processes affecting the cerebral vascular system, including arterial thromboembolism, arterial stenosis, and arterial aneurysms, all of which can lead to restrictions in cerebral blood flow due to ischemia or hemorrhage. Endovascular techniques, including endovascular pharmacologic thrombolysis, endovascular mechanical embolectomy using one of several types of devices, endovascular deployment of several types of stents, and angioplasty with or without stenting, have been investigated for treatment of cerebrovascular diseases.

This policy only addresses endovascular therapies used on intracranial vessels.

MEDICAL CRITERIA

Not applicable

PRIOR AUTHORIZATION

Prior authorization review is not required.

POLICY STATEMENT

BlueCHiP for Medicare and Commercial Products

Intracranial stent placement

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.

Commercial Products

Intracranial percutaneous transluminal angioplasty

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

Intracranial percutaneous transluminal angioplasty

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 U.S. Food and Drug Administration (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 the Centers for Medicare and Medicaid Services (CMS), such as national coverage determinations or local coverage determinations. In addition to benefit differences, CMS may reach different conclusions regarding the scientific evidence than BCBSRI. Medicare and BCBSRI policies may

differ. However, BlueCHiP for Medicare members must be offered, at least, the same services that Medicare offers.

COVERAGE

Benefits may vary between groups and contracts. Please refer to the appropriate Evidence of Coverage or Subscriber Agreement for the applicable surgery coverage/benefits.

BACKGROUND

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 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 one 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 have 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 have been 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.

CODING

BlueCHiP for Medicare

The following CPT code is medically necessary:

- 61630** Balloon angioplasty, intracranial (e.g., atherosclerotic stenosis), percutaneous
- 61635** Transcatheter placement of intravascular stent(s), intracranial (e.g., atherosclerotic stenosis), including balloon angioplasty, if performed
- 61645** Percutaneous arterial transluminal mechanical thrombectomy and/or infusion for thrombolysis, intracranial, any method, including diagnostic angiography, fluoroscopic guidance, catheter placement, and intraprocedural pharmacological thrombolytic injection(s)

Commercial Products

The following CPT code is not medically necessary when filed with one of the diagnosis noted below:

- 61630** Balloon angioplasty, intracranial (e.g., atherosclerotic stenosis), percutaneous
- 61645** Percutaneous arterial transluminal mechanical thrombectomy and/or infusion for thrombolysis, intracranial, any method, including diagnostic angiography, fluoroscopic guidance, catheter placement, and intraprocedural pharmacological thrombolytic injection(s)

ICD-9

430 or 437.3

ICD-10

I67.2

The following CPT code is medically necessary only when filed with one of the diagnosis noted below:

61635 Transcatheter placement of intravascular stent(s), intracranial (e.g., atherosclerotic stenosis), including balloon angioplasty, if performed:

ICD-9

437.0 or 437.1

ICD-10

I67.2

RELATED POLICIES

None

PUBLISHED

Provider Update, June 2016
Provider Update, May 2015
Provider Update, July 2013
Provider Update, May 2012
Provider Update, May 2011
Provider Update, January 2011
Provider Update, January 2010
Provider Update, February 2009

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2. 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.
3. 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.
4. 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.
5. 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>.

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