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**
Original Effective Date	**02/16/06**
Committee Approval 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, 02/20/20, 02/18/21, 02/17/22, 02/16/23**
Current Effective Date	**02/22/24**
Archived Date	**02/16/23**
Archive Review Date	**02/22/24**
Product Disclaimer	• *Services are contract dependent; 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 or Child Health Plus product), medical policy criteria apply to the benefit.* • *If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.* • *If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) 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.* • *If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.*

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, therefore, is considered **investigational** for treatment of intracranial atherosclerotic stenosis.

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

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

Refer to Corporate Medical Policy #11.01.10 Clinical Trials

DESCRIPTION

Approximately 795,000 people suffer from stroke in the United States annually, of which 87% 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. Most 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

The Wingspan Stent System with Gateway PTA Balloon Catheter (Stryker Neurovascular) is the only Food and Drug Administration (FDA) approved system currently indicated for improving cerebral artery lumen diameter in patients 22-80 years old with recurrent (2 or more) strokes refractory to a comprehensive regimen of medical therapy and due to atherosclerotic disease of intracranial vessels with 70-99% stenosis and that are accessible to the stent system. Patients in this subset have a poor prognosis, and treatment options are limited. The 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. The Wingspan was approved following a prospective, multi-center, single-arm trial of 45 patients enrolled at 12 international centers (Bose, et al 2007). The primary safety endpoint was 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 six months. The type and frequency of observed adverse events, including stroke, were 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 considering the probable risks and benefits of currently available alternative forms of treatment. The system is authorized under a Humanitarian Device Exemption and requires institutional review board approval prior to clinical site use.

The Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMMPRIS) trial was a randomized, controlled trial (RCT) by Chimowitz et al, (2011) with a follow up study published by C.P. Derdeyn and colleagues (2014) 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%. That trial used the Wingspan Stent System, implanted by experienced neurointerventionists who had been credentialed to participate in the trial. The authors 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.

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). The absolute differences in the primary endpoint rates between the two groups were 7.1% at year one (95% CI 0.2 to 13.8%; p=0.0428), 6.5% at year two (-0.5 to 13.5%; p=0.07), and 9.0% at year three (1.5 to 16.5%; p=0.0193). The occurrence of the following adverse events was higher in the stenting group than in the medical group: any stroke (59 [26%] of 224 patients versus 42 [19%] of 227 patients; p=0.0468) and major hemorrhage (29 [13%] of 224 patients versus 10 [4%] of 227 patients; p=0.0009). The researchers 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.

The FDA Neurological Devices Panel met on 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 do not support its safety and efficacy as a treatment for ischemic stroke in adults and warranted continued research. Based on that panel meeting, the FDA mandated Stryker to conduct a postmarket surveillance study and narrowed the indications for the use of Wingspan (FDA Medwatch, August 2012), stating:

> 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 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.

The long-term follow up to the SAMMPRIS trial from C.P. Derdeyn and colleagues (2014) discovered that-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).The absolute differences in the primary endpoint rates between the two groups were 7.1% at year one (95% CI 0.2 to 13.8%; p=0.0428), 6.5% at year two (-0.5 to 13.5%; p=0.07), and 9.0% at year three (1.5 to 16.5%; p=0.0193). The occurrence of the following adverse events was higher in the stenting group than in the medical group: any stroke (59 [26%] of 224 patients versus 42 [19%] of 227 patients; p=0.0468) and major hemorrhage (29 [13%] of 224 patients versus 10 [4%] of 227 patients; p=0.0009). The researchers 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.

