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

Effective: July 1, 2017

Next Review: May 2018
Last Review: June 2017

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

A balloon catheter is inserted into the artery and inflated to expand the size of the artery. A stent (wire-mesh tube) may be inserted to keep the artery open or to block off an aneurysm (a bleb on the artery).

MEDICAL POLICY CRITERIA

Note: This policy does not address percutaneous angioplasty and stenting of extracranial carotid arteries or venous vessels, or the use of mechanical embolectomy or thrombectomy devices which are addressed in separate medical policies (see Cross References below).

1. Intracranial stent placement may be considered medically necessary as part of the endovascular treatment of intracranial aneurysms when all of the following criteria are met:
   A. Surgical treatment is not appropriate
   B. 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
C Use of FDA-approved *flow-diverting stents* may be indicated for treatment of intracranial aneurysms when *all* of the following criteria are met:

1. The aneurysm is in the internal carotid artery from the petrous to the superior hypophyseal segments
2. The aneurysm is large or giant (10 mm or more) and wide-necked (4 mm or more)

II All other intracranial endovascular angioplasty and/or stenting is considered **investigational** including but not limited to the following:

A Intracranial stent placement in the treatment of intracranial aneurysms except as noted above
B Intracranial percutaneous transluminal angioplasty with or without stenting in the treatment of atherosclerotic cerebrovascular disease
C Intracranial angioplasty with or without stenting for acute ischemic stroke

**NOTE:** A summary of the supporting rationale for the policy criteria is at the end of the policy.

**CROSS REFERENCES**

1. [Extracranial Carotid Angioplasty/Stenting](https://example.com), Surgery, Policy No. 93
2. [Percutaneous Angioplasty and Stenting of Veins](https://example.com), Surgery, Policy No. 109
3. [Mechanical Embolectomy for Treatment of Acute Stroke](https://example.com), Surgery, Policy No. 158

**BACKGROUND**

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 WASID trial (Warfarin-Aspirin Symptomatic Intracranial Disease) 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 are 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 one 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 due to the risk of embolism, which may result in devastating complications if it occurs in the posterior fossa or brain stem. However, improvement in catheter trackability, allowing catheterization of tortuous veins, and the increased use of stents has created ongoing interest in exploring PTA as a minimally invasive treatment of this difficult-to-treat population. Most of the published studies of intracranial PTA have focused on the vertebrobasilar circulation. Intracranial vessels on which angioplasty has been performed include:

- Anterior cerebral artery
- Basilar artery
- Carotid siphon
- Internal carotid
- Middle cerebral artery
- Ophthalmic artery
- Posterior cerebral artery
- Vertebral artery (distal)

Intracranial stents are also being used in the treatment of cerebral aneurysms. Stent-assisted coil embolization 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.

**REGULATORY STATUS**

Currently, approval of intracranial stents by the U.S. Food and Drug Administration (FDA) has been through the humanitarian device exemption (HDE) process. This form of FDA approval is available for devices used in the treatment or diagnosis of conditions that affect fewer than 4,000 individuals in the United States per year; the FDA only requires data showing “probable safety and effectiveness.” An approved HDE authorizes marketing of the humanitarian use device (HUD). However, an HUD may only be used after an internal review board (IRB) approval has been obtained for the use of the device for the FDA approved indication. The labeling for an HUD must state that the device is a humanitarian use device and that, although the device is authorized by Federal Law, the effectiveness of the device for the specific indication has not been demonstrated.

**Stents for Intracranial Atherosclerosis**

There are currently two devices that have received FDA approval for humanitarian use in the treatment of intracranial atherosclerosis. Their labeled indications are as follows:

- **NEUROLINK® System (Guidant)** 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."[1]

- **Wingspan™ Stent System with Gateway™ PTA Balloon Catheter (Boston Scientific)** is indicated for patients who “have had two or more strokes despite aggressive medical management,” have 70% to 99% stenosis of the intracranial artery due to atherosclerosis, and have “made good recovery from previous stroke,” with a Modified Rankin Scale score of 3 or less.[2] 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 arteries are difficult to access with a balloon-mounted stent, such as the NEUROLINK system.[3]

**Stents for Intracranial Aneurysm**

**Endovascular Stents for Use with Coils**

The following devices have received FDA approval for humanitarian use with embolic coils in the treatment of unruptured wide-neck intracranial aneurysms:

- The Neuroform™ Microdelivery Stent System (Boston Scientific) (H020002)
- The Enterprise™ Vascular Reconstruction Device and Delivery System (Cordis Neurovascular, Inc./DePuy Companies) (H060001)
- The LVIS® or LVIS® Jr. Low-Profile Visualized Intraluminal Support Device (MicroVention®, Inc.) (H130005)

The Solitaire AB retrievable stent (Covidien) has not received FDA approval for use in the United States outside the clinical trial setting.

**Flow-Diverting Stents**

- In 2011, the Pipeline® Embolization Device (Covidien eV3 Neurovascular), which falls into a new device category called “intracranial aneurysm flow diverters,” or flow-diverting stent, received FDA premarket approval for endovascular treatment of large or giant wide-necked intracranial aneurysms in the internal carotid artery from the petrous to the superior hypophyseal segments in adult patients aged 22 years or older. The Pipeline device is a braided, wire mesh device that is placed within the parent artery of an aneurysm to redirect blood flow away from the aneurysm with the goal of preventing aneurysm rupture and possibly decreasing aneurysm size.
- The SILK Reconstruction device (Balt Extrusion) and the Surpass Flow Diverting Stent (Stryker) have not received FDA approval for use in the United States.

**EVIDENCE SUMMARY**

Evaluating the safety and effectiveness of intracranial endovascular angioplasty with or without stenting requires evidence from well-designed, well-conducted randomized controlled trials (RCTs) that compare the health outcomes following endovascular procedures with those following treatment with standard medical or surgical treatment. Nonrandomized comparative studies and uncontrolled studies can provide useful information on health outcomes such as adverse events, but are prone to biases such as noncomparability of treatment groups, nonspecific effects such as the placebo effect, and the variable natural history of the condition.

