APPENDIX to Percutaneous Transluminal Intracranial Angioplasty and Stenting Policy

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

Patients with ischemic stroke or transient ischemic attack (TIA) are at high risk of recurrent events. Endovascular interventions have been used to treat patients with symptomatic intracranial stenosis who have failed medical therapy. Treatment options include balloon angioplasty or balloon angioplasty with stenting.

It is estimated that intracranial atherosclerosis causes about 8% of all ischemic strokes. Intracranial stenosis may contribute to stroke 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 to 12% per year with atherosclerosis of the intracranial anterior circulation and 2.5% to 15% per year with lesions of the posterior (vertebrobasilar) circulation. Medical treatment typically includes either anticoagulant therapy (i.e., warfarin) or antiplatelet therapy (e.g., aspirin). The “Warfarin-Aspirin Symptomatic Intracranial Disease (WASID) trial was a randomized trial that compared the incidence of stroke, brain hemorrhage or death among patients randomized to receive either aspirin or warfarin. The trial found that over a mean 1.8 years of follow-up,

warfarin provided no benefit over aspirin and was associated with a significantly higher rate of complications. In addition, if symptoms could be attributed to low flow ischemia, agents to increase mean arterial blood pressure and avoidance of orthostatic hypotension may be recommended. However, medical therapy has been considered less than optimal. For example, in patients with persistent symptoms despite antithrombotic therapy, the subsequent rate of stroke or death has been extremely high, estimated in one study at 45%, with recurrent events occurring within 1 month of the initial recurrence. Surgical approaches have met with limited success. The widely quoted extracranial-intracranial (EC/IC) bypass study randomized 1,377 patients with symptomatic atherosclerosis of the internal carotid or middle cerebral arteries to medical care or EC/IC bypass. The outcomes in the two groups were similar, suggesting that the EC/IC bypass is ineffective in preventing cerebral ischemia. Due to inaccessibility, surgical options for the posterior circulation are even more limited.

Percutaneous transluminal angioplasty (PTA) has been approached cautiously for use in the intracranial circulation, due to technical difficulties in catheter and stent design and the risk of embolism, which may result in devastating complications if occurring in the posterior fossa or brain stem. However, improvement in the ability to track catheterization, allowing catheterization of tortuous vessels, and the increased use of stents have created ongoing interest in exploring PTA as a minimally invasive treatment of this difficult-to-treat population. The majority of published studies of intracranial PTA have focused on the vertebrobasilar circulation.

Intracranial stents are also being used in the treatment of cerebral aneurysms. Stent-assisted coiling began as an approach to treat fusiform or wide-neck aneurysms in which other surgical or endovascular treatment strategies may not be feasible. As experience grew, stenting was also used in smaller berry aneurysms as an approach to decrease the rate of retreatment needed in patients who receive coiling. A randomized trial has demonstrated that treatment of ruptured intracranial aneurysms with coiling leads to improved short-term outcome compared to surgical clipping; however, patients who receive coiling have a need for more repeat/follow-up procedures.

Percutaneous Transluminal Angioplasty Devices

Two devices have received U.S. Food and Drug Administration (FDA) approval for treatment of intracranial atherosclerotic disease through the humanitarian device exemption (HDE) process.

Neurolink System®

The clinical study investigating the Neurolink device is known as the Stenting of Symptomatic Atherosclerosis Lesions in the Vertebral or Intracranial Arteries (SSYLVIA) study, a prospective, nonrandomized, multicenter, international study of 61 patients. Patients eligible for participation in the study were symptomatic (previous stroke or TIA) attributed to an angiographically demonstrated discrete stenosis (50% or greater) in an extracranial or intracranial artery. The primary endpoint was a composite endpoint of stroke or death through 30 days; four 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 of the WASID study on aspirin and warfarin therapy noted the rate of fatal or nonfatal stroke was 14.6% and 22.5% respectively. Follow-up of study participants at 15 to19 months post-procedure suggested a potentially superior outcome with the Neurolink device.

However, the short length of follow-up in the Neurolink study prevents meaningful comparisons. The FDA 2010 Summary of Safety and Probable Benefit states,

> 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 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, which are difficult to access with a balloon-mounted stent, such as the Neurolink system (Bose et al., 2007).

