MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**ANGIOPLASTY OF INTRACRANIAL ATHEROSCLEROTIC STENOSES WITH OR WITHOUT STENTING**
Policy Number	**7.01.70**
Category	**Technology Assessment**
Effective Date	**02/16/06**
Revised Date	**11/16/06, 09/20/07, 10/23/08, 09/17/09, 08/19/10, 07/21/11, 06/21/12, 05/23/13, 04/17/14, 03/19/15, 03/17/16, 03/16/17, 03/15/18, 02/21/19**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

POLICY STATEMENT

Based upon our criteria and assessment of the peer-reviewed literature, intracranial percutaneous transluminal angioplasty, with or without stenting, has not been medically proven to be effective and is considered **investigational** for treatment of intracranial atherosclerotic stenosis.

Refer to Corporate Medical Policy # 7.01.60 regarding Extracranial Carotid and Vertebral Artery Angioplasty and Stents.

Refer to Corporate Medical Policy #7.01.81 regarding Endovascular Repair (coil embolization) of Intracranial Aneurysms.

Refer to Corporate Medical Policy #7.01.82 regarding Endovascular Treatment of Acute Ischemic Stroke (e.g. Mechanical Embolectomy).

Refer to Corporate Medical Policy #11.01.03 regarding Experimental and Investigational Services.

Refer to Corporate Medical Policy #11.01.10 regarding Clinical Trials.

POLICY GUIDELINES

The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

Approximately 750,000 strokes occur in the US annually, of which 85% are ischemic. A significant number of ischemic strokes are due to intracranial atherosclerosis. Intracranial stenosis may contribute to stroke either by thrombosis or low flow ischemia (symptomatic stenosis) in the absence of collateral circulation. Medical treatment with either antithrombotic therapy or agents to increase mean arterial blood pressure is considered less than optimal and surgical options have resulted in only minimal success.

Percutaneous transluminal angioplasty (PTA) has been approached cautiously in the intracranial circulation, due to technical difficulties in catheter and stent design, and the risk of embolism. However, improvement in catheter trackability, and the increased use of stents have created ongoing interest in exploring PTA as a minimally invasive treatment for the prevention of stroke in patients with intracranial artery stenosis. The bulk of published studies of intracranial PTA have focused on the vertebrobasilar circulation as treatment for symptomatic stenosis. A few studies

have explored the use of stents as a rescue measure in situations of failed thrombolytic therapy or in patients who are not candidates for thrombolytic treatment.

RATIONALE

Currently two PTA devices have received approval from the 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."

The Neurolink® System (Guidant Corporation) 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 greater than or equal to 50% stenosis and that are accessible to the stent system. Patients in this subset have a poor prognosis, and treatment options are limited. A 2004 prospective, nonrandomized, multicenter, study, (SSYLVIA [Stenting of Symptomatic Atherosclerosis Lesions in the Vertebral or Intracranial Arteries]) investigated the device. The primary endpoint was a composite of stroke and death at 30 days, which occurred in 6.6% of patients. The FDA summary notes that in the WASID study of aspirin and warfarin therapy, the rate of fatal or non-fatal stroke was 14.6% and total/stroke or death was 22.5%. The FDA Summary of Safety and Probable Benefit concludes, "… that the probable benefit to health from using the Neurolink System for intracranial stenting for recurrent stroke attributable to intracranial atherosclerosis refractory to medical therapy outweighs the risk of illness or injury, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment, when used as indicated in accordance with the directions of use." Despite receiving HDE approval from the FDA, the Guidant Corporation no longer manufactures the Neurolink Stent System.

The Wingspan™ Stent System with Gateway™ PTA Balloon Catheter (Boston Scientific), is indicated for improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with greater than or equal to 50% stenosis that are accessible to the system. The Wingspan Stent System consists of a highly flexible, microcatheter delivered self-expanding nitinol stent, which may be suitable for lesions in the distal internal carotid and middle cerebral arteries. These lesions are difficult to access with a balloon mounted stent, such as the Neurolink system. The Wingspan was studied in a prospective, multicenter, single arm trial of 45 patients enrolled at 12 international centers. The primary safety endpoint was similar to that of the SSYLVIA study, i.e., a composite of stroke and death clinical outcomes at 30 days, which occurred in 4.5% of patients. Clinical follow-up (42 patients) and angiographic follow-up (40 patients) were performed at 6 months. The type and frequency of observed adverse events including stroke are consistent with or lower than similar neurovascular procedures. Therefore, the FDA concluded that the probable benefit to health from using the Wingspan Stent System with Gateway PTA Balloon Catheter for treating transcranial stenosis outweighs the risk of illness or injury when used in accordance with the Instructions for Use and when taking into account the probable risks and benefits of currently available alternative forms of treatment.