**INTRACRANIAL ATHEROSCLEROTIC DISEASE**

**DATA INCLUDED IN U.S. FOOD AND DRUG ADMINISTRATION (FDA) SUBMISSIONS**

- NEUROLINK® System[1]

The clinical study investigating the NEUROLINK device is known as the SSYLVIA study (Stenting of Symptomatic Atherosclerosis Lesions in the Vertebral or Intracranial Arteries), a prospective, nonrandomized, multicenter, international study of 61 patients. Patients
were eligible for participation in the study if they were symptomatic (previous stroke or TIA) attributed to an angiographically demonstrated, discrete stenosis >50%, in an extracranial or intracranial artery. The primary endpoint was a composite of stroke and death clinical outcomes at 30 days; 4 patients experienced strokes (6.6%) and there were no deaths. Mean follow-up was 216 days and lower bound for ipsilateral stroke at 12 months was estimated to be 11.5%. The FDA summary notes that in the WASID study of aspirin and warfarin therapy, the rate of fatal or nonfatal stroke was 14.6% and total stroke or death was 22.5% with a follow-up of 15-19 months, suggesting a potentially superior outcome with the NEUROLINK device. However, the short length of follow-up in the NEUROLINK study prevents meaningful comparisons. The FDA Summary of Safety and Probable Benefit concludes, “Therefore, it is reasonable to conclude 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.”

- **Wingspan Stent System**

  The Wingspan was studied in a prospective, multicenter, single arm trial of 45 patients enrolled at 12 international centers. Patients were considered eligible if they presented with evidence of recurrent stroke, refractory to medical therapy and thought to be secondary to intracranial stenosis of 50% or greater. The primary safety endpoint was similar to the SSYLVIA study, i.e., a composite of stroke and death clinical outcomes at 30 days, which occurred in 4.5% of patients (2/45), one with death following a hemorrhagic stroke and one stroke.

  The FDA summary provided a comparison of various outcomes of the NEUROLINK and Wingspan device studies as follows:

<table>
<thead>
<tr>
<th>Clinical study</th>
<th>Follow-up</th>
<th>All Stroke</th>
<th>Death</th>
<th>Stroke + Death</th>
<th>Ipsilateral Stroke</th>
</tr>
</thead>
<tbody>
<tr>
<td>SSYLVIA (n=61)</td>
<td>Mean: 216 days (n=48 at 6 mos)</td>
<td>13.1%</td>
<td>6.6%</td>
<td>13.1%</td>
<td>11.5%</td>
</tr>
<tr>
<td>Wingspan (n=45)</td>
<td>Mean: 174 days (n=42 at 6 mos)</td>
<td>9.5%</td>
<td>2.4%</td>
<td>9.5%</td>
<td>7.1%</td>
</tr>
</tbody>
</table>

The FDA offered the following conclusions concerning the Wingspan device and appeared to base its approval, in part, on the favorable comparison to the NEUROLINK device:

“The Wingspan clinical study treated 45 patients with symptomatic atherosclerotic lesions in intracranial arteries who were refractory to medical therapy. The lesions were predilated and stented. 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, it is reasonable to conclude that the probable benefit to health from using the Wingspan Stent System with Gateway PTA Balloon Catheter for treating in 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.”
In 2015, after review of further data, the FDA narrowed the indications for the devices use, due to the risk of death or stroke in certain populations.[2]

ELECTIVE TREATMENT OF SYMPTOMATIC INTRACRANIAL STENOSIS

The following literature review focused on systematic reviews, RCTs, and nonrandomized comparative studies of stent-assisted angioplasty for stroke prevention in patients with intracranial artery stenosis. This review did not include treatments for acute stroke.

Systematic Reviews

A systematic review by Tsivgoulis (2016) compared percutaneous transluminal angioplasty (PTAS) with medical therapy for symptomatic intracranial arterial stenosis using data from three RCTs with 678 total participants.[5] All three studies were assessed as having a high risk of bias in one domain; for two studies, this was due to a lack of blinding at follow-up visits, and for the other, industry sponsors were heavily involved in all aspects of study design and analysis. A random effects meta-analysis of data from these studies showed that PTAS was associated with increased risk of recurrent ischemic stroke in the same region within 30 days (risk ratio [RR] 2.21, 95% confidence interval [CI] 1.10 to 4.43) and within one year (RR 1.92, 95% CI 1.10 to 3.36). In addition, there was a higher risk of intracranial hemorrhage and a composite outcome of stroke or death within one year (RR 8.15, 95% CI 1.50 to 44.34; and RR 2.29, 95% CI 1.13 to 4.66, respectively). The authors concluded that, due to the adverse early and late outcomes, PTAS should not be recommended for this population.

Abuzinadah (2014) conducted a systematic review and meta-analysis of studies reporting the rates of stroke recurrence or death (the primary outcome) in symptomatic intracranial vertebrobasilar stenosis with medical or endovascular treatment.[6] The authors identified 23 studies involving 592 medical treatment patients and 480 endovascular treatment patients. In pooled analysis, the stroke or death rate was 14.8 per 100 person-years (95% CI 9.5 to 20.1) in the medical therapy group and 8.9 per 100 person-years (95% CI, 6.9 to 11.0) in the endovascular group (incidence rate ratio [IRR], 1.3, 95% CI 1.0 to 1.7). The stroke recurrence rate was 9.6 per 100 person-years (95% CI, 5.1 to 14.1) in the medical group and 7.2 per 100 person-years (95% CI 5.5 to 9) in the endovascular group (IRR=1.1, 95% CI 0.8 to 1.5). However, the wide confidence interval in some outcomes increases the uncertainty of the accuracy of the reported effects and generally indicates that more data are needed.