The Wingspan was evaluated in a prospective study of 45 patients enrolled at 12 international centers. Patients were considered eligible if they presented with evidence of recurrent symptoms, refractory to medical therapy and attributed to an intracranial stenosis (50% or greater). The primary safety endpoint was similar to that of the SSYLVIA study (stroke or death through 30 days) and was reached by 2 patients (4.5%; 1 death following a hemorrhagic stroke and 1 stroke).

In 2010 the FDA offered the following conclusions and appears to have based 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 that 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 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.

Acute Stroke

Evidence on the use of endovascular procedures in the setting of acute stroke is limited. A few retrospective case series have been published, and one prospective, FDA-sponsored case series has been published (Levy et al., 2011). In this prospective series, 20 patients with acute ischemic stroke presenting within 8 hours of symptom onset, with an NIH stroke score of at least 8, and for whom thrombolysis was either contraindicated or ineffective, were treated with the Wingspan intracranial self-expanding stent. All patients were treated with aspirin and clopidogrel, and follow-up was for 6 months. Mortality at 6 months was 35% (7 of 20). At 6 months, 60% of patients (12 of 20) had an NIH stroke score of 3 or less, and 55% (11 of 20) had a score of 2 or less. A total of 85% of patients (11 of 13) who were alive at 6 months had a follow-up

angiogram, and all showed patency of the stent graft with Thrombolysis in Myocardial Infarction (TIMI) level 3 flow or greater.

Elective Treatment of Symptomatic Intracranial Stenosis

The evidence on this question consists of at least 2 randomized controlled trials (RCTs), a number of non-randomized comparative studies, and numerous single-arm series. The most clinically relevant studies are reviewed below.

Randomized Controlled Trials

The Stenting and Aggressive Medical Management for Preventing Recurrent Stroke in Intracranial Stenosis (SAMMPRIS) was an RCT comparing aggressive medical management alone to aggressive medical management plus stenting in patients with symptomatic cerebrovascular disease and an intracranial stenosis between 70% to 99% (Chimowitz et al., 2011). This trial used the Wingspan stent system implanted by experienced neuro-interventionists 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% confidence interval [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 1 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.

The Carotid and Vertebral Artery Transluminal Angioplasty Study (CAVATAS) randomized 16 patients with symptomatic vertebral artery stenosis to endovascular therapy (balloon angioplasty or stenting) or best medical treatment alone (Coward et al., 2007). Endovascular intervention was technically successful in all 8 patients, but 2 patients experienced TIAs at the time of endovascular treatment. During a mean follow-up of 4.7 years, no patient in either treatment group experienced a vertebrobasilar territory stroke, but 3 patients in each arm died of myocardial infarction (MI) or carotid territory stroke, and 1 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 MI during follow-up than have recurrent vertebrobasilar stroke. While they noted the trial failed to show a benefit of endovascular treatment of vertebral artery stenosis, the small number of patients enrolled severely limits conclusions.

Non-Randomized Comparative Studies

A number of non-randomized studies have compared outcomes of endovascular procedures with medical therapy. These studies have either been retrospective, or based on registry data, and

provide relatively weak evidence on the comparative efficacy of endovascular procedures compared to medical therapy. A representative sample of such studies is given below.

Tang et al. (2011) performed a retrospective comparison of 53 patients with at least 70% intracranial stenosis treated with stenting, compared with 61 patients treated with medical therapy. The participants were matched for age, gender, vascular risk factors, degree of baseline stenosis, and baseline functional status. After a mean follow-up of 17.3 months, a composite outcome of stroke, TIA, or vascular death was not different for the stent group compared to medical therapy (22.6% versus 24.6%, respectively; p = 0.99). A good functional outcome, defined as a modified Rankin Score of 0 to 3, was more frequent in the stent group compared to medical therapy (94.3% versus 78.7%, respectively; p = 0.045).

Qureshi et al. (2008) compared outcomes of angioplasty with (n = 22) or without (n = 22) stenting in patients with symptomatic intracranial stenosis 50% or greater identified retrospectively from a registry (angioplasty was used preferentially in patients with more technically challenging lesions). Although, at 12 months, no differences in stroke-related outcomes or mortality were noted (stroke-free survival of 95% and 93% after stenting and angioplasty alone, respectively), the small sample, nonrandom treatment assignment, and event rates prevent valid comparisons. The author concluded further comparison studies to medical therapy is required.