The Wingspan postmarket surveillance study, the WEAVE trial, was published by Alexander and colleagues in 2019. It was a prospective, single-arm, multicenter, consecutive enrollment study. The primary objective was to evaluate the rate of stroke and death within 72 hours post stenting in patients treated with the Wingspan Stent System, strictly according to the Instructions for Use (n=198). A total of 152 patients met on-label indications and underwent the procedure, and 46 patients did not meet the approved indications for use criteria. Mean target artery stenosis before the procedure was 83% and mean target stenosis after stenting was 28%. There was a 2.6% periprocedural complication rate (2 deaths, 2 strokes without death) in the cohort who met FDA-approved indications). This was lower than the 4% periprocedural primary event safety benchmark set for the interim analysis in the study, and the trial was stopped early. There was a 23.9% periprocedural complication rate for those patients who did not meet the FDA-approved indications for use (2 deaths, 9 strokes without death all occurring in the territory of the stented artery). Mean Wingspan case experience for interventionalists in the WEAVE trial was 37 stents. Those with more than 50 Wingspan cases prior to the study had 0% periprocedural stroke and death index rate, while interventionalists with less than 50 Wingspan cases before trial had a 4.8% index event rate in trial patients. The authors compared this data to the median number of Wingspan stents delivered by interventionalists in the SAMMPRIS trial before beginning enrollment (10 stents) demonstrating the WEAVE trial had more experienced interventionalists than those involved in SAMMPRIS. The WOVEN study (Alexander, et al 2021) conducted a one year follow up chart review and imaging analysis of 129 patients from the original cohort. The goal was to provide a more homogenous patient group for analysis, and evaluate 1-year stroke and death rates in stented patients, which was 8.5%. The authors concluded that with experienced interventionalists, and proper patient selection following the on-label usage guidelines, the use of the Wingspan stent for intracranial atherosclerotic disease demonstrated a low periprocedural complication rate and excellent safety profile.

Given the results of the mandated post-market study, the FDA issued a safety communication in April 2019 reiterating that the use of Wingspan in patients who do not meet the FDA-approved indications for use criteria have a significantly increased risk of stroke or death and also called out the revised indications for its use: patients between 22 and 80 years of age and who have had two or more strokes despite aggressive medical management; whose most recent stroke occurred more than seven days prior to planned treatment with Wingspan; who have 70-99% stenosis due to atherosclerosis of the intracranial artery related to the recurrent strokes; and who have made good recovery from the previous stroke and have a modified Rankin Scale score of three or less prior to Wingspan treatment.

A 2020 Cochrane Systematic Review by Wang, et al. aimed to compare the safety and efficacy of endovascular therapy with medical management versus medical management alone for the treatment of symptomatic intracranial atherosclerotic stenosis. Primary outcomes were death of any cause or non-fatal stroke within three months of randomization. The literature search yielded three RCTs, representing 632 patients. Modalities for endovascular therapy included angioplasty alone, balloon- mounted stent use, and angioplasty followed by a placement of a self-expanding stent. Medical management consisted of controlling risk factors (hypertension, hyperlipidemia and diabetes) as well as antiplatelet therapy. Endovascular therapy was associated with worse outcomes in the 30-day death and stroke rate (risk ratio (RR) 3.07, 95% Confidence Interval (CI) 1.80 to 5.24), and one-year death or stroke rate (RR 1.69, 95%CI, 1.21-2.36). Blinding is not possible in these studies due to the intervention. The studies were terminated early, and there were high

rates of loss to follow-up. The authors concluded that for individuals with symptomatic severe intracranial atherosclerotic stenosis, endovascular therapy does not prevent recurrent strokes and has an increased risk of harm.

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
36221	Non-selective catheter placement, thoracic aorta, with angiography of the extracranial 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
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 extracranial carotid and cervicocerebral arch, when performed
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)
61630 **(E/I)**	Balloon angioplasty, intracranial (e.g., atherosclerotic stenosis), percutaneous
61635 **(E/I)**	Transcatheter placement of intravascular stent(s), intracranial (e.g., atherosclerotic stenosis), including balloon angioplasty, if performed

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, At, Neurolink System, Wingspan Stent.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD#20.7) for Percutaneous Transluminal Angioplasty (PTA). 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&] accessed 01/02/24.