Zhou (2012) attempted a systematic review of double-blind RCTs of angioplasty with stenting for symptomatic intracranial atherosclerosis defined as more than 50% stenosis on angiogram.[7] A comprehensive literature search was described which included English language databases, Chinese academic journals, and the reference lists of selected articles. Participants with acute ischemic events were excluded. The primary outcome of interest was the occurrence of post-procedure stroke. No studies were found that met inclusion criteria. However, the SAMMPRIS trial[8] was reviewed. This RCT, which was terminated early due to the risk of stroke or periprocedural death in the stent group, is summarized below. The authors concluded that more RCT evidence is needed before widespread application of stent-assisted intracranial angioplasty can be recommended.

Groschel (2009) conducted a systematic review on outcomes after stenting for intracranial atherosclerosis.[9] The authors identified 31 studies including 1,177 procedures, which had mainly been performed in patients with a symptomatic (98%) intracranial high-grade stenosis (mean: 78.7%) with high technical success rates (median: 96%; interquartile range: 90% to
The periprocedural minor or major stroke and death rates ranged from 0% to 50%, with a median of 7.7%. Periprocedural complications were significantly higher in the posterior versus the anterior circulation (12.1% vs. 6.6%, p<0.01), but did not differ between patients treated with a balloon-mounted (n=906) versus those who had been treated with a self-expandable stent (n=271; 9.5% vs. 7.7%, p=0.47). Restenosis greater than 50% occurred more frequently after the use of a self-expandable stent (16/92; 17.4%, mean follow-up time: 5.4 months) than a balloon-mounted stent (61/443; 13.8%, mean follow-up time: 8.7 months; p<0.001). The authors concluded that although intracranial stenting appears to be feasible, adverse events vary widely and thus given a high rate of restenoses and no clear impact of new stent devices on outcome, the widespread application of intracranial stenting outside the setting of randomized trials and in inexperienced centers currently does not seem to be justified.

**Randomized Clinical Trials (RCTs)**

VAST is the largest RCT published to date on stenting versus medical therapy in patients with symptomatic vertebral artery disease.[10] This multicenter phase 2 study included 115 patients who had a transient ischemic attack or minor stroke attributed to vertebral artery stenosis. Randomization to stenting or medical therapy was stratified by center and by the level of stenosis; 83.5% of patients had extracranial lesions and the rest had intracranial lesions. The median interval between symptoms and randomization was 25 days, with a median interval between randomization and stenting of seven days. The particular stent used was by surgeon preference. All patients received best medical therapy and were followed yearly by telephone. The primary outcome was the composite of vascular death, stroke, or myocardial infarction within 30 days. Secondary outcomes were stroke in the territory of the symptomatic artery, the composite outcome measure during follow-up, and the degree of restenosis. The median follow-up was 3.0 years (range, 1.3 to 4.1).

Endovascular therapy plus best medical therapy was not superior to best medical therapy alone in this trial. The primary outcome occurred in 3 of 57 (5%, 95% CI 0% to 11%) patients in the stenting group and 1 of 58 (2%, 95% CI 0% to 5%) patients in the medical treatment group. Of these four patients, all had a vertebrobasilar stroke and two of them occurred in the group of nine patients with intracranial stenosis who received endovascular therapy. One of the strokes in the stenting group was fatal. During follow-up, the composite outcome occurred in 11 (19%) patients in the stenting group compared to 10 (17%) patients in the medical therapy group. The periprocedural risk of a major vascular event in the stenting group was 5%. The authors questioned the need and feasibility of a phase 3 trial, given the low risk of recurrent stroke with best medical therapy.

Zaidat (2015) published results of the VISSIT trial, an RCT comparing a balloon-expandable stent plus medical management to medical management alone among patients with symptomatic intracranial stenosis of 70% or greater.[11] Eligible patients had stenosis of 70% to 99% of the internal carotid, middle cerebral, intracranial vertebral, or basilar arteries with a transient ischemic attack (TIA) or stroke attributable to the territory of the target lesion within the prior 30 days. Enrollment was planned for up to 250 participants. However, an early unplanned analysis was conducted by the trial sponsor after the results of the SAMMPRIS trial were published (see below). A total of 112 patients were enrolled from 2009 to 2012 and randomized to balloon-expandable stent (Vitesse stent) plus medical management (stent group; n=59) or medical management alone (medical group; n=53). Medical management included clopidogrel (75 mg daily) for the first three months post-enrollment and aspirin (81-
325 mg/d) for the duration of the study, along with management of hypercholesterolemia and/or hypertension, if necessary. The study used a primary composite endpoint that included any stroke in the same territory as the presenting event within one year of randomization and “hard TIA” in the same territory as the presenting event from two days to one year after randomization. Among 29 patients who met one of the primary end points within one year of randomization, eight (15.1%) patients were in the medical group and 21 (36.2%) were in the stent group (risk difference 21.1%, 95% CI 5.4% to 36.8%; p=0.02). The rates of stroke within 30 days of randomization or TIA were 9.4% in the medical group and 24.1% in the stent group (risk difference 14.7%, 95% CI 1.2% to 28.2%; p=0.05). The 30-day all-cause mortality rate was 5.2% and 0% in the stent and the medical groups, respectively (risk difference 5.2%, 95% CI -0.5% to 10.9%; p=0.25). The authors concluded that results did not support the use of a balloon-expandable stent for patients with symptomatic intracranial stenosis.

The Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS) randomized 16 patients with symptomatic vertebral artery stenoses in a 1:1 ratio to receive best medical treatment plus endovascular therapy (balloon angioplasty or stenting) or best medical treatment alone.[12] Endovascular intervention was technically successful in all eight patients, but two patients experienced transient ischemic attack at the time of endovascular treatment. During a mean follow-up period of 4.7 years, no patient in either treatment group experienced a vertebrobasilar territory stroke, but three patients in each treatment arm died of myocardial infarction or carotid territory stroke, and one patient in the endovascular arm had a nonfatal carotid territory stroke. The investigators concluded that patients with vertebral artery stenosis were more likely to have carotid territory stroke and myocardial infarction during follow up than have recurrent vertebrobasilar stroke. While they noted that the trial failed to show a benefit of endovascular treatment of vertebral artery stenosis, the small number of patients enrolled severely limits conclusions.