Samaniego et al. (2009) retrospectively reviewed outcomes at a single institution comparing study of best medical therapy to angioplasty and stenting in 111 patients with symptomatic intracranial atherosclerotic disease treated from July 2004 to September 2007. Treatment decisions were made by a multidisciplinary committee. Important baseline differences between the best medical therapy and angioplasty groups, respectively, included presenting with acute stroke (74% versus 57%) or TIA (26% versus 43%), emergency department (53% versus 28%), or outpatient (19% versus 47%) presentation, or prior TIA (19% versus 55%). The best medical therapy group also had more diffuse disease, respectively (67% versus 28%) rather than single lesions. In this series, 31 lesions were treated with the Wingspan system, 12 with the Neuroform stent, and 14 with various balloon-expandable stent systems. Mean follow-up was 14 months in both groups. Combined ischemic endpoints of TIA, stroke, and vascular death were similar, 24% (n = 14) in the best medical therapy group and 28% (n = 15) in the angioplasty and stenting group. However, inability to account for nonrandom treatment assignment and systematic differences between groups prevents conclusions.

Single-Arm Case Series and Registry Studies

Numerous single arm case series have been published. These studies provide some information on the success rates and the adverse events that occur with this procedure, but offer very limited evidence on the comparative efficacy of endovascular approaches versus medical therapy. Some of these case series are reviewed below.

Marks and colleagues (2006) reported a series of 120 patients with 124 cases of intracranial stenosis who were treated by primary angioplasty. There were 3 strokes and 4 deaths (all neurological) within 30 days of the procedure, giving a combined peri-procedural stroke and death rate of 5.8%. A total of 116 patients (96.7%) were observed for a mean follow-up of 42.3 months.

Fiorella et al. (2007) reported on initial peri-procedural experience with the Wingspan stent in 78 patients, average age 64 years. Eighty-one of 82 lesions were successfully stented, and percent stenosis was reduced (from 75% to 27% after stent placement). There were 5 (6.1%) major peri-procedural neurologic complications with 4 patient deaths within 30 days. Long-term outcomes were not reported.

Zaidat et al. (2008) reported on the NIH registry on use of the Wingspan stent for symptomatic intracranial stenosis; 129 patients from 16 medical centers were treated with a Wingspan stent between November 2005 and October 2006. 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 incidence of 50% or greater restenosis on follow-up angiography was demonstrated in 13 of 52 (25%).

INTRASTENT is a European 18-center registry enrolling patients with symptomatic intracranial stenosis greater than 50. From the registry, Kurre et al. (2010) reported that in 372 patients with 388 cases of stenosis, stenting was successful in 90.2% of patients. In-hospital death and disabling stroke rates were 2.2% and 4.8%, respectively. No subgroups with increased risk of procedure-related morbidity or mortality were discerned.

Albuquerque et al. (2008) examined angiographic patterns of in-stent restenosis with the Wingspan device. Imaging follow-up (3 to 15.5 months) was available for 127 intracranial stenotic lesions. Forty-one lesions (32.3%) developed either in stent restenosis (n = 6; 28.3%) or complete stent occlusion (n = 5; 3.9%) after treatment.

Systematic Reviews

In 2005 Coward and colleagues conducted a Cochrane review of angioplasty and stenting for vertebral artery stenosis. 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 trial". In addition, the authors noted,

> “little is known about the natural history of vertebral artery stenosis and what constitutes best medical treatment. Future trials should concentrate on comparing different medical treatment such as antiplatelet and anticoagulant drugs as well as comparing endovascular intervention with medical treatment".

In 2006, Cruz-Flores and Diamond conducted a Cochrane review investigating angioplasty for intracranial artery stenosis. The authors identified no RCTs but 79 publications of interest consisting of case series with 3 or more cases. The safety profile showed an overall peri-operative rate of stroke of 7.9% (95% CI: 5.5% to 10.4%) and peri-operative stroke or death of 9.5% (95% CI: 7.0% to 12.0%). Overall, the authors concluded the evidence 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 showed the procedure was feasible, although carrying significant morbidity and mortality risks. Furthermore, evidence from RCTs is needed to assess the safety of angioplasty and its effectiveness in preventing recurrent stroke.