The FDA Neurological Devices Panel met March 23, 2012 to discuss the continued approval of the Wingspan stent after the poor results of the SAMMPRIS trial. In an informal vote, the panel agreed unanimously that the current data on the device does not support its safety and efficacy as a treatment for ischemic stroke in adults and called for continued research. Based on this meeting, the FDA has narrowed the indications for the use of Wingspan (FDA Medwatch Aug 2012). "After reviewing the available safety information, the FDA believes that a very specific group of patients with severe intracranial stenosis and recurrent stroke despite continued medical management – who have not had any new symptoms of stroke within the 7 days prior to planned treatment with Wingspan – may benefit from the use of the device," the FDA statement said. "The agency's assessment of benefits and risks for this device considered that these patients are at serious risk of life-threatening stroke and have limited alternative treatment options."

A 2005 Cochrane review focused on randomized trials of angioplasty of vertebral artery stenosis compared with best medical therapy alone, and included a review of the SSYLVIA study and a large number of case series. The authors concluded "… there is currently insufficient evidence to support the routine use of percutaneous transluminal angioplasty (PTA) and stenting for vertebral artery stenosis. Endovascular treatment of vertebral artery stenosis should only be performed within the context of randomized controlled trials."

In October 2005, the American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American society of Neuroradiology (ASNR) issued a position statement regarding intracranial angioplasty and stenting for cerebral atherosclerosis. This position statement reviewed a number of case series and also the SSYLVIA and Wingspan multi-institutional studies and concluded that sufficient evidence exists to recommend that intracranial angioplasty with or without stenting be offered to symptomatic patients with intracranial stenoses greater than 50% who have failed medical therapy.

A 2006 Cochrane Review focused on angioplasty for intracranial artery stenosis. The authors indicated that no randomized controlled trials were found. There were 79 articles of interest consisting of case series with three or more cases. The safety profile showed an overall perioperative rate of stroke of 7.9% and perioperative stroke or death of 9.5%. The authors concluded that the evidence is insufficient to recommend angioplasty with or without stent placement in routine practice for the prevention of stroke in patients with intracranial artery stenosis. The descriptive studies show that the procedure is feasible although carries significant morbidity and mortality risks. Evidence from randomized controlled trials is needed to assess the safety of angioplasty and its effectiveness in preventing recurrent stroke.

A 2007 assessment of endovascular stent insertion for intracranial atherosclerotic disease by the National Institute for Health and Clinical Excellence (NICE) concluded: "The evidence on the efficacy of endovascular stent insertion for intracranial atherosclerotic disease is currently inadequate and the procedure poses potentially serious safety concerns. Therefore, this procedure should only be used in the context of clinical research including collecting data which should be submitted to a national register when available. Research should clearly define patient selection and be designed to provide outcome data based on follow-up of at least two (2) years."

Qureshi, et al. (2008) reported on a non-randomized comparison (angioplasty was used preferentially in patients with more technically challenging lesions) of 44 patients who underwent angioplasty with or without stenting for symptomatic intracranial stenosis. At 12 months, there were no statistically significant differences between groups. However, there was no comparative medical group and the sample size was relatively small.

Firoella reported on initial periprocedural experience with the Wingspan stent in a study of 78 patients, average age 64 years. In this study, 81 of 82 lesions were successfully stented and percent stenosis was reduced (from 75% to 27% after stent placement.) There were 5 (6.1%) major periprocedural neurologic complications with 4 patient deaths within 30 days. Long-term outcomes were not reported in this initial report.

Zaidat, et al. (2008) reported on the NIH registry on use of the Wingspan stent for symptomatic intracranial stenosis. This article reported on 129 patients from 16 medical centers treated with a Wingspan stent in this registry between November 2005 and October 2006. Patients with symptomatic 70% to 99% intracranial stenosis were enrolled. The technical success rate was 96.7%. The mean pre- and post-stent stenoses were 82% and 20%. The frequency of any stroke, intracerebral hemorrhage, or death within 30 days or ipsilateral stroke beyond 30 days was 14.0% at 6 months (95% CI = 8.7% to 22.1%). The frequency of 50% or more restenosis on follow-up angiography was 13/52 (25%). The authors concluded that the use of a Wingspan stent in patients with severe intracranial stenosis is relatively safe with a moderately high rate of restenosis. They also noted that comparison of the event rates in high-risk patients in Warfarin-Aspirin Symptomatic Intracranial Disease (WASID) vs. this registry does not rule out either that stenting could be associated with a substantial relative risk reduction or has no advantage compared with medical therapy; thus, a randomized trial comparing stenting with medical therapy is needed.

The literature continues to be dominated by single institution case series, and non-randomized prospective trials. As noted in the 2006 Cochrane Review and NICE assessment, the evidence is insufficient to recommend angioplasty with or without stent placement in routine practice for the prevention of stroke in patients with intracranial artery stenosis. Research is needed to clearly define patient selection and be designed to provide outcome data based on follow-up of at least two (2) years. Given the uncertain impact of this procedure on clinical outcomes, it is considered investigational.