The Stenting versus Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMMPRIS) trial was an 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%.[8] This 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% (95% CI 10.7% to 20.1%) compared to a rate of 5.8% (95% CI 3.4% to 9.7%; 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% (95% CI 15.2% to 26.0%) in the stenting group compared to 12.2% (95% CI 8.4% to 17.6%; 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.

In 2013, the SAMMPRIS investigators published results from long-term subject follow up.[13] Primary end points included stroke or death within 30 days of enrollment, ischemic stroke in the territory of the qualifying artery beyond 30 days after enrollment, or stroke or death within 30 days after a revascularization procedure of the qualifying lesion. During a median follow up
of 32.4 months, 34 of 227 (15%) of patients in the best medical management group and 52 of 224 (23%) of patients in the stenting group had a primary endpoint event, with a significantly higher cumulative probability of a primary end point in the stenting group than in the best medical management group (p=0.025). Compared with the best medical management group, subjects in the stenting group had higher rates of any stroke (59/224 [26%] vs 42/227 [19%], p=0.047) and major hemorrhage (29/224 [13%] vs 10/227 [4%], p<0.001). The authors concluded that the benefits of aggressive medical management over percutaneous angioplasty and stenting among patients with intracranial stenosis persist over long-term follow up.

Lutsep (2015) published a subgroup analysis of the SAMMPRIS trial results to evaluate whether outcomes differed for patients whose qualifying events occurred on or off antithrombotic therapy.[14] Similar to the overall trial results, outcomes were worse in the stent group than in the best medical management group: of the 284 patients on antithrombotic therapy at the time of the qualifying event, 140 patients were randomized to medical management and 144 to stenting; in Kaplan-Meier analysis, two-year rates of the primary end point were 15.6% in the medical management group and 21.6% in the stent group (p=0.043). In other subgroup analyses of the SAMMPRIS trial results, two-year event rates were higher in the stent group for most variables evaluated.[15] The interaction between treatment and the subgroup variables was not significant for any variable.

NONRANDOMIZED TRIALS

A number of nonrandomized studies have compared outcomes of endovascular procedures with medical therapy.[16-20] These studies have either been retrospective, or based on registry data, and provided relatively weak evidence on the efficacy of endovascular procedures compared with medical therapy for intracranial atherosclerosis.

Numerous single arm non-comparative case series have also been published.[21-27] These studies provide some information on the success rates and the adverse events that occur with this procedure, but the lack of a control group does not provide evidence on the comparative efficacy of endovascular approaches versus medical therapy.

SECTION SUMMARY

The strongest evidence on the efficacy of endovascular treatment for symptomatic intracranial stenosis is from the SAMMPRIS RCT. This trial was stopped early due to harms, as the rate of stroke or death at 30 days following treatment was higher in the patients who received percutaneous angioplasty with stenting compared to the medical management arm. Follow up of the SAMMPRIS subjects demonstrated no long-term benefit from endovascular therapy. This supports the conclusion that outcomes of endovascular treatment are worse than medical therapy in patients with symptomatic intracranial stenosis.

STENT-ASSISTED TREATMENT OF INTRACRANIAL ANEURYSM

SYSTEMATIC REVIEWS

Ryu (2015) systematically reviewed studies reporting complications after stent-assisted coiling of ruptured intracranial aneurysms, with a focus on complications related to antiplatelet therapy.[28] The review included 33 studies, three of which were prospective and the remaining 30 were retrospective (total N=1090 patients). In pooled analysis, thromboembolic
complications occurred in 108 patients (event rate, 11.2%; 95% CI, 9.2% to 13.6%). Intraprocedural hemorrhage occurred in 46 (event rate, 5.4%; 95% CI, 4.1% to 7.1%).

Hong (2014) reported the results of a systematic review and meta-analysis of studies that compared stent-assisted coiling (N=753) with coiling alone (N=1,813) for the treatment of intracranial aneurysms. The authors included ten retrospective cohort studies, ranging in size from 9 to 1109 patients (N=2,566). In pooled analysis, compared to coiling alone, stent-assisted coiling was associated with higher rates of progressive thrombosis (37.5% vs 19.4%; OR 2.75; 95% CI 1.95 to 3.86; P<0.0001) and lower rates of recurrence (16.2% vs 34.4%; OR 0.35; 95% CI 0.25 to 0.49; P<0.00001). Mortality was 9.1% for stent-assisted coiling, compared with 2.6% for coiling alone; this difference was not statistically significant (OR 2.31; 95% CI 0.68 to 7.82; P=0.18). Similarly, permanent complication rates and thromboembolic complication rates were not significantly different between the two groups. The authors recommended cautious interpretation of their study, noting methodological limitations of their analysis and of the included studies. These limitations included the pooling of data from observational studies with variable baseline characteristics among the included studies such as the location of the aneurysms treated, ruptured and non-ruptured aneurysms, and different interventions.

A systematic review by Shapiro (2012) identified 39 articles reporting on 1517 patients, most of which were single-arm, retrospective series. The majority of patients treated had unruptured aneurysms, but 22% of patients had ruptured aneurysms. The authors noted a large amount of heterogeneity in reporting outcome data, particularly for adverse events. The periprocedural mortality rate was 2.1%, and the overall complication rate was 19%. Immediately following treatment, approximately 45% of patients had occlusion of the aneurysm. At an average of 13 months posttreatment, the stroke rate in the stented area was 3.2%.