Groschel et al. (2009) conducted a systematic review on outcomes after stenting for intracranial atherosclerosis. 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 100%). The peri-procedural minor or major stroke and death rates ranged from 0% to 50%, with a median of 7.7%. Peri-procedural complications were significantly higher in the posterior versus the anterior circulation (12.1% versus 6.6%, $p < 0.01$), but did not differ between patients treated with a balloon-mounted stent (n = 906) versus those who had been treated with a self-expandable stent (n = 271 [9.5% versus 7.7%, respectively; $p = 0.47$]). Re-stenosis greater than 50% occurred more frequently after the use of a self-expandable stent (16 of 92; 17.4%, mean follow-up time: 5.4 months) than a balloon-mounted stent (61 of 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. Thus, given a high rate of re-stenosis 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.

Stent-Assisted Treatment of Intracranial Aneurysms

The literature search did not identify any trials of stent-assisted treatment of intracranial aneurysms compared to standard neurosurgical treatment. The available evidence consists of single-arm case series, registry studies, and non-randomized comparative studies.

Non-Randomized Comparative Studies

The largest comparative series describing use of stents compared to coiling alone for treating intracranial aneurysms was described by Piotin and colleagues (2010). They report on a series of 1,137 patients (1,325 aneurysms) treated between 2002 and 2009. In this series, 1,109 aneurysms (83.5%) were treated without stents (coiling), and 216 (16.5%) were treated with stents (15 balloon-expandable and 201 self-expandable stents). 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: 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 $p = 0.006$; odds ratio: 0.116; 95% CI: 0.025 to 0.531). Thus far, the authors have 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 ($p < 0.0001$; odds ratio: 0.3485; 95% CI: 0.2038 to 0.5960).

Colby et al. (2012) reported on 90 consecutive patients undergoing treatment for para-ophthalmic aneurysms, 30 of whom were treated with coil alone versus 60 who were treated with stent-assisted coils. On initial angiography following the procedure, complete occlusion of the aneurysm was achieved in 43.3% of stented patients compared to 31.7% of non-stented patients. At a mean of 14.5 months follow-up, the recurrence rate was lower for the stented group at 15.4% (4 of 26) versus 41.5% (17 of 41) in the non-stented group ($p < 0.05$).

A non-randomized comparative study from Korea (Hwang et al., 2011) reported on 126 aneurysms that were treated with stent-assisted coiling compared to 86 patients treated with coil alone. At 2 years of follow-up, the authors reported rates of occlusion and recurrence.

Progressive occlusion was noted in 42.5% of the stent group (17 of 40) compared to 39.5% of the non-stented group (34 of 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 non-stent group.

Single-Arm Series

There are a large number of single-arm series reporting on outcomes of stent-assisted coiling. A systematic review by Shapiro et al. (2012) identified 39 articles reporting on 1,517 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 peri-procedural 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 post-treatment, the stroke rate in the stented area was 3.2%.

A systematic review that was restricted to ruptured aneurysms was published by Bodily et al. in 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 of 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 of 288) having a clinically significant thromboembolic event.

Mocco and colleagues (2009) reported results from a collaborative registry from 10 institutions describing initial experience in using the Enterprise stent. In this series, 141 patients with 142 aneurysms underwent 143 attempted stent deployments. The use of Enterprise assistance with aneurysm coiling was associated with a 76% rate of 90% or greater occlusion. An inability to navigate or deploy the stent was experienced in 3% of cases, as well as a 2% occurrence of inaccurate deployment. Data demonstrated a 6% temporary morbidity, 2.8% permanent morbidity, and 2% mortality (0.8% unruptured, 12% ruptured).

