

## Corporate Medical Policy

### Endovascular Procedures for Intracranial Arterial Disease

**File Name:** endovascular\_procedures\_for\_intracranial\_arterial\_disease  
**Origination:** 2/1996  
**Last CAP Review:** 5/2011  
**Next CAP Review:** 5/2012  
**Last Review:** 5/2011

#### Description of Procedure or Service

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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). The Warfarin-Aspirin Symptomatic Intracranial Disease (WASID) trial was a randomized trial that compared the incidence of stroke brain hemorrhage or death among patients randomized to receive either aspirin or warfarin. The report indicated that, with a mean 1.8 years of follow-up, warfarin provided no benefit over aspirin and was associated with a significantly higher rate of complications. In addition, if symptoms could be attributed to low flow ischemia, agents to increase mean arterial blood pressure and avoidance of orthostatic hypotension may be recommended. 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 1 study at 45%, with recurrent events occurring within a 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 veins, 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.

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.

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## Regulatory Status:

Currently two devices have received approval from the U.S. Food and Drug Administration (FDA) through the humanitarian device exemption (HDE) process. This form of FDA approval is available for devices used to treat conditions with an incidence of 4,000 or less per year and the FDA only requires data showing “probable safety and effectiveness.” Devices with their labeled indications are as follows:

Neurolink System® (Guidant, Santa Clara, CA)

“The Neurolink system is indicated for the treatment of patients with recurrent intracranial stroke attributable to atherosclerotic disease refractory to medical therapy in intracranial vessels ranging from 2.5 to 4.5 mm in diameter with  $\geq 50\%$  stenosis and that are accessible to the stent system.”

Wingspan™ Stent System (Boston Scientific, Fremont, CA)

“The Wingspan Stent System with Gateway PTA Balloon Catheter is indicated for use in improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with  $\geq 50\%$  stenosis that are accessible to the system.”

Two stents have received FDA approval through the Humanitarian Device Exemption (HDE) program for treatment of intracranial aneurysms. In 2002, based on a series of approximately 30 patients with 6-month follow-up, the Neuroform Microdelivery Stent System was approved (HDE) for use with embolic coils for treatment of wide-neck intracranial aneurysms that cannot be treated by surgical clipping (H020002). Similarly, in 2007, based on a series of approximately 30 patients with 6-month follow-up, the Enterprise Vascular Reconstruction Device and Delivery System (Cordis Neurovascular, Inc.) was approved (HDE) for use with embolic coils for treatment of wide-neck, intracranial, saccular or fusiform aneurysms (H060001).

## Related Policies:

Carotid Artery Angioplasty/Stenting (CAS)  
Mechanical Embolectomy for Treatment of Acute Stroke

*\*\*\*Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.*

## Policy

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**BCBSNC will provide coverage for Endovascular Procedures (Angioplasty and/or Stenting) for Intracranial Arterial Disease (Atherosclerosis and Aneurysms) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.**

## Benefits Application

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This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

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## **When Endovascular Procedures for Intracranial Arterial Disease is covered**

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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.

## **When Endovascular Procedures for Intracranial Arterial Disease is not covered**

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Intracranial stent placement is considered investigational in the treatment of intracranial aneurysms except as noted above.

Intracranial percutaneous transluminal angioplasty with or without stenting is considered investigational in the treatment of atherosclerotic cerebrovascular disease.

## **Policy Guidelines**

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In summary, case series demonstrate that stents can be deployed in the treatment of intracranial aneurysms. Use is generally reserved for cases where successful occlusion of the aneurysm cannot be obtained with standard endovascular techniques, e.g., wide-neck aneurysms. Series show high levels of short-term success (placement). In addition, these series demonstrate persistent occlusion for many aneurysms. Comparative trials with and without stenting for this clinical situation seem unlikely. There is strong clinical support for selective use of stents as part of endovascular treatment of these aneurysms.

## **Billing/Coding/Physician Documentation Information**

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This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at [www.bcbsnc.com](http://www.bcbsnc.com). They are listed in the Category Search on the Medical Policy search page.