A systematic review that was restricted to ruptured aneurysms was published by Bodily (2011). This review included 17 articles that described treatment in 212 patients. Technical success was high at 93%, and 2% of patients required open surgery due to stent failure or intraoperative aneurysm rupture. A total of 63% (130/207) of aneurysms were successfully occluded. The overall mortality rate was 19%, and 14% of patients had poor clinical outcomes. There was a relatively high rate of adverse events reported, with 8% of patients having an acute intracranial bleed related to the procedure, and 6% (16/288) having a clinically significant thromboembolic event.

RANDOMIZED CONTROLLED TRIALS (RCTS)

No trials were found in the published literature that compared stent-assisted treatment of intracranial aneurysms with standard neurosurgical treatment (i.e., surgical clipping or endovascular coils). This contrasts with therapy of ruptured aneurysms in which a randomized trial compared treatment with coiling versus surgical clipping.

NONRANDOMIZED COMPARATIVE STUDIES

Coiling with vs. without Stenting

The largest clinical case series describing use of stents in treating intracranial aneurysms was a retrospective cohort study reported by Piotin (2010). This study was included in the Hong (2014) systematic review summarized above. The authors reported on a series of 1,137 patients (1,325 aneurysms) treated between 2002 and 2009. In this series, coiling was
performed without stent-assist in 1,109 aneurysms (83.5%), and with stent assistance in 216 aneurysms (16.5%) (15 balloon-expandable and 201 self-expandable stents). Stents were delivered after coiling in 55% (119/216) and before coiling in 45% (97/216) of the cases. Permanent neurological procedure-related complications occurred in 7.4% (16 of 216) of the procedures with stents versus 3.8% (42 of 1,109) in the procedures without stents (logistic regression p=0.644; odds ratio [OR] 1.289, 95% CI 0.439 to 3.779). Procedure-induced mortality occurred in 4.6% (10 of 216) of the procedures with stents versus 1.2% (13 of 1,109) in the procedures without stents (logistic regression p=0.006; OR 0.116, 95% CI 0.025 to 0.531). The authors followed 53% (114 of 216) of aneurysms treated with stents and 70% (774 of 1,109) of aneurysms treated without stents, with angiographic recurrence in 14.9% (17 of 114) versus 33.5% (259 of 774), respectively (p<0.0001; OR 0.3485, 95% CI 0.2038 to 0.5960). Based on this series, the authors concluded that use of stents was associated with a significant decrease of angiographic recurrences but with more lethal complications compared to coiling without stents.

Hetts (2014) compared outcomes for patients treated with stent-assisted coiling (n=137) with those treated with coiling alone (n=224) for patients with unruptured intracranial aneurysms enrolled in the prospective, nonrandomized, multicenter Matrix and Platinum Science (MAPS) Trial, which was designed to compare bare-metal aneurysm coils and polymer-coated aneurysm coils.[33] Patients treated with stent-assisted coiling more often had wide-neck aneurysms (62% vs 33%; p<0.000) and had aneurysms with lower dome-to-neck ratio (1.3 vs 1.8; p<0.001). Periprocedural serious adverse events occurred in 6.6% of those treated with stent-assisted-coiling, compared with 4.5% of those treated with coiling alone (p=0.039). At one year, ischemic strokes were significantly more common in patients who received a stent-assisted coil than in patients who received a coil alone (8.8% vs 2.2%; p=0.005). However, in multivariable analysis, stent use did not independently predict ischemic stroke at two years (adjusted OR=1.1; p=0.94). This study had a number of methodological limitations that hinder conclusions, particularly post hoc data analysis of a prospective trial that was conducted to compare different coils. The use of stents was at the discretion of the operating physician; some centers used no stents, and a higher rate of stent use was found in North America. The authors also noted that some aneurysm morphologies (e.g., wide neck) were not conducive to treatment with coils alone and required stent-assist. In addition, use of postprocedure antiplatelet medication was not uniform, a limitation which the authors considered significant since the delayed stroke rate for stent-assisting coiling could be associated with antiplatelet management. Other limitations included poor image quality of angiograms and the inability to directly visualize stent struts on digital subtraction angiography.

Liu (2014) compared the aneurysms recurrence rates for patients with posterior communicating artery aneurysms treated with stent-assisted coiling to rates for those treated with coiling alone in a retrospective comparative study.[34] A total of 291 coiling procedures were performed, including 56 aneurysms treated with a self-expandable stent. Complete aneurysm occlusion on initial angiography occurred in 41.1% of stent-assisted coiling patients compared with 35.3% of nonstented patients (statistical comparison not reported). At last follow-up (mean, 14.3 months for stent-assisted coiling and 13.2 months for nonstent patients), aneurysms recurred in 10.6% of stent-assisted coiling patients compared with 28.1% of nonstent patients (p=0.014). Procedural complications occurred in 10.7% of stent-assisted coiling patients compared with 11.5% of nonstent patients (not significantly different).

A nonrandomized comparative study reported on 126 aneurysms that were treated with stent-assisted coiling compared with 86 patients treated with coil alone.[35] At two-year follow-up, the
authors reported rates of occlusion and recurrence. Progressive occlusion was noted in 42.5% of the stent group (17/40) compared with 39.5% of the nonstented group (34/86), a difference that was not statistically significant. The rates of aneurysm recurrence were also not statistically different between groups. Recurrence occurred in 17.5% of patients in the stent group versus 21.0% in the nonstent group.