Wajnberg et al. (2009) reported on results for 24 patients (2005 to 2008) with wide-necked cerebral aneurysms who were treated with stent reconstruction of the aneurysm neck. Clinical outcome was assessed with the Glasgow Outcome Scale (GOS). In this series, the stent was easily navigated and positioned in 24 of 26 cases. However, technical difficulties occurred in 9 patients, including difficulties in crossing the stent's interstice (n = 6), inadvertent stent delivery (n = 1), incapacity of stent delivery (n = 1) and incapacity of crossing the neck (n = 1). These latter 2 cases were classified as failures of the stent-assisted technique. A single procedural complication occurred, involving transient non-occlusive intra-stent thrombus formation, which was treated uneventfully. Seventeen patients experienced excellent clinical outcomes (GOS 5), with good outcomes (GOS 4) in 5 patients, and a poor outcome (GOS 3) in 2 patients. There were no treatment-related deaths or neurologic complications with mean follow-up of 12 months

Biondi et al. (2007) reported on the midterm results of stent-assisted coil embolization in the treatment of wide-necked cerebral aneurysms. This was a retrospective review of 42 patients with 46 wide-necked cerebral aneurysms enrolled in a prospective single-center registry of

patients treated with a Neuroform stent, a flexible self-expanding nitinol stent. Twenty-seven of 46 aneurysms were unruptured aneurysms, 14 were recanulized aneurysms, and 5 were acutely ruptured. Mean aneurysm size was 9.8 mm. Stenting before coiling was performed in 13 of 45 aneurysms (29%), coiling before stenting in 27 of 45 aneurysms (60%), and stenting alone in 5 of 45 aneurysms (11%). In 40 aneurysms treated with stent-assisted coiling, angiographic results showed 14 (35%) aneurysm occlusions, 18 (45%) neck remnants, and eight (20%) residual aneurysms. At angiographic follow-up in 30 aneurysms treated with stent-assisted coiling, there were 17 (57%) aneurysm occlusions, 7 (23%) neck remnants, and 6 (20%) residual aneurysms. Procedural morbidity was observed in 2 of 42 patients (4.8%) and 1 patient died.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

For treatment of intracranial stenosis, the majority of those providing input would consider use of this technology in selected patients who remained symptomatic from intracranial atherosclerotic disease despite maximum medical therapy. There was unanimous support for use of this technology in selected patients with intracranial aneurysms; i.e., in those patients for whom surgical treatment is not possible and for whom endovascular treatment (coils) does not completely isolate the aneurysm.

Summary

For elective treatment of symptomatic intracranial stenosis, endovascular procedures with or without stenting have not been shown to be superior to best medical care. One very small RCT did not report benefit and a larger RCT was terminated prematurely due to an excess of the primary outcome of death or stroke in the endovascular group. This evidence suggests that the adverse event rate with endovascular procedures is relatively high and may outweigh the benefit in preventing recurrent ischemic events. As a result, endovascular procedures with or without stenting are considered investigational for the elective treatment of symptomatic intracranial stenosis.

For acute stroke, the evidence is very limited, consisting of only small case series. This evidence is insufficient to form conclusions about the effect of endovascular interventions in acute stroke, and as a result, endovascular interventions are considered investigational for the treatment of acute stroke.

For the treatment of intracranial aneurysms, there are no RCTs of stent-assisted coiling with coiling alone. Non-randomized comparative studies report occlusion rates that are similar to coiling alone, and recurrence rates that may be lower than for coiling alone. Results of Blue Cross Blue Shield Association (BCBSA) input indicated strong support for treatment of aneurysms that are not amenable to surgery or simple coiling. Comparative trials with and without stenting for this clinical situation are unlikely. As a result, use of stent-assisted coiling for the treatment of intracranial aneurysms may be considered medically necessary when surgical treatment is not appropriate and standard endovascular techniques do not allow for complete isolation of the aneurysm.

Practice Guidelines and Position Statements

In 2005, The American Society of Interventional and Therapeutic Neuroradiology (ASITN), the Society of Interventional Radiology (SIR), and the American Society of Neuroradiology (ASNR) jointly published a position paper regarding angioplasty and stenting for cerebral atherosclerosis (Higashida et al., 2005). This position statement reviewed a number of case series and also the SSYLVIA and Wingspan multi-institutional studies. The following position 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 stenosis who have failed medical therapy. Endovascular interventions are intensive services provided to patients who are at very high risk for strokes and typically have multiple co-morbidities. Similar to revascularization for extracranial carotid artery stenosis, patient benefit from revascularization for symptomatic intracranial arterial stenosis is critically dependent on a low per procedural stroke and death rate and should thus be performed by experienced neuro-interventionists. 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.