*Applicable service codes: 61630, 61635, 61640, 64641, 64642.*

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

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## **Scientific Background and Reference Sources**

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### **Cerebral Angioplasty**

Food and Drug Administration

Medical Policy Advisory Group Review - 3/99

Specialty Matched Consultant Advisory Panel - 10/2000

Consultant Review - 11/2000

Polin RS, Coenen VA, Hansen CA, et al. Efficacy of transluminal angioplasty for the management of symptomatic cerebral vasospasm following aneurysmal subarachnoid hemorrhage. *J Neurosurg.* 2000 Feb;92(2):284-90.

Mori T, Fukuoka M, Kazita K, Mori K. Follow-up study after percutaneous transluminal cerebral angioplasty. *Eur Radiol.* 1998;8(3):403-8.

Albers GW. Management of acute ischemic stroke. An update for primary care physicians. *West J Med.* 1997 Apr;166(4):253-62.

Specialty Matched Consultant Advisory Panel - 7/2002

BCBSA Medical Policy Reference Manual, 2.01.54; 12/18/02

Specialty Matched Consultant Advisory Panel - 7/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.54, 3/15/2005

Specialty Matched Consultant Advisory Panel - 6/2005

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.54, 4/25/2006

Specialty Matched Consultant Advisory Panel - 5/2007

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.54, 7/10/2008

Specialty Matched Consultant Advisory Panel - 5/2009

### **Title Change – Endovascular Procedures for Intracranial Arterial Disease**

BCBSA Medical Policy Reference Manual [Electronic Version]. 2.01.54, 2/10/11

Specialty Matched Consultant Advisory Panel - 5/2011

## **Policy Implementation/Update Information**

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2/96 Original policy issued.

# Endovascular Procedures for Intracranial Arterial Disease

- 2/97 Reaffirmed
- 3/99 Reaffirmed
- 8/99 Reformatted, Medical Term Definitions added.
- 10/00 System coding changes.
- 11/00 Specialty Matched Consultant Advisory Panel review. Consultant review. Literature search through 11/2000 in MEDLINE and MD Consult. No change in criteria. Reaffirm.
- 11/01 Coding format change.
- 8/02 Specialty Matched Consultant Advisory Panel review 7/12/2002. No changes.
- 7/03 Specialty Matched Consultant Advisory Panel review 7/15/03. No changes to criteria. Benefits Application section revised. Codes 36100, 36215-36218, 35475 added to Billing/Coding section.
- 1/04 Billing/Coding section updated for consistency.
- 7/7/05 Specialty Matched Consultant Advisory Panel review 6/24/2005. No changes to criteria. Rationale added to "Policy Guidelines" section. Policy number added to "Policy Key Words" section. References added.
- 7/10/06 Added new 2006 CPT codes 61640, 61641, and 61642 to the Billing/Coding section. Added "with or without stenting" to "Policy" section. "Neurolink System" and "Wingspan Stent System with Gateway PTA Balloon Catheter" added to "Policy Key Words" section.
- 12/11/06 Added CPT codes 61630 and 61635 to the "Billing/Coding" section.
- 8/13/07 Specialty Matched Consultant Advisory Panel review 5/23/07. Updated "Description" section. Added statement; "\*\*\*Please note that this policy does not pertain to Carotid Artery Angioplasty/Stenting (CAS), policy number SUR6115." References added.
- 7/6/09 Specialty Matched Consultant Advisory Panel review 5/28/09. Revised "Description" section. No change to policy statement. References added. (btw)
- 6/22/10 Policy Number(s) removed (amw)
- 6/21/11 Policy title changed from "Cerebral Angioplasty" to "Endovascular Procedures for Intracranial Arterial Disease". Specialty Matched Consultant Advisory Panel review 5/25/2011. Revised "Description" section to include information regarding endovascular procedures for aneurysm. Changed the "Policy" statement; "BCBSNC will provide coverage for Endovascular Procedures (Angioplasty and/or Stenting) for Intracranial Arterial Disease (Atherosclerosis and Aneurysms) when it is determined to be medically necessary because the medical criteria and guidelines shown below are met." Added the following statement to the "When Covered" section; "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." Revised the "When Not Covered" section to; "Intracranial stent placement is considered investigational in the treatment of intracranial aneurysms except as noted above. Intracranial percutaneous transluminal angioplasty with or without

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stenting is considered investigational in the treatment of atherosclerotic cerebrovascular disease.” Updated “Policy Guidelines” section. References added. (btw)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.