**Coiling with Stenting vs. Coiling with Balloon**

Consoli (2016) compared stent-assisted coiling with balloon-assisted coiling in patients with unruptured wide-necked intracranial aneurysms treated at a single center.[36] The study included 268 patients (286 aneurysms), 117 (122 aneurysms) of whom were treated with stent-assisted coiling and 151 (164 aneurysms) of whom were treated with balloon-assisted coiling. At discharge, 97.9% and 97.3% of those in the balloon-assisted and stent-assisted groups, respectively, had Modified Rankin Scale scores of 0 or 1 (statistical comparison not reported). After 6 months, 97.9% and 98% of those in the balloon-assisted and stent-assisted groups, respectively, had Modified Rankin Scale score of 0 or 1, while mortality rates were 2.6% and 1.7% in the balloon-assisted and stent-assisted groups, respectively (statistical comparisons not reported). At six months, aneurysm recurrence rates were 11.1% and 5.8% in the balloon-assisted and stent-assisted groups, respectively. In multivariable analysis, the use of stent-assisted coiling was significantly associated with complete occlusion at the end of the procedure (regression coefficient not reported; p=0.024) and complete occlusion after six months (regression coefficient not reported; p=0.05).

**Comparisons between Stents**

Nonrandomized studies, summarized in a systematic review by King (2015), have compared devices used for stent-assisted coiling of intracranial aneurysms.[37] The authors reviewed published studies reporting on stent-assisted coiling with the Neuroform and Enterprise systems to assess outcomes between the devices. The analysis included 47 studies with a total of 4039 patients (4238 aneurysms; 2111 treated with Neuroform and 2127 with Enterprise). Most (81%) studies were retrospective. Compared with those treated with the Enterprise system, patients treated with the Neuroform system were more likely to have deployment failure (2.3% vs 0.2%, p<0.001) and have a higher mortality rate (2.8% vs 1.8%, p=0.04), less likely to have 100% aneurysm occlusion at last follow-up (61.1% vs 74.7%, p<0.001), and more likely to have recanalization (13.9% vs 10.6%, p=0.02).

Kadkhodayan (2013) reported results from a nonrandomized comparison of the Neuroform and Enterprise systems in the treatment of intracranial aneurysms not amenable to surgical clipping based on evaluation of prospectively collected registry data.[38] Patients who received the Neuroform device (n=160) were enrolled starting in February 2003, and patients who received the Enterprise device (n=98) were enrolled starting in March 2007. Indications for the devices differed slightly based on FDA HDE criteria: both have an indication for wide-necked aneurysms (neck ≥4 mm or a dome-to-neck ratio <2 mm) not amenable to surgical clipping. For the Enterprise, stents were used for saccular or fusiform aneurysms arising from a parent vessel with a diameter of ≥2 mm and ≤4 mm; for the Neuroform, stents were used for saccular aneurysms arising from a parent vessel with a diameter of ≥2.5 mm and ≤4 mm. The authors reported that Enterprise deployment success was high (108 of 115 attempts, 93.9%) compared with Neuroform (173 of 214 attempts, 80.8%, p=0.001). Rates of stent movement, misplacement, and symptomatic hemorrhage were similar for the two stent types, but symptomatic thromboembolic events were more frequent with the Enterprise stent (8.7% vs
1.4%, p=0.002).

NONRANDOMIZED SINGLE-ARM STUDIES

Since the publication of the Shapiro (2012) and Bodily (2011) systematic reviews described above, a number of noncomparative studies evaluating the use of stent-assisted endovascular treatments in intracranial aneurysms have been published.[39-47] In general, these series demonstrate high rates of technical success of stent deployment with high rates of aneurysm occlusion; however, variable complication rates, particularly related to thromboembolic events were observed. Long-term follow up, particularly beyond one year, was limited. Interpretation of these studies is limited by significant methodologic limitations, including but not limited to the lack of a control group for comparison, short-term outcomes, and potential selection bias.

FLOW-DIVERTING STENTS FOR INTRACRANIAL ANEURYSM

SYSTEMATIC REVIEWS AND META-ANALYSES

Zhou (2016) reported results of a systematic review of studies comparing flow-diverting devices with endovascular coiling for intracranial aneurysms, which included nine retrospective comparative studies (total N=863 subjects).[48] This review included studies of patients with ruptured or unruptured aneurysms. Across the nine studies, 305 patients were treated with flow-diverting devices, 558 with coil embolization therapy, and 324 with stent-assisted coiling alone. In pooled analysis, the use of flow-diverting devices was associated with a significantly higher complete occlusion rate compared with coil embolization therapy (OR=3.13; 95% CI, 2.11 to 4.65; $I^2=18\%$) or with stent-assisted coiling (OR=2.08; 95% CI, 1.34 to 3.24; $I^2=0\%$). Rates of overall morbidity did not differ significantly between patients treated with flow-diverting devices and coil embolization therapy, or between flow-diverting devices and stent-assisted coiling.

The largest meta-analysis, by Brinjikji (2013), included 1451 patients with 1654 aneurysms reported in a total of 29 studies published through 2012.[49] The authors evaluated aneurysmal occlusion rates at six months, and procedure-related morbidity, mortality, and complications across studies. They found a high rate of complete aneurysmal occlusion (76% [95% CI, 70% to 81%]), but also a high rate of procedure-related morbidity and mortality (5% [95% CI, 4% to 7%] and 4% [95% CI, 3% to 6%], respectively). This systematic review included the study upon which the FDA approval of the Pipeline Embolization Device was made.[50]

Arrese (2013) reported results of a meta-analysis that used somewhat more restrictive inclusion criteria that included 897 patients with 1018 aneurysms reported in a total of 15 studies.[51] All but two of the studies were included in the Brinjikji (2013) meta-analysis described above. The authors determined rates of complete or nearly complete occlusion of the treated aneurysm with a patent parent artery and early procedure-related mortality and neurologic morbidity. Similar to the Brinjikji (2013) meta-analysis, this study found a high overall rate of complete aneurysmal occlusion (76.2% [95% CI, 72.1 to 80.2%]), but also a high rate of procedure-related morbidity and mortality (2.8% [95% CI, 1.7%–3.8%] and 7.3% [95% CI, 5.7% to 9%], respectively). The authors assessed for publication bias using funnel plots and the Egger’s test to assess whether the study estimate size is related to the size of the study, and found $p<0.001$ for the Egger’s test for both early and late morbidity and aneurysmal occlusion, suggestive of publication bias.
RANDOMIZED CONTROLLED TRIALS (RCTS)

No RCTs were found in which flow-diverting stents were used for the treatment of intracranial aneurysms.