The stenting and aggressive medical management for preventing recurrent stroke in intracranial stenosis (SAMMPRIS) was a randomized controlled trial (RCT) comparing aggressive medical management alone to aggressive medical management plus stenting in patients with symptomatic cerebrovascular disease and an intracranial stenosis of between 70-99%. This trial used the Wingspan stent system implanted by experienced neurointerventionists who had been credentialed to participate in the trial. The authors (Chimowitz, et al. 2011) had planned for an enrollment of

approximately 750 patients based on power calculations. However, the trial was stopped early for futility after 451 patients had been randomized. The trial was terminated due to an excess of the primary outcome, stroke or death, at 30 days in the stenting group. In the stenting group, the rate of stroke or death at 30 days was 14.7% compared to a rate of 5.8% (p=0.002) in the medical management group. At the time of termination, the mean follow-up was 11.9 months. Kaplan-Meier estimates of the primary outcome of stroke or death at one year was 20.5% in the stenting group compared to 12.2% (p=0.009) in the medical management group. These results represented an excess rate of early adverse events with stenting over what was expected together with a decreased rate of stroke and death in the medical management group compared to expected values.

CP Derdeyn and colleagues (2014) reported on the long-term outcome of the SAMMPRIS study. They randomly assigned 451 patients with recent transient ischemic attack or stroke related to 70-99% stenosis of a major intracranial artery to aggressive medical management (antiplatelet therapy, intensive management of vascular risk factors, and a lifestyle-modification program) or aggressive medical management plus stenting with the Wingspan stent. The primary endpoint was any of the following: stroke or death within 30 days after enrolment, ischemic stroke in the territory of the qualifying artery beyond 30 days of enrolment, or stroke or death within 30 days after a revascularization procedure of the qualifying lesion during follow-up. Primary endpoint analysis of between-group differences with log-rank test was by intention to treat. During a median follow-up of 32·4 months, 34 (15%) of 227 patients in the medical group and 52 (23%) of 224 patients in the stenting group had a primary endpoint event. The cumulative probability of the primary endpoints was smaller in the medical group versus the percutaneous transluminal angioplasty and stenting (PTAS) group (p=0·0252). Beyond 30 days, 21 (10%) of 210 patients in the medical group and 19 (10%) of 191 patients in the stenting group had a primary endpoint. The absolute differences in the primary endpoint rates between the two groups were 7·1% at year 1 (95% CI 0·2 to 13·8%; p=0·0428), 6·5% at year 2 (-0·5 to 13·5%; p=0·07) and 9·0% at year 3 (1·5 to 16·5%; p=0·0193). The occurrence of the following adverse events was higher in the PTAS group than in the medical group: any stroke (59 [26%] of 224 patients vs. 42 [19%] of 227 patients; p=0·0468) and major hemorrhage (29 [13%] of 224 patients vs. 10 [4%] of 227 patients; p=0·0009). CP Derdeyn and colleagues concluded that for high-risk patients with intracranial stenosis, aggressive medical management is superior to stenting with the Wingspan device at both early and later phases of follow-up.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN)*

CPT Codes

Code	Description
61630 **(E/I)**	Balloon angioplasty, intracranial, percutaneous
61635 **(E/I)**	Transcatheter placement of intravascular stent(s), intracranial, including balloon angioplasty, if performed
36221	Non-selective catheter placement, thoracic aorta, with angiography of the external carotid, vertebral, and/or intracranial vessels, unilateral or bilateral, 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

Code	Description
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 external carotid and 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 selective vessel circulation and all associated radiological supervision and interpretation (e.g., middle cerebral artery, posterior inferior cerebellar artery) (List separately in addition to code for primary procedure)

HCPCS Codes

Code	Description
No codes	

ICD10 Codes

Code	Description
Investigational for all diagnosis codes	

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*Key Article

KEY WORDS

Angioplasty, Intracranial Circulation, Percutaneous Transluminal Angioplasty, Vertebrobasilar Stenosis, Neurolink® System, Wingspan™ Stent.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for percutaneous transluminal angioplasty (PTA) and a CMS decision memo related to percutaneous transluminal angioplasty (PTA) with intracranial stent placement. Please refer to the following NCD website for Medicare Members:
http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=201&ncdver=10&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&CptHcpcsCode=36514&bc=gAAAABAAAAAAAA%3d%3d&

Decision memo:
http://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=214&NcaName=Intracranial+Stenting+and+Angioplasty&SearchType=Advanced&CoverageSelection=Both&NCSelection=NCA%7CCAL%7CNCD%7CMEDCAC%7CTA%7CMCD&ArticleType=SAD%7CEd&PolicyType=Final&s=---%7C5%7C6%7C66%7C67%7C44&KeyWord=percutaneous+transluminal+angioplasty+(PTA)+with+intracranial+stent+placement&KeyWordLookUp=Doc&KeyWordSearchType=Exact&kq=true&bc=IAAAABAACAAAAA%3D%3D&