In April 2009, the American Heart Association (AHA), along with several other organizations, published an AHA scientific statement on indications for intracranial endovascular neuro-interventional procedures (Meyers et al., 2009). The recommendation related to endovascular treatment of symptomatic intracranial stenosis was noted as Class IIb, Level of Evidence C (usefulness or effectiveness is unknown or unclear). The level of evidence was the same for use of angioplasty and stenting in the treatment of acute ischemic stroke.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the

terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

Type	Number	Description
CPT	35475	Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel
	61630	Balloon angioplasty, intracranial (e.g., atherosclerotic stenosis), percutaneous
	61635	Transcatheter placement of intravascular stent(s), intracranial (e.g., atherosclerotic stenosis), including balloon angioplasty, if performed
	61640	Balloon dilatation of intracranial vasospasm, percutaneous; initial vessel
	61641	Balloon dilatation of intracranial vasospasm, percutaneous; each additional vessel in same vascular family (List separately in addition to code for primary procedure)
	61642	Balloon dilatation of intracranial vasospasm, percutaneous; each additional vessel in different vascular family (List separately in addition to code for primary procedure)
HCPC	None	
ICD9 Procedure	00.62	Percutaneous angioplasty or atherectomy of intracranial vessel(s)
	00.64	Percutaneous insertion of other precerebral (extracranial) artery stent(s)
	00.65	Percutaneous insertion of intracranial vascular stent(s)
	037G3DZ	Dilation of Intracranial Artery with Intraluminal Device, Percutaneous Approach
	037G3ZZ	Dilation of Intracranial Artery, Percutaneous Approach
	037G44Z	Dilation of Intracranial Artery with Drug-eluting Intraluminal Device, Percutaneous Endoscopic Approach
	037G4DZ	Dilation of Intracranial Artery with Intraluminal Device, Percutaneous Endoscopic Approach
	037G4ZZ	Dilation of Intracranial Artery, Percutaneous Endoscopic Approach
ICD9	All Diagnoses	

Type	Number	Description
Diagnosis		
Place of Service	All Places of Service	

Tables

N/A

Definitions

Balloon angioplasty - A procedure in which inflation and deflation of a balloon catheter occurs inside an artery, stretching the intima and leaving a ragged interior surface, triggering a healing response and breaking up of plaque.

Percutaneous transluminal angioplasty - A procedure used to widen vessels narrowed by stenosis or occlusions via entry through the skin then navigating to the area of the vessel of interest or communicating vessels.

Vertebral arteries - Arteries located at the back of the neck that originates from the subclavian arteries; the vertebral arteries and their subsequent branches supply approximately 20% of the brain's blood supply.

Wide neck aneurysm - An intracranial aneurysm with a dome-to-neck ratio less than 2.0 and/or a neck length of 4 mm or more.

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

N/A

Key / Related Searchable Words

- Balloon angioplasty
- Cerebral artery angioplasty
- Endovascular treatment
- Intracranial angioplasty
- Intracranial percutaneous transluminal angioplasty
- Neurolink system
- Transluminal balloon angioplasty
- Vertebrobasilar angioplasty

- Wingspan stent system

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Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
6/12/2002	New policy	Medical Policy Committee
8/23/2002	Policy Review	Medical Policy Committee
3/1/2005	Policy Review MPC accepted as CTAF consent: BCBSA TEC Vol. 19, No. 15.	Medical Policy Committee
10/1/2005	Policy Review Title modification	Administrative Review
12/1/2005	Policy revision without position change MPC accepted CTAF recommendation; policy updated, statement unchanged	Medical Policy Committee
12/8/2008	Coding update	Administrative Review
12/18/2009	Policy revision with position change Title change from Extracranial Carotid Angioplasty and Stenting and Cerebral Angioplasty and Stenting for Atherosclerosis, Stroke and Vasospasm	Medical Policy Committee
7/11/2011	Coding Update	Administrative Review
1/11/2013	Policy revision with position change	Medical Policy Committee

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