NONRANDOMIZED COMPARATIVE STUDIES

Since the publication of the systematic reviews summarized above, several additional studies have been published.

Guedon (2016) reported on late ischemic complications after flow-diverting stent placement.\[^{[52]}\] Among 86 patients treated at a single institution, mean angiographic follow up was available to 15.7 months (SD=11.8 months; range, 8-21 months) and mean clinical follow-up was available to 16.9 months (SD=12.9 months; range 10-22 months). Five (5.8%) patients developed ischemic complications.

The longest follow-up reported is from a series of 98 patients with 119 aneurysms treated with the Pipeline Embolization Device and followed for at least two years.\[^{[53]}\] Of the 119 aneurysms, all had clinical follow-up and 88.8% had imaging follow-up for two or more years postprocedure. Aneurysm occlusion rates were 81.6%, 84.1%, and 93.2% at six-month, one-year, and two-year follow-ups, respectively. Three (2.8%) cases of in-stent stenosis occurred. From 0 to 6 months, rates of TIA, minor stroke, and major stroke were 4.2%, 3.4%, and 0.8%, respectively.

Kallmes (2015) conducted a retrospective analysis of patients treated with the Pipeline device at 17 centers worldwide.\[^{[54]}\] The authors identified 793 patients with 906 aneurysms who were enrolled in the International Retrospective Study of Pipeline Embolization Device (IntrePED) registry. Of the total number of aneurysms, 311 were in the anterior ICA circulation and at least 10 mm, 349 of which were in the anterior circulation and less than 10 mm, 59 of which were in the posterior circulation, 179 of which were in a non-ICA anterior circulation location and less than 10 mm, and 10 of which had no aneurysm size specified. Overall neurologic morbidity and mortality was 8.4%, highest in the posterior circulation group (16.4%) and lowest in the less than 10-mm ICA group (4.8%; p=0.01). The overall spontaneous rupture rate was 0.6%, and the intracranial hemorrhage rate was 2.4%. Ischemic stroke rates were 4.7%, again highest in the posterior circulation group (7.3%) and lowest in the less than 10-mm ICA group (2.7%; p=0.16). In a subsequent study using data from the same registry, Brinjikji (2015) reported on risk factors for hemorrhagic complications after Pipeline device placement.\[^{[55]}\] Twenty patients had an intraparenchymal hemorrhage, most often (75%) within 30 days of treatment. The only procedure- or device-related variable associated with intraparenchymal hemorrhage was receiving 3 or more Pipeline devices (OR=4.10; 95% CI, 1.34 to 12.58; p=0.04). Additional analyses from this registry have evaluated the effect of age on outcomes after Pipeline placement\[^{[56]}\] and differences in complication rates between aneurysms treated with the Pipeline with or without coil embolization.\[^{[57]}\]

Van Rooij (2014) reported outcomes for 550 consecutive patients treated with endovascular methods for intracranial aneurysms at a single European center from 2009 to 2013.\[^{[58]}\] Endovascular treatments consisted of selective coiling in 445 (80.8%), stent-assisted coiling in 68 (12.4%), balloon-assisted coiling in 13 (2.4%), parent vessel occlusion in 12 (2.2%), and flow-diverter treatment in 12 (2.2%). Among the 11 patients treated with flow diverters, two patients had ruptured dissecting aneurysms, two deaths occurred, one patient had permanent morbidity, and two aneurysms were not occluded at 30 months follow-up. Direct comparisons
with outcomes from alternative treatments were not reported. However, based on these poor outcomes and the high complication rates reported in other studies, the authors recommended against the use of flow-diverter devices in aneurysms that are amenable to other techniques.

A comparative study based on registry data of health outcomes following insertion of the Pipeline device versus endovascular coiling. They identified a total of 229 patients enrolled during their data collection period from 2004-2013, 54 treated with the Pipeline device and 175 with coiling. Patients treated with the Pipeline device were significantly older and had significantly larger aneurysms that were more likely to be fusiform. Because of this, the authors excluded patients with fusiform or anterior communicating artery aneurysms and conducted their analysis in 160 patients (40 Pipeline and 120 coil patients) who were matched in a 1:3 ratio based on patient age and aneurysm size. Aneurysm neck size, overall size, and anterior versus posterior circulation location were similar between the groups. Of the patients treated with the Pipeline device, four patients (10%) also required adjunctive coil placement. Of the patients treated with endovascular coiling, 67 (56%) were treated with coiling, while 52 (43%) were treated with stent-assisted coiling and 1 (1%) with balloon-assisted coiling. Primary outcomes included obliteration of the aneurysm on follow-up imaging and clinical outcomes, measured by Modified Rankin Scale score of 0-2 (vs 3-6).

At the time of latest follow up, a higher proportion of aneurysms treated with the Pipeline device compared with those treated with coiling achieved complete obliteration (30/35 [86%] vs 37/90 [41%], p<0.001). However, angiographic follow-up was available for a greater proportion of patients treated with the Pipeline (35/40 [87.5%]) than those treated with coiling (90/120 [75%]), and the median angiographic follow-up time differed significantly between the groups (7 months in the Pipeline group and 12 months in the coil group, p<0.001). In terms of clinical outcomes, similar proportions of the Pipeline and coil groups had a Modified Rankin Scale score 0 to 2 (35/38 [92%] in the Pipeline group vs 97/103 [94%], p=0.8). Similar to the angiographic follow up results, the median clinical follow-up time differed significantly between the groups. Treatment type was not significantly associated with rates of procedure-related complications. While this study directly compares patients treated with the Pipeline endovascular device and those treated with coiling, it is limited by its nonrandomized, retrospective design. In particular, patients treated with coiling were treated in an earlier period (2004-2011) than those treated with the Pipeline device (2011-2012); this may have systematically biased the study in favor of the Pipeline device because aspects of neurointerventional care other than the device used may have differed over time.

The remaining studies were single-arm studies showing feasibility and short-term outcomes up to one year. Interpretation of these studies is limited by significant methodologic limitations, including but not limited to the lack of a control group for comparison, short-term outcomes, and small sample size.

**ACUTE STROKE**

There are currently no randomized controlled trials for intracranial angioplasty with or without stenting for acute ischemic stroke. A number of case series have been published including the Stent-Assisted Recanalization for Acute Ischemic Stroke (SARIS) trial. This study was a prospective series of 20 patients with acute ischemic stroke who presented within eight hours of symptom onset, with a NIH stroke score of at least 8, and for whom thrombolysis was either contraindicated or ineffective. All patients were treated with the Wingspan intracranial self-expanding stent, aspirin, and clopidogrel. At six months follow-up, mortality was 35% (7/20),
NIH stroke score was 3 or less in 60% of patients (12/20), and 55% (11/20) had an NIH stroke score of 2 or less. A total of 11/13 (85%) patients who were alive at six months had a follow-up angiogram and all showed patency of the stent graft with TIMI level 3 flow or greater.

**PRACTICE GUIDELINE SUMMARY**

**INTRACRANIAL ATHEROSCLEROSIS**

**The Society for NeuroInterventional Surgery (SNIS)**

In 2012, the SNIS published consensus-based recommendations in a clinical standards statement on endovascular angioplasty and/or stenting of intracranial atherosclerosis.[71] The only randomized controlled trial found was the SAMMPRIS trial, described above. This trial was ranked as AHA evidence level B, defined as limited evidence from a single randomized trial or other nonrandomized studies. The remaining included studies were nonrandomized studies that were uncontrolled or did not have objective outcome measures; these were classified as AHA evidence level C, defined as based on expert opinion, case studies, or standard of care. The following recommendations were made:

- Medical therapy was recommended over angioplasty and stent therapy (Class IIa recommendation: Weight of evidence/opinion is in favor of usefulness/efficacy).
- For symptomatic 70-99% intracranial stenosis refractory to aggressive maximal medical therapy, angioplasty or stenting may be considered (Class IIb recommendation: Usefulness/efficacy less well-established by evidence/opinion).
- There is insufficient evidence to recommend between angioplasty and balloon mounted drug eluting or self-expanding stent systems (Class III recommendation: Intervention is not useful/effective and may be harmful).

**The American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR)**

In 2005 the ASITN, SIR, and ASNR jointly published a position paper on intracranial endovascular procedures.[72] This position statement reviewed a number of case series and also the SSYLVIA and Wingspan studies. It was republished in 2009 without an updated evidence review.[73] The following statement was offered, although the underlying rationale and process for development for the position statement was not provided:

“The ASITN, SIR, and ASNR concur that sufficient evidence now exists to recommend that intracranial angioplasty with or without stenting should be offered to symptomatic patients with intracranial stenoses who have failed medical therapy. Endovascular interventions are intensive services provided to patients who are at very high risk for stroke and typically have multiple comorbidities. Similar to revascularization for extracranial carotid artery stenosis, patient benefit from revascularization for symptomatic intracranial arterial stenosis is critically dependent on a low periprocedural stroke and death rate and should thus be performed by experienced neurointerventionists. We recommend reimbursement by third party insurers so that these patients may have access to such interventions. Continued attempts to improve the benefits of endovascular therapy are warranted.”

**The American Heart Association (AHA)**
In April 2009, the AHA, along with several other organizations, published a statement on indications for intracranial endovascular neuro-interventional procedures. The statement recommended that angioplasty and/or stenting be considered for patients with symptomatic severe intracranial stenoses (>70% luminal narrowing) that has been unresponsive to optimal medical therapy (Class IIb, Level of Evidence C, defined above).

**INTRACRANIAL ANEURYSM**

No clinical practice guidelines or position statements from U.S. professional societies were found that provided recommendations for stenting in the treatment of intracranial aneurysms. The 2009 AHA statement mentioned that stent deployment is being investigated to assist in coil embolization of certain aneurysms, but did not include stenting in the recommendations.

**ACUTE STROKE**

The American Heart Association (AHA) and the Society for NeuroInterventional Surgery (SNIS)

In separate position statements, the AHA and the SNIS recommended that the usefulness of endovascular devices other than mechanical thrombectomy devices “is not yet established, but may be beneficial and may be considered” (Class IIb, Level of Evidence C, defined above).

**SUMMARY**

There is enough research to show that the use of endovascular stents can improve health outcomes in certain people with intracranial aneurysms. Therefore, use of stents may be considered medically necessary as part of the endovascular treatment of intracranial aneurysms in selected cases that meet the medical policy criteria.

There is not enough research to show that the use of endovascular stents improves health outcomes for patients with intracranial aneurysms that do not meet the policy criteria. Therefore, the use of stents to treat intracranial aneurysms is considered investigational when the policy criteria are not met.

There is not enough research to show that endovascular angioplasty, with or without stents, improves health outcomes in people with intracranial artery stenosis or atherosclerosis. In addition, there are no clinical guidelines based on research that recommend angioplasty with or without stenting for treatment of intracranial artery stenosis. Therefore, endovascular angioplasty with or without stenting is considered investigational for the elective treatment of symptomatic intracranial stenosis or atherosclerosis.

There is not enough research to show that endovascular angioplasty, with or without stenting, improves survival and other health outcomes for patients having a stroke. In addition, there are no clinical guidelines based on research that recommend angioplasty, with or without stenting, for treatment of acute ischemic stroke. Therefore, endovascular angioplasty, with or without stenting, is considered investigational for the treatment of acute ischemic stroke.

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### CODES

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